An empirical study of scientists' reasoning in the Canadian regulatory evaluation of traditional, homeopathic, herbal, and other "natural" medicines

An ethnographic account paying particular attention to how scientists used standards in their evaluations of safety and efficacy and to manifestations of multiculturalism and managerialism in the federal public service

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Abstract

How do one hundred scientists reason in a uniform manner during the regulatory review of proposed medicines?

This ethnographic account of scientists' reasoning is based on thirteen months of anthropological fieldwork among the hundred scientists in a Canadian government directorate mandated to assess the safety and efficacy of proposed medicines while "respecting philosophical and cultural diversity." The scientists themselves cannot be considered uniform. They were born in numerous countries around the world and educated in many scientific disciplines. Many scientists were also health practitioners, in a variety of traditions. The scientists expressed a wide range of opinions about the usefulness of traditional medicines and other "natural health products."

This dissertation describes the ways in which scientists reasoned in their assessment work. Many scientists attributed the uniformity in their reasoning to their use of standards and to their frequent consultation of expert peers. I argue that these activities do not account for the most striking features of scientists' uniform style of reasoning, including scientists': directed perception; repetition of phrases like "we have to be flexible" in situations of uncertainty; acute sensitivity to fairness; common affective dispositions towards certain file traits; agnostic perspective towards the relation of textual standards to "reality"; and consideration of the licensing backlog. These features were inseparable from the omnipresent tools of managerialism such as quotas for the number of evaluations to be completed weekly. Certain of these striking features appeared to be further entrenched by the temporary, rather than permanent, appointment of half the scientific staff to their positions.

This uniform style of reasoning had very little, if anything, to do with scientists' pre-existing "beliefs" and convictions. I argue that scientists were interpellated into this style of reasoning (including common directed perception and affective dispositions) through participation in the material and social structuring of activities in the Directorate, even though the pre-structuring of reasoning activities was never fully determined. The dissertation begins and ends with Ludwik Fleck's observation that "every epistemological theory is trivial that does not take th[e] sociological dependence of all cognition into account in a fundamental and detailed manner" (1979:43).

Une étude empirique du raisonnement des scientifiques en matière d'évaluation et de réglementation des médicaments traditionnels, homéopathiques et autres « produits de santé naturels » au Canada

Comment les scientifiques appliquent les normes, et quelles sont les manifestations de multiculturalisme et de gestionnariat dans la fonction publique fédérale.

Résumé

Comment les scientifiques arrivent-ils à raisonner de façon si uniforme dans leur travail d'évaluation de l'innocuité et de l'efficacité des médicaments?

Cette ethnographie du raisonnement des scientifiques est basée sur treize mois de recherches en 2006 et 2007 parmi une centaine de scientifiques au sein de la Direction des produits de santé naturels de Santé Canada. Les scientifiques qui y travaillent ont des origines et des trajectoires variées : ils sont nés dans le monde entier, se sont formés dans différentes disciplines scientifiques, pratiquent une gamme de traditions médicales en dehors de leur travail et ont des opinions diverses quant à l'utilité des médecines traditionnelles et autres médecines « naturelles ».

Plusieurs scientifiques attribuent l'uniformité de leur raisonnement à l'utilisation de normes et à leur empressement à consulter leurs pairs. La thèse décrit la façon dont les scientifiques raisonnent à l'aide de normes textuelles et numériques ainsi que de consultations ciblées avec leurs collègues. Toutefois, ces activités n'expliquent pas les caractéristiques les plus frappantes du style de raisonnement des scientifiques, telles que leur « perception dirigée »; la répétition de phrases telles que « nous devons être flexibles » dans des situations de doutes; une sensibilité aiguë à l'équité; des dispositions affectives communes envers certains dossiers; un point de vue agnostique envers la relation entre normes textuelles et « réalité »; et la prise en considération du retard dans l'octroi de licences. Ces caractéristiques sont inséparables de certains outils clés du gestionnariat tels que les quotas pour le nombre d'évaluations hebdomadaires.

Ce style de raisonnement a très peu, sinon rien à voir avec les « croyances » et les convictions préexistantes des scientifiques. Je soutiens que les scientifiques sont amenés à ce style de raisonnement à travers leur participation à l'organisation matérielle et sociale des activités de la Direction. La thèse s'ouvre et s'achève sur l'observation de Ludwik Fleck selon laquelle « toute théorie épistémologique est triviale si elle ne prend pas en considération la dépendance sociologique de toute connaissance de façon fondamentale et détaillée ».[1]

[1] Ludwik Fleck (1979:43), traduit par Karine Peschard.

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Note

This dissertation reflects *my* research experience and analysis. Although I have had several institutional affiliations since the beginning of this research project, I am not speaking for any organization. Although I have had wonderful support from faculty, colleagues, friends and family, the dissertation is my voice only.

No other organization or person has condoned the arguments of this dissertation.

In other words, no argument in this dissertation should be construed as anything other than my own, personal, anthropological analysis. Any errors or defects remain my responsibility.

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List of Abbreviations

The first day I arrived in my fieldsite, I noticed that someone had helpfully provided ten pages of acronyms, thumbtacked to my cubicle wall. I provide a similar, abridged list for the reader. List refers to entities existing in 2007 or prior.

ADM	Associate Deputy Minister or Assistant Deputy Minister
AO	Assessment officer at the NHPD
BCTHS	Bureau of Clinical Trials and Health Sciences at the NHPD
BGTD	Biologics and Genetic Therapies Directorate; in HPFB
BPRA	Bureau of Product Review and Assessment at the NHPD (also BRA)
BRA	Bureau of Regulatory Assessment at the NHPD (variant of BPRA)
CAM	Complementary and alternative medicine
CGI	Canada Gazette, Part I; where *proposed* regulations are published
CGII	Canada Gazette, Part II; where regulations are published
CIHR	Canadian Institutes of Health Research
CTU	Clinical Trials Unit in the NHPD's BCTHS
DG	Director General
DIN	Drug Identification Number
DIN-HM	Drug Identification Number for Homeopathic Medicines
DM	Deputy Minister
EAC	Expert Advisory Committee; there are many at HC, generally composed of non-public servants considered experts in their field
EBM	Evidence-based medicine
EMEA	European Medicines Evaluation Agency
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration (US)
GEDS	Government Electronic Directory Services
GMP	Good Manufacturing Practices
HC	Health Canada
HECSB	Healthy Environments and Consumer Safety Branch
HMU	Homeopathic Medicines Unit in the NHPD's BPRA
HPB	Health Protection Branch; became HPFB and HECSB in 2000
HPFB	Health Products and Foods Branch
HWC	Health and Welfare Canada; precursor of Health Canada
IAS	Issue Analysis Summary; a type of internal HC document

L1	Level 1, screening of applications submitted to the NHPD
L2	Level 2, processing of applications submitted to the NHPD
L3	Level 3, assessment of applications submitted to the NHPD
L4	Level 4, the decision taken on an application submitted to the NHPD
MAC	Management Advisory Committee at the NHPD; composed of "stakeholders"
MHPD	Marketed Health Products Directorate; in HPFB
MI	Medicinal ingredient
NHP	Natural health product
NHPD	Natural Health Products Directorate; in HPFB
NHPP	Natural Health Products Programme; not an organization, but a conceptual programme of all activities within Health Canada relating to natural health products
NHW	National Health and Welfare; synonym of Health and Welfare Canada
NMI	Non-medicinal ingredient
NPN	Natural Health Product Number
OHNP	Office of Natural Health Products (1999-2000); became NHPD
OTC	Over-the-counter [medicine]
PLA	Product Licence Application at the NHPD
QAR	Quality Assessment Report at the NHPD
REB	Research Ethics Board
SEAR	Safety and Efficacy Assessment Report at the NHPD
SOE	Standards of evidence
SOPs	Standard Operating Protocols or Standard Operating Procedures
TCM	Traditional Chinese medicine
TMU	Traditional Medicines Unit in NHPD's BPRA
TPD	Therapeutic Products Directorate; in HPFB
TPP	Therapeutic Products Programme; not an organization, but a conceptual programme of all activities within Health Canada relating to therapeutic products; also the precursor of activities now falling under ambit of TPD, BGTD, NHPD, MHPD, and VDD
TT	Transition Team (1999-2000) at the ONHP and then NHPD
VDD	Veterinary Drugs Directorate; in HPFB
WHO	World Health Organization

Hierarchy and the Natural Health Products Directorate

Lower positions report to the position immediately above

Positions above the Directorate

Position	*Responsible for*
Minister	federal department of health (political accountability)
Deputy Minister	Health Canada (administrative responsibility)
(Associate Deputy Minister	assists Deputy Minister)
Assistant Deputy Ministers	Branches

N.B. The Governor in Council appoints the Minister, Deputy Minister, and Associate Deputy Minister. Regular public service employment rules apply at the level of Assistant Deputy Ministers and all subordinate ranks; in other words, at the level of the Assistant Deputy Ministers and below, appointments fall under the authority of the Public Service Commission.

Positions within the Natural Health Products Directorate

Position	*Responsible for*
Director General	Directorate
Director*	Bureau
Manager*	Division
Unit Head*	Unit
Assessment Officer*	(self)

* indicates multiple equivalent positions in the Natural Health Products Directorate

In the text that follows, exact job titles are indicated by the use of the upper case, for instance “Unit Head,” “Manager.” While *Manager* indicates an exact position title, the *manager* refers to any official in management in the widely used sense of the term (having responsibilities in the supervision of other personnel), which in this case is any official higher in the hierarchy than an assessment officer.

I sometimes characterize scientists in management positions as scientists, managers or both: whichever is most appropriate in context.

I use *lower management* to refer to Unit Heads and Managers. I use *upper management* to encompass Managers, Directors, and the Director General in the context of the Natural Health Products Directorate; Director Generals and the Assistant Deputy Minister in any discussions of the larger branch; and ADMs and the Deputy Minister at the departmental level.

Names, genders and quotations used in dissertation

Pseudonyms and identifying details

For reasons of confidentiality, the names of most scientists in this dissertation are pseudonyms. Pseudonyms are recognizable as such because they consist only of a first name. True names, used only when scientists chose to sign an additional consent, are distinguishable through the use of both first and last names.

I do not provide much background detail on individual scientists because details are tantamount to naming. I have used the following rule in writing this dissertation: that if a detail, or a combination of details, could only be associated with one or two scientists, it must be considered identifying. In some instances I have used referred to a particular scientist using two pseudonyms; this was done only when the sum of background detail provided in separate chapters could be identifying if an avid reader from the Directorate were to compile information from separate chapters. In many instances, I have changed scientists' genders, because in smaller units this could frequently be an identifying characteristic; therefore no inferences about gender should be made from this dissertation.

Quotations

All interviews with NHPD staff were conducted in English. Because interviews were generally recorded if the interviewee granted permission, most, but definitely not all, quotations *from interviews* are verbatim. Even so-called verbatim quotations may nonetheless have been edited to remove repetitions, quirks of speech or other identifying details. Statements from outside the interview context were generally composed from memory, written down at the end of the workday. Very occasionally they are verbatim if they stem from written communication or were made during a meeting in which I was taking notes.

In quotations, interviewees' abandoned utterances or jumps to a new sentence are indicated by a slash, "/." Anything in square brackets are my additions. Ellipses in square parentheses "[…]" represent my deletion of some comments; ellipses without square parentheses indicate a pause, which may also be indicated by [pause]. Bold typeface indicates a very strong emphasis on utterances by the speaker. Italic typeface indicates my questions or interjections *as an anthropologist*. In contexts in which my colleagues were interacting with me primarily or only *as a work colleague* (and not an anthropologist), I refer to myself as "Jennifer," using my first name like the first (pseudo)names I use for my colleagues.

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An ethnographic account paying particular attention to how scientists used standards in their evaluations of safety and efficacy, and to manifestations of multiculturalism and managerialism in the federal public service

Chapter summaries

Chapter 1. An empirical study of scientists' reasoning in public health protection

This dissertation is an ethnographic account of how government scientists reasoned in the regulatory evaluation of medicines. The account is based on thirteen months of anthropological fieldwork in a Canadian federal government department mandated to promote and preserve the health of the people of Canada.

The dissertation in no way evaluates the success of the organization; nevertheless I have no doubt that each and every scientist I encountered was committed to the department's mandate. The dissertation describes how, rather than whether, the scientists contributed to this mandate.

Naïve outsiders to government often have unrealistic expectations of how large governmental organizations operate. Naïve outsiders to science-based endeavors often have unrealistic expectations of scientists' reasoning. In both cases, such expectations often involve omniscient (and occasionally omnipotent) individuals who are somehow removed from mundane social interactions and imperatives that come with being human. Naïve outsiders may also assume that Weberian-style idealized characterizations of rational or bureaucratic processes can transparently stand in for empirical observation of those processes. It is not that these expectations and assumptions are entirely due to naïveté; often the entire purpose of large governmental and science-based institutions is to have hundreds, even

thousands, of individuals acting and speaking as one, and so there are many tools – some might even say ideologies – that maintain the image of the organization as an entirely unified, rule-bound and rational, operation. From the inside, however, *any* such large operation will always appear more chaotic, less rule-governed, than it might to outsiders. Anyone with experience inside large governmental or science-based operations would likely acknowledge that scientists' everyday reasoning activities in the face of uncertainty are more unpredictable, and more socially-embedded, than naïve outsiders may expect.

This chapter provides an overview of the dissertation's approach to scientists' reasoning, contributing a study of "how institutions think" (cf. Douglas 1986) based on the previous work of scholars studying scientific institutions, most notably on Ludwik Fleck's observations in *Genesis and development of a scientific fact* (1979). The chapter also outlines the research methods used during fieldwork.

Chapter 2. Scientists' reasoning in a Canadian government directorate, 2006-2007. (A thesis and chapter overview).

The dissertation is an empirical study of scientists' reasoning and judgement in public health protection. It is empirical because it addresses scientists' observable actions, statements, and emotional expressions. It is a study of reasoning because it examines the processes by which scientists came to a decision (judgement). It is a study of public health protection because the decisions made by the scientists included a recommendation regarding whether a particular medicine should be licenced for sale to the general public on the basis of evidence of safety and efficacy.

The dissertation's central puzzle is how one hundred very different scientists reasoned in a relatively uniform matter during their work in public health

protection. I argue this uniformity cannot be explained by some common demographic or psychological trait among scientists prior to their work in Health Canada's Natural Health Products Directorate (the research fieldsite). The scientists' backgrounds, training and perspectives were simply too diverse.

Many scientists attributed this uniform style of reasoning to the existence of standards and the presence of subject experts in their midst. These official standards and frequent consultations, however, do not account for the most striking features of scientists' uniform style of reasoning. These striking features included scientists': agnostic perspective towards the validity of various textual standards; repetition of phrases such as "we have to be flexible," especially in moments of uncertainty; acute and explicit sensitivity to fairness and the limits of their own authority; common affective disposition towards certain traits of files such as their easiness or messiness; directed perception of "issues" in files; and explicit consideration given to the licensing backlog. These features were inseparable from the omnipresent tools of managerialism such as performance standards (quotas for the number of evaluations to be produced weekly), and the style of reasoning appeared to be further entrenched by many scientists' tenuous staffing appointments and by their perception that the existence of the entire Directorate was tenuous. Chapter two provides an overview of these features and an indication of where these features will be discussed throughout the dissertation. The ethnographer's task is to articulate the way in which, in this *particular* institution, these *particular* features of scientists' style of reasoning interrelate.

The approach taken to the examination of the particular features of scientists' style of reasoning is to examine sequentially: the most salient official standards, textual standards, numerical standards, and people standards in the Directorate. A reflection on incommensurability occurs at

the dissertation's midpoint, to explain why the project's central puzzle shifted between research and writing phases.

There is no way out of the human situation: humans are social creatures; humans are never completely outside society and human reason is therefore never outside society. Thus the reader must not have unrealistic expectations of how large governmental and science-based organizations can operate. This dissertation begins and ends with Ludwik Fleck's observation, that "every epistemological theory is trivial that does not take th [e] sociological dependence of all cognition into account in a fundamental and detailed manner" (1979:43).

Chapter 3. Natural health products as standard: "A New Vision," "A Fresh Start," a new order

The first and most important standard in scientists' reasoning about the efficacy of medicines in the Natural Health Products Directorate was the definition of the type of medicines the Directorate's scientists were evaluating: "natural health products." The regulatory definition of natural health product came about as the regulatory solution for a quandary in the Canadian pre-market evaluation of medicine. That quandary, dating to the early 1980s, was how the federal department of health should appropriately regulate packaged traditional and ethnic herbal medicines. For more than twenty years, this quandary was put to advisory committee after committee, first within the department, and later also within Canadian federal parliament. The regulatory solution, in the form of the *Natural Health Products Regulations* (2003), included in its scope much more than commodified traditional and ethnic herbal medicines; the scope was expanded to include vitamins, deodorants, homeopathic medicines, synthetic duplicates of naturally-occurring compounds, probiotics, conventional toothpastes, smoking-cessation products, and more.

This new regulatory categorization of medicines, referred to in various committee reports as “a new vision” and “a fresh start,” reconfigured, by implication, the regulatory category of (pharmaceutical) drugs. In this coproduction of regulatory categories of commodified medicines, the safety of natural health products was a self-fulfilling prophesy, as government officials made “risky natural health products” into oxymorons, formally and informally.

Chapter 4. NHPD scientists and their two official explanations of regulatory evaluation

Officials from the Natural Health Products Directorate, when asked by outsiders or new employees how the Directorate evaluated natural health products for safety and efficacy, often gave one of two answers. The first answer was in terms of organizational process: *applications to market a medicine are evaluated through a four-level process, moving from level one (verification), level two (processing), through level three (assessment), to level four (decision)*. The other answer was in terms of regulatory texts. Officials would often politely tell inquirees to go read the rules: the *Natural Health Products Regulations* as well as various documents interpreting those regulations including the Directorate’s guidance documents, policies, and other textual standards. *The evaluation proceeds as outlined in the regulatory documents*.

These rote explanations were so entrenched that scientists often opined that practice was entirely captured by the procedural schema, or by the suite of regulatory documents. Through an exegesis of these rote explanations, and an overview of their instantiation in everyday work, Chapter 4 provides an overview of the scientists involved in the process at the Natural Health Products Directorate as well as their use of key regulatory and procedural textual standards.

Chapter 5. An introduction to cubicle life

When a company wished to market a natural health product in Canada, it required a licence, pre-market, from the Natural Health Products Directorate within Health Canada. To obtain a licence, the company had to submit a completed Product Licence Application Form along with various supporting documents to the Directorate.

The Directorate's evaluation was entirely paper-based: the applicant (company) submitted various forms and documents, and scientists and other officials in the Directorate evaluated whether this information was sufficient and consistent with the stipulations of various regulatory texts and standards. With the exception of the Directorate's upper managers, who had closed offices, each and every staff member – including the scientific staff – worked in an individual cubicle. Many evaluators spent most of their workday in their cubicles, leaving only to consult colleagues, to attend meetings, or to take breaks. There were no laboratories in the Directorate. Nor were there other federal government laboratories devoted to the pre-market regulatory evaluation of natural health products.

Two worm's-eye descriptions of cubicle-bound scientists, Alex and Guineviere, evaluating medicines for safety and efficacy, are presented as windows into the spatialized and specialized reasoning of the Directorate's scientists.

Chapter 6. Matching sensibilities: scientists' reasoning through taxonomy and comparison.

Overall, the Directorate's pre-market assessment of medicines proceeded according to a giant algorithm, multistep and branching. When staff could clearly establish, at each branch, the appropriate next step in the algorithm, assessment was routine: the application to market a medicine was easily

directed through the algorithm, which established the appropriate standards for scientists' evaluation. In some cases assessment was so routinized through standard operating procedures and checklists, evaluation was derided as "brainless."

Such routinized reasoning about the safety and efficacy of medicines, however, was only possible when at least three conditions were fulfilled. First, the application had to be arranged, presented in such a way that a comparison with appropriate standards of evidence was possible; at the NHPD, this condition was frequently the exception than the norm, and so much of scientists' time was devoted to cajoling applicants to "clean up" their "messy" applications so the appropriate step in licencing or standard of evidence could be discerned. Second, assessment only became routine when the assessment officer had trained eyes, knowing where and when to look in the mound of documentation involved. Finally, such routinized reasoning could be precluded at any point by an issue, or a full-fledged Issue. Issues, as log jams in the assessment streams, required an unpredictable course of reasoning to resolve. Generally, Issues could be resolved by either: (1) a decision, adding to the algorithm, or (2) an upstream redirection in the algorithm in reasoning, to obviate the Issue.

At the NHPD, scientists' reasoning through taxonomy and comparison apparently developed particular sensibilities, affects and dispositions; sensibilities, affects and dispositions that facilitated reasoning through taxonomy and comparison. The flow of files through the assessment stream became the norm, expected, unnoticed; for enculturated scientists, only decisions, issues and Issues became noticeable.

Chapter 7. The example of an unassuming garlic file and its Issue: a study of a scientist's notice

Not every safety concern leapt out from a file, batting the scientist's nose or otherwise commanding immediate attention. I present the case of my assessment, as a scientific regulator, of an unassuming garlic file, and a reconstruction of the events that made an element of the file into an Issue. My notice, reasoning, and activities with the Issue are presented as a study of regulation in a situation of uncertainty within a complex institution in public health protection in an era of little authority.

The chapter's first argument has to do with my rather malleable notice. When I first reviewed the application to market a garlic medicine – reviewing it like I did any other file – I recommended it for licencing. When I reviewed the file because it had been made into an exceptional case, presumably with a problem, I noticed a significant safety concern. I present possible reasons for my change in notice.

I argue that as a scientific regulator, my reasoning through checklists and standard operating protocols discouraged my notice of a potential safety concern. Notwithstanding the original (apparent) impediment to this notice, once the possible safety issue had been noticed and declared an Issue, the only reasonable course of action in the Directorate was to reason through the safety Issue to its fullest extent.

No scientific staff member, even the most experienced and educated, is an expert on all things, but nevertheless: all need to act (reason and judge). A Decision on an Issue required either familiarity (expertise) or time (to get the expertise, workable standards).

I hope the reconstructed event permits the reader a peak into the everyday world of science-based regulation in which questions of who-knew-what-

when in the pre-market evaluation of medicines in large complex institutions are both impossible to answer, and indicative of a fundamental misunderstanding of regulatory scientists' reasoning in situations of uncertainty. As Mary Douglas concludes in *How Institutions Think,* individuals "have no other way to make the big decisions except within the scope of the institutions they build" (1986:128).

Chapter 8. The evaluation of traditional medicines: the challenge becomes change

Although traditional herbal medicines were the archetype for the new regulatory category of natural health products, applications for traditional medicines, as defined by the Natural Health Products Directorate, represented only a small proportion (16 percent) of all Product Licence Applications received by the Directorate by mid-2007. Despite the Directorate's scientists having devoted substantial planning to ensure the Directorate could evaluate pre-market applications from many "healing paradigms," nearly all successful applications for traditional medicines were tied to one of three medical traditions: Western herbalism, traditional Chinese medicine, and, to a much lesser extent, Ayurvedic medicine.

This chapter describes the organization of, and everyday work in, the Directorate's Traditional Assessment Stream. Pre-market applications for traditional medicines were not required to include randomized clinical trials as evidence of safety and efficacy. Another type of standard typified assessment in the Traditional Assessment Stream: the pharmacopoeial entry. I was told there were no *measures* of efficacy in the Traditional Assessment Stream; as long as the proposed medicine matched all features of a traditionally used medicine, the documented traditional use was used as a "barometer of efficacy" *in that particular, traditional paradigm.* Two worm's-eye views of scientists, Kieran and Terry, at work in their cubicles are

provided to demonstrate the ways in which scientists reasoned with phamacopoeial and other standards in the Traditional Assessment Stream.

Given the particular definition of traditional medicine at the Directorate, and given scientists' reliance on textual standards such as pharmacopoeiae in the Traditional Assessment Stream, it is no surprise that the central "challenge" for the bureaucracy in evaluating these applications, then, was "the problem of change" in or from these textual standards. I describe three challenges, as formulated by the Traditional Medicines Unit, regarding the assessment of traditional Chinese medicines for safety and efficacy.

Chapter 9. Homeopathic medicines and *acting as if* one believes

This chapter describes how scientists inside and outside the Homeopathic Medicines Unit engaged with the evaluation of homeopathic medicines for quality, safety, and efficacy. I argue that the evaluation of homeopathic medicines at the NHPD was commensurable with the evaluation of other types of natural health products, when one takes the literal meaning of "commensurability": a common metric or measure. Theoretical, hypothetical, and typical incommensurability of any logics of homeopathy and science (or biomedicine) were irrelevant in the practice of assessment at the NHPD. Such incommensurability only occurred in instances prior to practice. In practice, differences became workable.

An entire science-based bureaucracy can, and quite clearly did, operate smoothly while individual scientists expressed a range of convictions regarding whether a particular homeopathic medicine, or homeopathy in general, "works." I argue this was possible because the directorate's scientists and managers – whether they were homeopaths or not – were required to *act as if* they believed in the "paradigm" of homeopathy in assessment. While I make this argument for the evaluation of homeopathic

medicines, because the question of (dis)belief was most explicit regarding homeopathy, my discussion of the dispositions required of scientists is equally applicable to the evaluation of many other medicine types.

Chapter 10. Scientists' opinions on the science and cultural and philosophical diversity in their work

I chose the fieldsite of my dissertation research – the Natural Health Products Directorate – because of its rather particular dual mandate. The Directorate was simultaneously a science-based regulatory agency (first mandate), with the following role (second mandate):

> « Through the Natural Health Products Directorate, Health Canada ensures that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.»

Reference to the Directorate's mandate was very rare in the mundane workaday world of regulatory scientists. I therefore asked scientists in interview and in a survey: *How does the NHPD's role in respecting cultural and philosophical diversity come into play in <u>your</u> work?* I also asked many of them whether they felt their work was science. This chapter summarizes their responses. Not all scientific staff members were sure that what they were doing *was* science, but even those that were not sure (roughly half) conceded that assessment is *based on* science. Nearly all interviewees, however, responded by complexifying science.

To some extent, scientists' professed experience of "respect for cultural and philosophical diversity" – when there was any such experience – was experienced as a feature of organizational structure or staffing. In their responses, some scientists separated organizational structure or processes from diversity among staff; others felt that the diversity among staff was what allowed the organizational structure to respect cultural and

philosophical diversity. Still other scientists redirected my line of questioning about the relevance of that formulation of NHPD's official mandate.

From the perspective of many assessment officers, whether their daily work was *science* or involved "respect for cultural and philosophical diversity," was not self-evident.

Chapter 11. Where is multiculturalism?

From my perspective as an anthropologist, whether the scientists' work had any relation to Canada's official policy of multiculturalism was likewise not self-evident.

Chapter 12. Appropriate reasoners

For the vast majority of scientists who regularly evaluated traditional and homeopathic medicines, the evaluation of their safety and efficacy was neither mysterious nor obscure. It involved clear standards. For the vast majority of scientists who regularly evaluated medicines according to "the totality of the evidence," the evaluation was neither mysterious nor obscure. It involved clear standards.

Nevertheless, in scientists' evaluations of any type of medicine for safety and efficacy, scientists could follow the standard operating protocols to the letter and do the assessment badly or masterfully, in ways that other assessment officers would recognize. To reason appropriately, scientists not only had to gain expertise with the particular standards but also had to notice and frame the relevant comparisons in the evaluation of any given medicine. Appropriate reasoning required apt discernment and abduction; this was inseparable from scientists' biographies.

Chapter 13. Numbers of science

After some coworkers heard me describe my original research focus – the numbers and statistics used in the evaluation of natural health products – they reportedly joked: *What numbers does she mean? The file numbers?*

The overall disappearance of number transformation in scientists' mundane workday is consistent with other ethnographic studies of science, and of everyday life. Nearly every opportunity for calculation is reconfigured as an opportunity for comparison.

Because I was determined to redeem my original research focus (statistics), after I finished working as a scientific regulator in the Bureau licencing individual medicines for sale, I studied the work of the evaluators who recommended authorization of clinical trials of natural health products in Canada. *Grosso modo, c*alculation made the same disappearing act in the Clinical Trials Unit as it had in the units of the other Bureau. There had been instances, I was told, of scientists in the Unit raising concerns about the statistical analysis proposed for clinical trials, but these concerns were rationalized to fall outside the Directorate's mandate. This reasoning is inseparable from particular sociological features that strongly shaped reasoning in the Directorate, that are explicated for the remainder of the dissertation.

Chapter 14. Numbers of management

While assessment officers downplayed the importance of statistical work in their evaluation of safety and efficacy, assessment officers' approach to evaluation was strongly shaped by a different type of number: the productivity quota. The productivity quota – 7.5 Safety and Efficacy Assessment Reports per assessment officer weekly, in the Traditional and

Non-Traditional Assessment Streams – was introduced by the Directorate's management in 2006.

In this chapter, I present how scientific staff described the impact of quotas on assessment officers and their everyday work. The impact of productivity quotas was felt most keenly by the directorate's many temporary staff, many of whom believed that they would lose their jobs if they did not meet this quota. Staff also complained the productivity quota did not take into account the variable difficulty of assessing different product licence applications. These complaints, nevertheless, did not challenge the introduction of productivity quotas in any fundamental way, but rather quibbled with the conditions of their introduction.

The Directorate's management could not say whether the productivity quotas improved the "performance" of assessment officers. It thus remains speculative whether introducing quotas helped achieve the ostensible purpose of quotas: to reduce the backlog. Despite this questionable usefulness in reducing the backlog, productivity quotas did permit upper management to reckon the Directorate's location in the sea of product licence applications received. Productivity quotas also brought the backlog into the everyday work of assessment officers, and framed how they approached the evaluation of product licence applications. I argue that the productivity quotas oriented the assessment officer's affect to files, in a way that privileged quickly completable files, and lessened the chance that scientific staff noticed or investigated atypical "issues", including safety concerns.

Thus, while precise *numbers* like 7.5 can be altered without significant effect, the act of *numbering*, e.g. the introduction of productivity quotas, reconfigured assessment (Holmberg 2005; see also Hacking 1991, 1982). The introduction of productivity quotas brought the heuristic of the backlog,

an “apparently innocuous bureaucratic principle” to use Arjun Appadurai’s (1996:182) words on another subject, into the daily activities and imaginary of NHPD’s assessment officers. This particular way of reckoning health protection has shaped Health Canada’s scientific assessment activities, and undoubtedly will continue to shape federal health protection in many countries for years to come.

Chapter 15. The Backlog

The Directorate’s backlog – the completed Product Licence Applications submitted to the Directorate, but about which the Directorate had not yet made a decision – was a paradox. It was a paradox because it simultaneously indicated the need for the Directorate, and the impossibility of the Directorate.

To upper managers in the Canadian Public Service, backlogs are apparently unthinkable, unacceptable. They are unthinkable because their existence entails some failure as regulator, manager, administrator: as institution. “Unacceptable from a business perspective,” the NHPD’s backlog was the elephant in the room in 2006 and 2007 when it was not actually the explicit subject of discussion, which it was, most of the time. The backlog was an obsession: the activities of an entire Directorate were oriented towards backlog reduction, with managers characterizing the backlog and planning its elimination through calculations, “action plans,” even motivational Backlog Busting Progress Meters positioned by the Directorate’s elevators.

The backlog was a particular sort of measure – its mere existence, was damning. This predicament is not a parochial one; backlogs are apparently of concern to regulatory agencies worldwide.

Chapter 16. “Science culture” vs. “MBA culture”

It only took attendance at a few employee consultations and panels to diagnose a fundamental and persistent so-called “cultural” misunderstanding among the variety of public servants at Health Canada. I frame the disconnect as one of “science culture” versus “MBA culture.”

This chapter defines managerialism (MBA culture) and characterizes the managerialism and its tools relevant to the NHPD in 2006-2007. In the managerialist rationales of 2006-2007, there simply was no room for science. As a scientist remarked of managers in a science forum: “If we call it basic science, they [management] say universities should be doing it; if we call it applied science, they say that industry should be doing it.” Upper managers wanted the scientific “deliverables” like monographs and decisions without allowing for the unpredictable course of reasoning or time required.

NHPD scientists, in interview, did not necessarily blame upper managers for this state of affairs, although some expressed disappointment. Experienced government scientists seemed to have little expectation that executive-level managers in the department understood what their government scientists actually did. Nevertheless, upper managers – those in the MBA culture – were determining the conditions within which regulatory scientists’ activities occurred.

Chapter 17. Staffing matters: the high rate of temporary and tenuous employment among scientists.

During my participant observation in 2006-2007, over half the Directorate’s scientific staff was temporarily, rather than permanently, appointed to positions. This chapter documents the extent of the precarious (tenuous) appointments and describes the variety of temporary appointments and

employment in the Directorate. This high rate of tenuous appointment was experienced by many scientific staff as misfortune. I also argue that this high rate of tenuous appointment at the Directorate had the effect of promoting obsequiousness.

This analysis of appointments at the Directorate is important for two reasons. In the Directorate, staffing matters were one of the most frequent topics of gossip and rumor, and at the heart of rare overt displays of overwhelming emotion. Also, there is little or no documentation or description of the most common type of temporary appointment observed at the NHPD – employment via contract hiring agencies – in the Canadian Public Service.

Given the sociological dependence of all reasoning, it is important to examine the impact of temporary appointments on the reasoning of professionals in the service.

Chapter 18. Fairness in staffing, fairness in evaluating: Canadian nice and its impact.

Fairness was not only an explicit, official value in the Canadian Public Service and at Health Canada, but also a value that, I argue, held an important place in the moral economy of scientific assessments at the NHPD during the time of my fieldwork. As important as fairness was to discussions of scientific assessments, its importance in those discussions paled in comparison to its omnipresence in discussions of staffing matters.

I characterize this fairness through a description of scientific staff's ongoing moral accounting of hiring and promotions in the Directorate. This specific and robust particular fairness was:

(1) kind and considerate behavior,

(2) that hinged on the manager's manifestation of empathy for the staff member concerned,
(3) and that included a disposition to concede every reasonable claim.

But this behavior has a clearly limited application. Fairness:

(4) was not applicable to hypothetical people or groups, but only to known interlocutors.
(5) Considerate behavior towards any person was counterbalanced by the consideration and empathy due to other, comparable, persons,
(6) because in any instance, all commensurable interlocutors must be considered and treated equally.

Using these characteristics of the fairness in evidence at the NHPD, I further my analysis of scientists' evaluation of Product Licence Applications, by examining the impact of this fairness on scientists' relationships to applicants and "the public" in the regulatory evaluation of medicines.

Chapter 19. The sociological dependence of all reasoning

Conclusions.

Every epistemological theory is trivial that does not take th[e] sociological dependence of all cognition into account in a fundamental and detailed manner.

Ludwik Fleck, *Genesis and development of a scientific fact*

Part I. Introduction and thesis

Chapter 1
An empirical study of scientists' reasoning in public health protection

Social institution: Government

The project of social anthropology is, arguably, to characterize social institutions (Evans-Pritchard 1951, Douglas 1986). In nations around the world, an important social institution is the state, or government. There are many ways of approaching government as a social institution, anthropologically. One way is to examine the role of the institution in society at large (e.g., Herzfeld 1992). This dissertation, however, represents an ethnographic approach of another kind: an examination of daily life and its dynamics *within* the institution (e.g., Riles 2004).

Individuals unfamiliar with the processes of government often have unrealistic expectations of how large governmental organizations operate. These naïve outsiders may also assume that Weberian-style characterizations of rational or bureaucratic processes can transparently stand in for empirical observation of those processes. It is not that these expectations and assumptions are entirely due to naïveté; often the entire purpose of large governmental institutions is to have hundreds, even thousands, of individuals acting and speaking as one, and so there are many tools – some might even say ideologies or mythologies – that maintain the image of the organization as an entirely unified, rule-bound and rational, operation. From the inside, however, *any* such large operation will always appear more chaotic, less rule-governed, than it might to outsiders, naïve or not.[1] Anyone

with experience inside large governmental operations would likely acknowledge that bureaucrats' everyday reasoning activities in the face of uncertainty are more unpredictable, messier, and more socially-embedded, than naïve outsiders may expect.

In any study of daily life in a government institution, the anthropologists' task is not to discredit bureaucracy: for instance, to point to discrepancies between "actual practice" and rationalizations of processes. As anthropologists and organizational sociologists have shown, there is *always* more than is simply determined by official definitions or formal expressions of ideology. I am not speaking here of conspiracies, or subversion, or hypocrisy, or corruption; I am speaking of the fundamental way in which, as empirically demonstrated by organizational and other sociologists, there are norms for activity in every organization, internal routines, that are above and beyond the explicit (e.g., Wynne 1988). These informal norms and internal routines cannot be stripped away to get at "just" the official definitions; even if one takes away one informal norm, another, by definition, will replace the removed one. A useful analogy is the problematic substitution of "seeing as" with "seeing," outlined by Thomas Kuhn in his forward to Ludwik Fleck's *Genesis and development of a scientific fact*:

> What I saw when I looked at the famous duck-rabbit was either the duck or the rabbit, but not the lines on the page – at least not until after much conscious effort. The lines were not the facts of which the duck and the rabbit were alternative interpretations (in Fleck 1979:ix).

Central puzzle: uniformity of reasoning

It is not self-evident how dozens, hundreds, thousands of people come to embrace the same informal norms and routines. This lack of self-evidence is especially prominent when that group of people is a diverse group of scientists, trained in a motley of disciplines, roughly forty percent born and raised outside the country, and with a range of life experiences and interests. This lack of self-evidence becomes even more pronounced when those scientists are working in an area fraught with contention, disagreement, and misunderstandings: such as the regulatory evaluation of traditional, homeopathic, and herbal medicines for efficacy and safety. This dissertation examines the everyday work of such bureaucrats, in a federal Canadian government organization tasked with public health protection.

The central puzzle of this dissertation is how one hundred diverse and very differently-trained public servants came to speak, reason, even *notice* as one, in their work activities – despite many of them professing to reason in very different ways in their non-work lives. This dissertation details many of the mundane tools used in the social and technological co-ordination enabling these many individuals to speak-as-one and come to adopt a relatively uniform style of reasoning.

The dissertation draws from thirteen months of fieldwork inside the Canadian Public Service, among the one hundred scientists working in a federal government directorate responsible for the pre-market evaluation of medicines.[2] I will describe

my research methods later in the chapter; first I provide an overview of the organization and mandate of the bureaucracy that was my fieldsite.

The Natural Health Products Directorate, the directorate in which I did my fieldwork in 2006 and 2007, is a sub-organization of the Canadian federal department of health, Health Canada.[3] Health Canada is, by law and by interpretation, the federal government entity tasked with the promotion and preservation of the health of the people of Canada.[4] As should be clear from my framing of the central puzzle, this dissertation does not evaluate the success of the organization. I am convinced, nevertheless, that each and every scientist in my research fieldsite was utterly committed to the department's mandate. The dissertation describes *how*, rather than *whether*, the scientists contributed to the mandate.

In 2007, Health Canada employed approximately nine thousand public servants across the country of approximately thirty million. As in most Canadian federal government departments, these public servants worked within clearly delineated, hierarchical reporting relationships, with the positions at the apex of the pyramidal hierarchy appointed by the Prime Minister or delegate.[5] Like many federal Canadian departments, Health Canada was broken down organizationally into Branches; the Branches were broken down into Directorates; the Directorates were broken down into Bureaux; the Bureaux broken down into Divisions; the Divisions broken down into Units.[6] (This organizational hierarchy, for quick reference, is included in the preface matter. There were also many additional, ad hoc

organizational entities and positions at various levels, and not every level was always present; the schema of the pyramidal hierarchy, however, is sufficient for the purposes of this dissertation). The Branch of relevance to my fieldwork in Health Canada was the Health Products and Food Branch (HPFB). HPFB included several Directorates that regulated medicines, premarket: the Therapeutic Products [Drugs] Directorate (TPD), the Biologics and Genetic Therapies Directorate (BGTD), the Veterinary Drugs Directorate (VDD), and the Natural Health Products Directorate (NHPD), the site of my fieldwork. These four Directorates, along with the Directorate responsible for the *post*-market regulation of medicines, the Marketed Health Products Directorate (MHPD), are what I refer to as *sister directorates*. These five sister directorates employed many scientists and medical officers to meet their regulatory mandates in the review of medicines. In addition to the sister directorates, HPFB also had an Inspectorate responsible for compliance and enforcement of the Food and Drugs Act, the Food and Drug Regulations, and the Natural Health Products Regulations, among other laws.

Health Canada's organization and drug evaluation unremarkable, internationally

This organizational arrangement, while specific to Canada, contains very little that is exceptional among government regulatory bodies, internationally. Key activities in pre-market drug regulation have been common to many countries through the past several decades. Based on Arthur Daemmrich's comparative work in the history of regulatory drug evaluation (e.g., Daemmrich 2000, 2003a, 2003b), as well as Liora Salter's (1988) comparative account of the development of standards

in other areas of what she calls *mandated science* in public health protection, there is nothing particularly striking, or odd, about the ways in which Health Canada went about its public health protection mandate with respect to the review of medicines compared to those used in many other countries around the world. For many chemical and biological medicines, there are clear standards in the national premarket regulatory review of medicines that are more or less "harmonized," internationally;[7] while the standards used in the review of traditional, homeopathic, and herbal medicines are less standardized internationally, the fact of having standards used in the review of these medicines is itself standard, with many countries enacting regulations specific to herbal medicines in the last years of the twentieth century (WHO 2005:25).[8]

But again, formal standards and processes – whether harmonized internationally or not – never fully determine bureaucrats' reasoning and judgements in everyday practice. Arthur Daemmrich (2003a) and Mary Wiktorowicz (2003) establish that, despite the activity of pre-market drug regulation being common to many countries through the past several decades, there are notable differences among the decisions taken by different countries. This was also one of Liora Salter's findings regarding the development of standards for pollutants and contaminants in public health protection: "Canadian and American authorities relied upon a similar body of scientific information to develop standards, yet their standards often differed" (1988:161). Ethnographers in the broader realm of public health protection have similar findings. Thomas Chivens (2004), for example, describes the

reinterpretations, reenactments of public health protection protocols as they moved from their origins in the USA to their implementation in Poland.

Daemmrich attributes international discrepancies between pre-market regulatory decisions regarding pharmaceuticals to the importance of *national political cultures*: especially the timing of various regulatory projects, the interface of lobbies with regulating agencies, and societal representations of drug catastrophies (2003b:11). My study complements Daemmrich's study of national political cultures by explicating significant, local features from within the mundane bureaucratic culture of a regulatory agency, features that often do not appear in documentary traces.[9]

This dissertation not a study of policy, nor does it offer policy suggestions

While this dissertation is an ethnographic account of the mundane workings of scientists in a regulatory organization, it is *not* a study of *policy* (cf. Shore 1997; Wedel and Feldman 2005). I do not mean to split (definitional) hairs about "policy," but the activities described in this dissertation and in other studies of *regulation* (e.g., Salter 1988, Daemmrich 2000, 2003a,b) are often very different than those captured by texts addressing science *policy* and science *advice* (e.g., Jasanoff 1990, Jasanoff ed. 2004, Berridge 2005, Webster 2007, Bijker et al. 2009).[10] The difference is not attributable to nation nor to research methods; the difference holds even when examining ethnographic and anthropological accounts of Canadian health and science policy in particular (e.g., Cambrosio et al. 1990, Rock 2001, Strathern 2003, Bibeau 2004). Cambrosio, Limoges and Pronovost (1990) have

written a very useful ethnographic account of how policy dossiers are constituted in the Quebec government, an account that I suspect would be very relevant to the *policy bureau* of the directorate in which I did my fieldwork. The scientists described in this dissertation, however, were in a regulatory science bureaux and did not generally "do policy," except by accident or by special assignment. Even then, scientists' accidental or occasional forays into policy involved different activities and timelines than in the "policy shops" elsewhere in the department, and, as I found out, a regulatory scientist's foray could easily become a faux pas if the "policy people" were not expediently brought on board. If, by "policy," one wishes to capture anything and everything done by anyone remotely affiliated with government – then perhaps this dissertation aligns with that wide scope, although I would quibble with the use of the descriptor "policy."

Furthermore, the dissertation does not seek "engagement" with policy-makers (cf. Nowotny 2010), nor to make policy suggestions, nor to make any suggestions for government officials, for that matter.[11] What the dissertation provides is an ethnographic account of scientists' reasoning.

Regulatory scientists' reasoning

Just as naïve outsiders to government often have unrealistic expectations of how large governmental organizations operate, naïve outsiders to science-based endeavours may have unrealistic expectations of scientists' reasoning. In both cases, such expectations often involve formalized characterizations of reasoning,

as well as omniscient (and occasionally omnipotent) individuals who are somehow removed from mundane social interactions and imperatives that come with being human.

Empirical studies of scientific reasoning have disproven such unrealistic expectations, even in the "hardest" of laboratory and experimental sciences. All scientists work in a "messy" way (Nowotny 2010); this is not stated a criticism, but as the sum of empirical observations published in the social studies of science. The project of social anthropology remains the same. The importance of the human sociality and the human emotions – because, after all, emotionless reason is a formal oxymoron – does not all of a sudden disappear upon becoming a scientist (see Thagard 2006 for a review); and this is not, in these empirical accounts of scientific reasoning, a failure of scientists, but an obvious and unremarkable necessity. As Ludwik Fleck observed, "those who consider social dependence a necessary evil and an unfortunate human inadequacy which ought to be overcome fail to realize that without social conditioning no cognition is even possible" (Fleck 1979: 43).

I hope this ethnography contributes to this literature, to ethnographic accounts of scientists' reasoning. While common-sense tells me I cannot assume that any reader would not find previous ethnographies of laboratories revealing, I also cannot include a review of decades of scholarship to bring the reader to the point where this dissertation takes off.[12] Let me instead offer Allan Young's plain-

language observation of what the task of an ethnographer of science is understood to be in the field of social anthropology, in the early twenty-first century:

> The job is not to discredit science. [Philosopher Ian] Hacking says this very nicely, he said: 'I'm not interested in deconstructing what science does, I'm interested in knowing how science constructs knowledge, because that's my knowledge as well.' To talk about the contingencies that shape technology [and reasoning and judgements] doesn't make that knowledge any less science." (Duclos 2009:113)

Comparisons and contrasts to previous ethnographies of science

There are a few differences in emphasis in this dissertation's ethnography compared many previous ethnographies of science. This is in addition to the feature of being an ethnography of *regulatory* scien*tists* based on an extended period of participant-observation *in government*.

In Europe in the 1970s and 1980s, historians and sociologists of science used anthropology and ethnography as inspiration for their work.[13] Many conducted empirical studies of scientific laboratories, and called their work *anthropology* and their books *ethnography*.[14] These ethnographies were seen as novel not only because of method but also because of their persuasive arguments against the conceptualization of scientific reasoning then popular in contemporary epistemology.[15] The researchers variously argued that the discussion of scientific reasoning as purely logical and sequential mental activity – as separable from relationships, materials, bodies, routines, and machines – was flawed. Anthropologists, contemporaneously, were conducting fieldwork in physics laboratories.[16] Soon after, they began pursuing research into the processes and

impacts of biomedicine.[17] In these ethnographic accounts, the particular dynamics of the research community or epistemic culture *were* the ethnographic account.[18] This dissertation draws from sociology as well as scholarship in the social studies of science, even addressing a concern of primary interest to earlier, sociologically-inclined ethnographies of science: the *order* observed in science. It constitutes an explanation for the uniformity of scientists' reasoning in the particular government directorate in which I did my fieldwork, but as the reader will soon find out, this is inextricable from scientists' *particular* immediate evaluation activities and work relationships – and so the dissertation also draws from early anthropological ethnographies of science. Writing at this intersection is unremarkable in comparison with several recent ethnographies of science written by anthropologists in dialogue with the social studies of science (e.g., Hayden 2003, Petryna 2002, Rapp 2000) or by scholars working across disciplines (e.g., Cambrosio and Keating 1995).

The minor difference in emphasis is that, while I am studying scientists, I am not studying scientists-in-action in laboratories; nor am I describing *multi-sited* fieldwork like many anthropologists of biomedicine. My fieldwork was centred on a community of just over one hundred scientists in a single office building located in a suburb of Ottawa called Nepean, in Ontario, Canada. The scientists all worked (or had worked) in the two bureaus of the NHPD that employed all but a couple of the Directorate's scientific staff: the Bureau of Product Review and Assessment, and the Bureau of Clinical Trials and Health Sciences. With the exception of a

handful of upper managers who had closed offices, *all* of the scientists worked in individual cubicles with the approximate dimensions: two metres high, three metres long, and two metres wide. These cubicles were dispersed through three floors of the secure (non-public) government office building. The Directorate had no laboratories; the pre-market evaluation of traditional medications' safety and efficacy was entirely paper-based. This cubicle-boundedness of the scientists I studied does not make the study parochial; quite the opposite.

Much attention through the twentieth century has instead been paid to the 'heroic exceptions,' the individual scientist or doctor struggling or competing for The Truth.[19] Paul Starr, speaking of physicians nearly three decades ago, notes that "[b]ureaucratic professionals still seem anomalous even though they now represent the overwhelming majority of professionals" (1982:420). This observation still holds. The scientists I studied were in a social and environmental position found worldwide: they were white-collar workers in the lower or lowest rungs of a complex organizational hierarchy, working with documents in individual, computer-equipped cubicles (work stations). Fieldwork in this environment, as in any fieldwork environment, involved a particular combination of drudgery and fascination. While some might find the anthropological study of cubicle life rather dull, it is not parochial, in the sense that this social and physical environment is found around the globe. This atomized but worldwide environmental form, I believe, shapes human activity slightly differently than its equally atomized, but

worldwide predecessor (the bureau). It is also an environmental form found throughout the world in scientific institutions.

Reasoning, as approached by this research

I address *scientists' reasoning* rather than *scientific reasoning*, the latter phrasing more often used in the body of scholarship in the social studies of science. What do I mean by *reasoning*?

The dissertation's analysis builds on the approach to reasoning used by several scholars drawing from historical materials, an approach characterized by the work of Ludwik Fleck, Ian Hacking, Lorraine Daston, and Allan Young. These scholars have theorized reasoning – scientific reasoning, in particular – as a collective endeavour. Scientists' reasoning, for these scholars, is not individual or cognitive in the everyday sense of reasoning, but inclusive of the materials, narratives, techniques, social dynamics – institutions – involved with the production of facts.

This approach is consistent with work in social anthropology on reasoning more broadly (e.g., Douglas 1986). Surprise at the uniformity in reasoning among the members of a social group is as old as anthropology. Even before social anthropology was a discipline, Emile Durkheim discussed elements of this uniformity. He attributed uniformity in reason to 'society', writing how cognition is

structured by society.[20] As Mary Douglas explains in her summary of Durkheim's work a century later:

> Classifications, logical operations, and guiding metaphors are given to the individual by society. Above all, the sense of a priori rightness of some ideas and the nonsensicality of others are handed out as part of the social environment (Douglas 1986:10).

Because classifications are shared by and via interpersonal interactions, there is no way to reason outside society. A priori, in this logic, there is no universal "right" way to reason, she continues. This is not to say that anything can be considered reasonable. Within any social context, there are "right" ways to reason and judge, inappropriate or "wrong" ways to reason and judge, and, much more that is simply unrecognizable as either reason or judgement. This line of work in social anthropology is distinct from the long debate in social anthropology on *rationality*, although it sometimes draws from it.[21]

The objectives of the scholarship from which I draw are various. Mary Douglas aimed to develop a "theory of institutions," necessary "to amend the current unsociological view of human cognition" (1986:xi). Ian Hacking sought to explain the stability of laboratory sciences over time, and did so by working towards a framework of styles of reasoning in the sciences more broadly (1992a).[22] [23] [24] Lorraine Daston sought to explore how moral economies are "constitutive of those features conventionally (and, to [her] mind, correctly) deemed most characteristic of science as a way of knowing": empiricism, quantification, and objectivity (1995).[25] Allan Young detailed the history of psychiatric science through the twentieth century to show that while the types of research questions considered

reasonable, and what might constitute an answer, changed, the idea that findings in psychiatry were timeless remained constant (1995:9-10,264-286). Each of these accounts draws from Ludwik Fleck's *Genesis and development of a scientific fact*.

Ludwik Fleck (1896-1961), a medical doctor and accomplished laboratory researcher, finished writing the German-language *Entstehung und Entwicklung einer wissenschaftlichen Tatsache: Einfuehrung in die Lehre vom Denkstil und Denkkollektiv* in 1934. The book was reviewed and discussed in his native Poland as well as in Germany, Switzerland (where it was published in 1935), France and Italy at the time, and in his later homeland, Israel, and then largely fell into obscurity until an English translation was published in 1979 as *Genesis and development of a scientific fact* (in Fleck 1979:149-153).

Fleck's thesis in *Genesis and development of a scientific fact* is that the development of a scientific fact is inseparable from the ideas circulating in scientists' historical context, and from the inherent sociological dynamics of collective activity. He develops his thesis through a case study of the development of the Wassermann reaction, a reaction that simultaneously permitted the diagnosis of syphilis in two senses: it created syphilis as a medical diagnosis and disease, and allowed for its detection in the clinic and biomedical laboratory. He points out that scientists arrived at this fact, the Wassermann reaction, based on incorrect assumptions and irreproducible experiments – an important point, which was counter to much contemporary theorizing of science's ineluctable progress.

The question framing his work is: "*how, then, did this empirical fact originate and in what does it consist?*" (1979:xxviii).

To make his argument, Fleck develops a terminology specific to his work. He explains how initial studies into the carnal scourge were inseparable from hazy *proto-ideas* of syphilis including ideas of "bad blood" with assumptions regarding its cause, as well as what we might now call differential diagnosis through pharmaceutical treatment and social or class stereotyping. He characterizes these entities as proto-ideas because, for example, the "ethical-mystical disease entity" as well as the "empirical-therapeutic disease entity" were points of view that were contradictory as well as sometimes amalgamated, based on empirical observation, although never adhered to consistently (1979:5). There was no ineluctable relationship between these hazy proto-ideas – themselves "neither right nor wrong" (1979:25) – and the development of syphilis as an entity in the history of ideas. He argues that scientific facts become timeless, ahistoricized because of the *harmony of illusions* produced by successful research:

> Evidence conforms to conceptions just as often as conceptions conform to evidence. After all, conceptions …. are stylized units which either develop or atrophy just as they are or merge with their proofs into others. Analogously to social structures, every age has its own dominant conceptions as well as remnants of past ones and rudiments of those of the future. It is one of the most important tasks in comparative epistemology to find out how conceptions and hazy ideas pass from one thought style to another, how they emerge as spontaneously generated pre-ideas, and how they are preserved as enduring, rigid structures [or forms] owing to a kind of harmony of illusions. It is only by such a comparison and investigation of the relevant interrelations that we can begin to understand our own era (Fleck 1979:27-28).[26]

For Fleck, a thought style "determine[s] and condition[s] every single function of cognition" (1979:38). These thought styles do not float about, but rather are the product of, and exist through, thought collectives.[27] He defines a thought collective as a group of individuals exchanging ideas, interacting interpersonally on a non-imagined basis (cf. Anderson 1991); it is the collective's "given stock of knowledge and level of culture" that is the thought style (Fleck 1979:39). Fleck is explicit that there is no human cognition outside of society's mediations; there is *no outside* of thought collectives, and "every individual belongs to several thought collectives at once" (1979:45). He describes the dynamics of thought styles, articulating the different ways in which individuals at the periphery of a thought collective (e.g., "public opinion") shape but do not entirely determine the activities of scientists at the collective's core (e.g., "vanguard") (1979:102-124). The more deeply one enters into a scientific community – into the vanguard of the thought collective – the stronger one's reasoning is bound to that collective's thought style. Conversely, Fleck argues, the further one goes from the core of the vanguard's activity, the more certain the fact appears.[28] He ends *Genesis and development of a scientific fact* by making some initial observations on the "special intellectual mood [disposition] of modern science," which is in effect a "readiness to perceive in a stylized manner" (1979:xxv).

There are three points that Fleck makes that are crucial for my discussion of the most striking features of scientists' reasoning in the premarket review of medicines. As I will explain in the next chapter, to me the most striking feature was scientists'

notice of certain, but not other, features of the evidence supporting the safety and efficacy of proposed medicines; as well as the scientists' relatively uniform affective dispositions towards certain types of files. (Here, I am speaking of the *notice* and *affective dispositions* that are observable to an anthropologist, manifest in actions, statements, behavioural responses, and so on). There are two interconnected ways in which Fleck's work can inform how scientists' notice, or *directed perception*, may be shaped by the scientists' inclusion in a thought collective: social positioning and collective activity. These entities and their interconnections are sociological; as Fleck remarked, with slightly different intent, "every epistemological theory is trivial that does not take th[e] sociological dependence of all cognition into account in a fundamental and detailed manner" (1979:43).

As Fleck observes, empirical observation is inseparable from classification. Syphillus was only separated from many other venereal diseases after scientific advances in other fields enabled the separation. For Fleck, this proves that "so-called empirical observation" was insufficient for "the construction and fixation" of syphillus (1979:3). Structures of classification determine which research problems may be pursued, for instance; "to recognize a certain relation, many another relation must be misunderstood, denied, or overlooked (Fleck 1979:30).

Fleck's discussion of thought styles was contextualized, specific to the group of researchers developing the Wassermann reaction. However, philosopher A.C. Crombie has characterized six styles of scientific thought arising in the Western

scientific tradition, “distinguished by their objects of inquiry and their methods of argument” (1994:xi): (1) postulation, (2) experiment, (3) modelling, (4) taxonomy, (5) probabilistic and statistical analysis, and (6) historical derivation.[29] Crombie concludes:

> each style [of thought] then defined the questions to be put to its subject-matter, and those questions yielded answers within that style, so that an inquiry for postulated principles yielded just that, for taxonomy just that, for probabilities just that, for historical origins and diversification therefrom just that. In this way a change of style changed the questions put to the same subject-matter. (1994:xi-xii)

Crombie’s argument regarding styles of thought is non-psychological, in the everyday sense of the term, attending to an “integrated response of intellectual and social habits and dispositions to opportunities provided by a present combination of fruitful ideas with technical possibilities” (1994:88).

Perception is directed not only by classification, but also dispositions stabilized by social collectives. Part of the continuity of scientific thought styles, Ludwik Fleck implies in his analysis of the Wasserman reaction, is the stability of interactions in social groups, a stability that is facilitated by organizational structures. Fleck asserts that whenever two or more individuals are in discussion, a particular mood or disposition is created “which would otherwise affect none of the members and often recurs whenever these members meet again” (1979:103).[30] Moods, and the thoughts possible therein, are often transient because groups are transient. Nevertheless, relatively stable moods and thoughts are formed “particularly around organized social groups” (1979:103). Fleck’s discussions of mood are sociological, not psychological.

Fleck describes the way in which a thought style becomes “natural and, like breathing, almost unconscious, as a result of education and training as well as through [the research scientist’s] participation in the communication of thoughts within his [or her] collective”; conversely, “to the unsophisticated research worker limited by his [or her] own thought style, any alien thought style appears like a free flight of fancy” (1979:141). Among the scientists I describe, however, very few, I believe, would argue that their way of reasoning on-the-job was almost unconscious. They openly recognized many ways in which their style of reasoning was born of pragmatic choices given the felt non-authoritative position of the assessment officer, and was structured by forms created out of pragmatic and sometimes political imperatives.[31] That said, there were effects of the thought-style that were unintentional – “unconscious” – for instance my notice (and lack of notice) of a common-sense safety issue in a file.[32] It is to such unconscious effects or elements I apply Fleck’s emphasis on disposition, not to the development of forms in the style of reasoning that are explicitly recognized as borne of a particular interest or pragmatic happenstance. In reasoning, so much is encoded by the way in which the problem is apparent, and the concomitant dispositions engendered by the formulation of the problem.[33] Through this focus on socially-situated activity, one can analyze a change in notice, in directed perception, without involving a psychology. Fleck’s point is that cognition is “not an individual process of any theoretical “particular consciousness.” Rather it is the result of a social activity” (1979:38).

The ways in which an activity is structured – through its component forms (material, textual, ideational) as well as social structure of a group, and that group's emotional forms (including etiquette, habits, and moral constellations) – interpellate scientists into particular ways of classifying, and therefore reasoning. Perhaps the reverse is also true, but that is irrelevant for this dissertation, because I am not making an argument worthy of structure-functionalism as this dissertation's quandary is not about whether or how the pre-market evaluation of medicines maintains a certain social structure.[34] Rather, I investigate how scientists' participation in the thought collective, including the structuring of the social group and the structuring of the group's activities, shaped scientists' disposition, directed the scientists' attention to certain features, interpellated the scientists into a certain style of reasoning.

Approaching reasoning as a collective, materially- and socially- embedded activity is not the same as arguing that there exists a "suprapersonal cognitive system," which, as Mary Douglas notes, makes many people nervous because of its links to totalitarian imaginaries (1986). This is also not the same thing as advocating the abolishment of any human and non-human divide in the production of scientific fact, as advocated by a prolific contingent in the social studies of science (e.g., Haraway 1991, Latour 1993). These points are immaterial for this dissertation focussed on *scientists'* reasoning in public health protection. Even beyond taking the pragmatic approach of methodological individualism, I remain focussed on

individual reasoners. The dissertation does, however, investigate how the individuals' inclusion in thought collectives including the materially-embedded activities and habits of those collectives shapes reasoning. Approaching scientists' reasoning as activity enables me to address my puzzle – the surprising uniformity in scientists' reason – without reaching beyond the limits of my fieldsite, or conjecturing beyond what was empirically observable. It also underscores that the reasoning I am discussing is not in the heads of the scientists.

Research methods

The Natural Health Products Directorate is a science-based organization mandated to "ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity" (e.g., Health Canada – NHPD 2006b). The original objective of the research project was to document and analyze how the Directorate's scientists evaluate traditional and herbal medications, given the scientists' dual mandate: to do science-based evaluations, and respect cultural diversity.

This dissertation is based on 13 months of fieldwork among the Directorate's hundred or so scientific staff from August 2006 to September 2007.[35] Methods used during fieldwork inside the Directorate included participant-observation – I worked for a year, part-time, as a scientific regulator (details below) – as well as

formal interviews (with 40 staff members), periods of strict observation (of 12 officials), a survey of the Directorate's assessment officers, and the analysis of internal documents.[36] In addition to the 13 months fieldwork inside the Directorate, over the course of five years (2003-2008) I pursued archival and historical research, attended conferences and other events in Canada on the science-based evaluation of herbal and traditional medicines, and interviewed at least ten active participants in the Canadian natural health product research communities (these 10 interviews are in addition to the 40 formal interviews with Directorate staff members already mentioned).[37] This research project was approved by McGill University's Research Ethics Board 1 on February 22, 2006 with permissions renewed, with a few modifications, until February 2011.[38] While it is odd to state the following in an anthropology dissertation, the following statement would be conspicuous in its absence in any publication in the medical sciences: I have never received monies or gifts from a medicines company nor, to my knowledge, have I ever invested in any such company.

The Directorate is located in a secure government office building that non-staff cannot enter unless accompanied at all moments. To pursue my fieldwork, I accepted employment in the Directorate, with the explicit understanding between myself and my manager that I did so as a way to do my anthropological fieldwork.[39] I had never previously worked for the federal Canadian government. Although I entered the Directorate as a naïve outsider on August 21, 2006, until August 21, 2007 I worked four days a week as an assessment officer in the Directorate.[40] I

was an employee in the Public Service of Canada, in a science-based position, with duties directly tied to the assessment of natural health products. (I was not hired on the basis of my qualifications in anthropology, but on the basis of my bachelor of science in biochemistry). I continued my fieldwork in the Directorate for another five weeks after my work term was completed, although during that period I had to be accompanied on-site by staff. At various points in my fieldwork, I was both an employee of the Directorate and, at least outside the hours of my employment, an autonomous researcher. Because it is not the norm to do one's fieldwork partially through employment – although there are many precedents – I provide a brief commentary in Appendix 1 ("Employment, research methods, permissions") regarding the intersection of employment and fieldwork, more specifically the usefulness of employment as research method in this cubicle-bound fieldsite, and I also provide details on other research methods used in the fieldsite.

Going into the field, I presumed that the scientists in this regulatory body, to reconcile science-based evaluations with respect for cultural and philosophical diversity, would need to simultaneously pursue two opposing projects, namely, to: (1) develop common measures for medicines from various medical traditions (configuring commensurability), and (2) identify unique measures for medicines from various medical traditions (configuring incommensurability). I did not expect uniformity in reasoning among these scientists. Rather, the research project was originally designed to contribute to the recurring discussion in anthropology of how

to make appropriate cross-cultural comparisons (e.g., Strathern 2004a, Povinelli 2001), and more specifically to discussions of medical pluralism in the subdiscipline of medical anthropology (see Leslie ed. 1976, Leslie 1980, Kleinman 1980, Lock and Nichter 2002). My fieldwork was guided by the following central research question: *How are medicines, used in various traditions, made commensurable by a scientific regulatory body that values cultural diversity?* I was most interested in the literal sense of commensurability:[41] having a common measure (e.g., Pigg 2001).[42] Thus, I looked for measures of efficacy, paying particular attention to how, when and by whom measures of efficacy were enacted, through, for instance, paper shuffling (cf. Latour and Woolgar 1986), reports (cf. Strathern 2005), discussions (cf. Verran 2001), instruments (cf. Hacking 1992a), forms (cf. Thévenot 1984), categorization (cf. Hacking 1999, Bowker and Star 1999), algorithms, research collectives, techniques, divisions of labour (cf. Twohig 2005, Haraway 1997:23-48, Shapin 1989) and machines in calculation and computation (cf. Daston 1994).[43] The dissertation addresses the literal commensurability of different medical traditions, ethnographically. Chapter 3 approaches this commensurability *genealogically*, tracing how various traditional and herbal medicines have been evaluated and configured in Health Canada's Health Products and Food Branch and its precursors through the twentieth century.[44] The remainder of the dissertation provides an account of the standards and measures used in scientists' reasoning about the safety and efficacy of natural health products. It includes a discussion of standards and measures that featured in scientists' reasoning but of which I was previously unaware: things such as

backlogs, standard operating protocols, standard lines, high rates of hiring through contract agencies. The dissertation is loosely organized by type of measure and standard.

The dissertation contributes an ethnographic study of scientists' reasoning in the pre-market review of medicines. It complements a recent group of ethnographies written by anthropologists addressing various other elements of the evaluation of medicines in the sciences (e.g., Hayden 2003, Lakoff 2005, Petryna et al. 2006, Fisher 2009, Petryna 2009). The ethnographic account, although this was not intentional, responds to a rash of recent calls for ethnographic study of bureaucracy, since there are few such studies since the advent of so-called "New Public Management" in the 1980s, as well as for studies of regulation in cultural context.

I hope it will be clear in the pages that follow, that I have a deep respect for these scientists working in the pre-market evaluation of medicines. I hope the way I write about these scientists makes clear that what was important to some was not necessarily important to others (cf. Strathern 2004a), but that each showed agency, sense, integrity, and commitment to the department's mandate.

One remark on *agency.* Mary Douglas argues that to "suppose that individuals are caught in the toils of a complex machinery that they do not help to make is to suppose them to be passive objects, like sheep or robots." (Douglas 1986:32; see

also Herzfeld 1992:159). I do not suppose scientists to be sheep or robots in any way; and I do recount how some helped make the complex machinery of the pre-market evaluation of medicines; but I also cannot discount some scientists' accounts of feeling precisely like a cog in the machine.

I hope I do not give any impression that any scientist acted under "false consciousness", or, for that matter, that any scientist acted in a way not in the public interest. I do not believe there were instances of either, although there are many ways of conceptualizing the public interest or the common good (Boltanski and Thévenot 2006). Any problem, as I see it, and I hope I convincingly show in the dissertation, lies elsewhere.

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[1] Max Weber himself came to this conclusion after several failed attempts to operationalize a purely legal-rational bureaucracy in practice (Herzfeld 1992:19).

[2] I use the term "evaluation" in this dissertation, but that term was only rarely used in the Directorate. "Assessment" and "review" were the two terms used in the Directorate to describe scientists' activities with Product Licence Applications.For my purposes, however, these terms can be used interchangeably, as they are often used in dictionaries (with "evaluation" defined as "assessment", and "assessment" defined as "evaluation.") For clarity, however, I use "evaluation" most often, occasionally substituting with the less common term, "assessment."

[3] The Minister of Health's portfolio, along with Health Canada, includes the Canadian Institutes of Health Research, the Public Health Agency of Canada, the Patented Medicine Prices Review Board, the Hazardous Materials Information Review Commission, and Assisted Human Reproduction Canada.

[4] *Department of Health Act* 1996, c.8 4(1).

[5] The political accountability for the department lay with the Minister, who while elected as a federal Minister of Parliament was appointed by the Prime Minister to Cabinet as a departmental Minister. The administrative accountability for the department lay with the Deputy Minister (and Associate Deputy Minister), appointed by order-in-council (e.g., named by the Prime Minister). The remainder of officials in the department of health were public servants, not political appointees.

[6] To repeat the breakdown with the titles of the public servants: Health Canada was broken down organizationally into Branches, each headed by an Assistant Deputy Minister; the Branches contained Directorates, each headed by a Director General; the Directorates were broken down organizationally into Bureaux, each headed by a Director.

[7] Canada is an observer with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and a signatory to the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS), both of which play a significant role in the standardization of the pre-market regulation of medicines worldwide. Health Canada also has an implementation agreement for the pre-market review of medicines with the EU (see Health Canada – HPFB 2009) as well as with several other countries regarding specific facets of regulation (for more information, go to the "About us – legislation" section of the Health Canada website and select the pages for MOUs and agreements).

[8] Overviews of the regulation of herbal medicines worldwide are available in reports from the Traditional Medicines Programme of the World Health Organization (Zhang 1998; WHO 2005). These reports describe the wide range of official standards such as national pharmacopoeiae and monographs used by countries internationally. As part of its commitment to the Alma Ata Declaration of *Health for all for the Year 2000*, and its related advocacy for traditional medicines, the World Health Organization published a series of *Monographs on Selected Medicinal Plants* (volume 1: 1999; volume 2: 2002; volume 3: 2007). The monographs published by a committee of the German regulatory agency for medicines, a committee called *Kommission E* were very influential through the late 1990s in many English-speaking countries after they were translated into English by the (US) American Botanical Council in 1998. The commission ceased publishing these monographs as of 1993 because of the development of the EMEA, which in the domain of herbal medicines aims to harmonize European procedures. Since then, many standards have been developed in the European community, but these standards are also used by other countries elsewhere. The European Scientific Cooperative on Phytotherapy (ESCOP) began publishing monographs in the early 1990s, and, with an eye to EMEA needs, published a second edition of the monographs in 2003 and further supplements in 2009. In addition to the European registration procedures, NHPD management often discussed Australia's regulatory system (Australia's Therapeutic Goods Administration's website addressing complementary medicines is found at: http://www.health.gov.au/tga/cm/cm.htm). While the US funds research on complementary and alternative medicine through its National Center on Complementary and Alternative Medicine (NCCAM), at the time of my fieldwork, the US was not a useful model for NHPD officials because there was no premarket review or registration of most products. The legislation most relevant to the US state of affairs at the time was the *Dietary Supplement Health and Education Act* of 1994. My summary above pertains to English-language standards used for claims or safety; these were of primary concern to the regulators at the NHPD during my fieldwork.

[9] I use the adjective “mundane” in this dissertation to emphasize that the medicines in question had not become “political chemicals.” Salter (1988) used the term “political chemical” to characterize a chemical entity that can no longer be spoken of as any other; that has become identified with broader debate, debate from which it will never be extricated. “Once a chemical became a political chemical,” she concludes based on her study of controversies in Canada,

> it was difficult to conduct a specific assessment of it. The debates took the form of “set pieces” in a dramatic presentation. The scientific issues, the arguments, their style of presentation, and even the use of experts were similar from one chemical to the next. The specific attributes of a particular chemical became less important than the general debate (1988:167).

This was not the case for nearly all evaluation of individual medicines at the NHPD during the time of my fieldwork.

[10] For instance, the regulatory scientists I studied had no interest and no need to separate science from the political – a separation that, based on previous accounts, is a key activity in “policy” when done by politicians, propagandists, or politically-astute advisors; see Salter 1988 for two chapters on public controversy and standard-setting.

[11] This is primarily because the government officials I studied are far more competent than I in the realm of governance. Furthermore, while I only have a little experience in government, I have sufficient to be acutely aware of how suggestions may be put into practice in ways that acts counter to the intentions of the person making the suggestion. (*The best laid plans*…) The one “policy suggestion” I make in this dissertation is that managers in the Canadian public service read the summary of the Whitehall studies.

I should note that, as a scientific regulator inside the institution, I made a point to provide comments at every opportunity in which my comments were solicited. It is probably in the domain of suggestion-making that I experienced the clearest distinction between my dual role in fieldwork, as scientific regulator and anthropologist. As a scientific regulator and professional in government, I felt it behooved me to provide my perspective and recommendations regarding the impact of various policies and procedures on my ability to help “promote and protect the health of the people of Canada,” and to make suggestions regarding how the institution might better pursue its health protection function. As a scientific regulator, I was perfectly comfortable making extensive, repeated, and pointed evaluative comments. As an anthropologist, I am absolutely not.

[12] An introduction is available in Jan Golinski’s *Making natural knowledge: Constructivism and the history of science* (1998).

[13] Sociologists and historians of science drew on anthropology as *inspiration* long before they *identified* as anthropologists or as doing anthropology. In the early 1970s, on a BBC programme called “Science and Ideology,” Robert Young argued that a valuable way of approaching science was to work towards anthropology of science. He invoked the work of Marxist scholars and Mary Douglas to claim that the most basic knowledge – that of human nature and society – shapes scientific knowledge. His contemporary, Barry Barnes, devotes half an edited collection of writings in the sociology of science to the cultural (1972:14). By the 1980s, with the laboratory studies, researchers began identifying their methodology and their writing with anthropology.

[14] See, for instance, Latour and Woolgar (1986), Knorr-Cetina (1981), Collins (1992), and Lynch (1985). Knorr-Cetina and Mulkay (eds. 1983) provide a summary of these and other contemporary laboratory studies; for a very short listing of laboratory ethnographies, see Latour and Woolgar (1986:285 n4).

There were differences in how these researchers understood themselves to be doing *anthropology* or *ethnography*. In reviews, these researchers are often grouped into schools based on methodologies – the Edinburgh school, constructivists (Latour and Woolgar 1979, Knorr-Cetina 1981), the Bath school (e.g., Collins 1985), ethnomethodologists (e.g., Lynch 1985), actor-network theorists (e.g., Latour 1987, Callon 1986) – although in the 1980s each was, more or less, addressing epistemology.

As Lynch (1993) notes, there is a conventional history of (sociological) science studies that was oft repeated in both review articles and introductory paragraphs, including:

(1) a mention of at least one of: Robert K. Merton, Karl Mannheim, Thomas Kuhn, or less often Ludwik Fleck or Paul Feyerabend.
(2) a note of the move to empirical, field studies, not only by
    (a) early sociology of scientific knowledge (SSK), comprising both
        i. the Edinburgh school [Bloor, Barnes, Edge and McKenzie] and
        ii. the Bath school [Collins and his students Pinch and Travis],
    (b) the laboratory studies.
(3) the remark that this splintered into various theoretical and methodological positionings.

By the 1990s there was a somewhat cumulative shift in focus from epistemology to ontology. Material culture and technologies became central to many of the 1990s analyses (see ed. Pickering, 1992). Feminist scholarship is increasingly written into mainstream genealogies through the 1990s.

Of course, there are many ways of classifying trends; see Callon 2005 for an unusual classification of current studies of science into four categories based on the modelling of science as: (1) rational knowledge, (2) competition, (3) sociocultural practice, and (4) extended translation.

[15] Some ethnographers arguing so vehemently *against* epistemology that they called for the “long overdue” extinction of that discipline (Latour and Woolgar 1986:280).

[16] Sharon Traweek (1988) conducted fieldwork in laboratories in the 1970s. She, as well as two other researchers pursuing their Ph.D.s in the United States (Zabusky 1995, Gusterson 1996), wrote up results of their fieldwork among physicists in monograph form using the traditional genre of ethnography.

[17] Early analyses of biomedical science in book-length ethnographies include Martin, 2001 [1987], Lock 1993a, Young 1995, and Rabinow 1999.

[18] This is perhaps also in line with the staggered publication dates, with the increased attention to specificity and the non-unity of the sciences in the social studies of science of the early 1990s (ed. Pickering 1992).

[19] This attention consistent with late twentieth-century valuations of the self (cf. Ehrenberg 2010) in the cultures producing these accounts.

[20] One approach to analyzing the uniformity of scientists' reasoning could be to use Durkheim's communitas, to invoke some strong sense of social solidarity or community. Some scientists at the NHPD did express, in interviews or as part of their daily work, a sense of social solidarity or community among scientists. Nevertheless, just as many scientists reported feelings of isolation like "I work all day in my cube and hardly speak to anyone", even involuntary solitary confinement: "I've been 'cubed'!" No version of communitas could correctly serve as the source of, or useful approach to, scientists' uniform reasoning at the NHPD.

[21] As persuasively shown nearly a century ago by social anthropologist Evans Evans-Pritchard (1976 [1937]) in his discussion of witchcraft among the Azande, rationality is inseparable from social and material practices. This dissertation is not about rationality, however, because it is not about belief. Discussions of rationality frequently require the ethnographer to extend herself beyond that which is empirically observable. I discuss belief in a sustained way only in Chapter 9 when I describe the vast range of beliefs that scientists articulated about the efficacy of homeopathic medicines. These beliefs and convictions were so varied, they are of interest to this dissertation only to the extent that any satisfactory explanation of uniformity in scientists' reasoning must be completely disarticulated from scientists' professed beliefs about the efficacy or safety of medicines.

Several scientists did not expect their reasoning to make sense out of context, for example some explicitly described how their reasoning was tied to political imperatives and other pragmatic considerations of the day. The research question is not about whether scientists' expressed beliefs regarding the efficacy of medicines were rational; the puzzle, that I formulate in the next chapter, is how so many scientists reasoned as one despite such a wide range of expressed beliefs regarding efficacy. A discussion of reasoning need not follow (and indeed mine does not) from discussions of rationality, belief or mind.

[22] Ian Hacking, an analytical philosopher drawing from Ludwik Fleck, modified the phrase "style of scientific thinking" from A.C. Crombie (1994) and redefined it to bridge work in the social studies of science and that of the philosophy of science. In the 1980s, many analyses in the social studies of science emphasized the social influences on science. Hacking argued that, when a style of reasoning was in the making, social influences on the style were evident; however Hacking's framework differed from contemporary sociological work in that he argued not all elements of a style of reasoning could be attributed to interest groups or other, specific influences. For instance, Hacking argues that, in the statistical style of reasoning:

> There arose a certain style of solving practical problems by the collection of data. Nobody argued for this style; they merely found themselves practicing it (1991:192).

Whether originally shaped by social influences or not, styles of reasoning, Hacking argues, take on a momentum of their own and become *the* standard upon which any competent scientist in that field must draw from to reason. In this he argued that mature styles of reasoning therefore had more parallels with philosophical approaches to science than social science approaches. Hacking argued that his framework of "styles of reasoning" bridged work in the social studies of science, and philosophy of science, and thereby addressed epistemological concerns in the history of science in the 1980s.

([23] continued from previous) Styles of reasoning, Hacking argues (1992b), have family resemblances to, but are distinguishable from, several concepts in the philosophy of science. They are distinguishable from Wittgenstein's *language games* on account of their historicity. They are distinguishable from Kuhn's *paradigms* because styles of reasoning are not exclusionary. Finally, there is no reason why styles of reasoning should necessarily perish in the sense of Foucault's *discursive formations* or *epistemes*.

Hacking (1992a) outlines his framework for the dynamics of styles of reasoning with respect to specific styles, including that found in laboratory science, and statistical practices. He argues the stability of the laboratory style of reasoning emerged in the interplay and the mutual adjustment of three types of entities: ideas, things, and marks. His primary focus is on the matériel, or "things", a category in which he includes the target of the laboratory experiment, as well as the laboratory's detectors, tools, data generators. He describes this matériel as "flanked on the one side by ideas" (the researchers' questions, background knowledge, systematic theory, topical hypotheses, and modelling of apparatus), and on the other by "marks and their manipulation" (data, data assessment, data reduction, data analysis, and interpretation) (1992a:32). Hacking explains the stability of practicable laboratory sciences on the basis of a dynamic of self-vindication, in which matériel, ideas, and marks become mutually adjusted and designed for one another. He begins his description of the self-vindication of the laboratory sciences with an observation by Pierre Duhem. Duhem argued that if there is an observation that does not fit with the reigning theory, the theory can always be vindicated by either adding an auxiliary hypothesis or making the old theory a special case of a new theory. Hacking extends this thesis of self-vindication in a way that emphasizes the modification of apparatus, rather than the modification of theory:

> as a laboratory science matures, it develops a body of types of theory and types of apparatus and types of analysis that are mutually adjusted to each other [….and thus are] self-vindicating in the sense that any test of theory is against apparatus that has evolved in conjunction with it – and in conjunction with modes of data analysis (1992a:30).

His explanation of the laboratory style of reasoning's self-vindication exemplifies the way in which he approaches styles of reasoning as collective and distributed across materials, ideas and techniques. Hacking emphasizes that this dynamic of self-vindication is anchored by the materiel: the instruments, apparatus, material targets, and so on. Hacking's analytical emphasis, therefore, is resolutely *materialist*. (With this same emphasis on materials, Hacking (1983) had previously argued against contemporary philosophy of science) that scientific reasoning was related to intervention more than representation, the latter often a tool for the former, although they are inseparable.

While I am indebted to this work, Hacking's characterization of materiel is tailored, very specifically, to the laboratory style of reasoning and experimental practice. The material features of laboratory styles of reasoning – the physical target of study, detectors, tools, and other laboratory apparatus – were strikingly absent in my fieldsite. There were no laboratories involved in the pre-market evaluation of natural health products. Often, there were not even any actual medicines, and this not only in the Directorate: applicants characterized some of the medicines they described in Product Licence Applications as "hypothetical," to be manufactured to the specification of a product licence if it were obtained. (I was told that consultants would apply for a licence to market a medicine, and if they received the licence, they would sell the licence to another company, who would have to produce and market a medicine that matched the specifications on the licence.) The workaday world of the scientists I studied – at least with respect to the material medicines whose safety and efficacy the scientists were judging – never left the world of marks, of representation, to that of intervention in Hacking's sense.

([24] continued from previous) This lack of laboratory *matériel* does not preclude a focus on the material, although it does reshape it. Just as there are style(s) of reasoning particular to the laboratory, there are style(s) of reasoning particular to the cubicle. In the cubicle, much material culture is what Hacking might have discussed as marks and their manipulation. I will emphasize scientists' use of material culture in the cubicle; this material, for the most part, is textual (print or electronic), including files, databases, standard documents and sticky notes. Other scholars, following Latour's characterization of "immutable mobiles," have treated what Hacking addresses as *marks,* as materials or things. I do wish to recognize that these marks are different from what Hacking was discussing when he emphasized things in the stability of styles of reasoning through time; at the same time, I do not wish to overlook the fact that these marks are quite material.

[Elsewhere, Hacking discusses other styles of reasoning. For instance, Hacking remarks that the statistical style of reasoning is unusually transparent in its self-authentification. He argues that, once entrenched, styles of reasoning become self-authenticating in the sense that there is a circularity between truth and the way in which it is produced; this is because the style of reasoning, along with the questions it can address are co-produced. Improvements on the style of reasoning are judged by the standards of the style of reasoning itself (1992b:144).]

[25] "A moral economy," Daston outlines, "is a web of affect-saturated values that stand and function in well-defined relationship to one another"; in other words, a "balanced system of emotional forces, with equilibrium points and constraints" (1995:4). She argues that these moral economies are not the antithesis of science, but rather "are integral to science: to its sources of inspiration, its choice of subject matter and procedures, its sifting of evidence, and its standards of explanations" (1995:6).

[26] On Fleck's last point: "The scientific thinking found in a particular period or society or individual has got its vision and style from different but closely related kinds of intellectual and moral commitment or disposition," argues A.C. Crombie in *Styles of scientific thinking in the European tradition* (1994:56). The most relevant kinds of intellectual and moral commitments or dispositions among the scientists I studied were to fairness and managerialism. I will call fairness and managerialism "complexes," for lack of a better term. This dissertation describes these two complexes shaping scientists' workaday cubicle worlds that I suspect also have significant influence outside cubicles, in: science and biomedicine worldwide, public service in most Commonwealth countries, and quasi-public institutions (universities and so on) in many English-speaking countries. I suspect that these two complexes, like science itself, are recognizable cross-culturally and cross-situationally even when they are put to very different use and are imbued with different moral valences.

[27] The translator of *Genesis and development of a scientific fact* notes that the English translation is less a standard translation than an "interpretive translation" (Fleck 1979:xv), for reasons of interpretability. Key terms, therefore, such as *Denkkollectiv*, were the subject of some debate. A "thought collective," according to the translator, engages in collective work, has a collective thought style, produces collective experience and structures, and operates according to collective timelines (Fleck 1979:xvi); the translation of all these terms is difficult. I follow Ian Hacking's shift, however, and replace the word "thought" with "reasoning" to try and reduce the likelihood that the reader believes I am referring to something going on in the heads of scientists.

[28] Hacking, and Daston do not assume that the right, wrong, and unrecognizable in scientists' reasoning is entirely shared by a broader 'society,' although each articulates how broader societal concerns or forces shape scientific reasoning. Ian Hacking on his idea of style of reasoning: "It starts by being pushed and shaped by social vectors of every sort; we end with a self-sustaining mode of knowledge" (1992b:132); Lorraine Daston on moral economies: "Although moral economies in science draw routinely and liberally upon the values and affects of ambient culture, the reworking that results usually becomes the peculiar property of scientists" (1995:7). Durkheim discussed the way in which "whole world of sentiments, ideas and images which, once born, obey laws all their own. They attract each other, repel each other, unit, divide themselves, and multiply, though these combinations are not commanded and necessitated by the condition of the underlying reality" (quoted in Sahlins 1976:113). This formulation seems like it could be consistent with the quotation from Daston.

[29] Crombie's (1994) purpose in characterizing these styles of reasoning are different from those of Hacking (1992a). Crombie was concerned with "the historical process by which the analytical sciences, with medicine and technology, acquired their identity in the intellectual culture of Europe" (1994:88). This was the development of styles of scientific inquiry and argumentation, "with their characteristic modes of control under the common criteria of logical consistency and fit with experience. The novelty was in the style" (1994:88).

[30] The translators chose to use the English "mood" for the translation of *Stimmung*, but note, in the introduction, that it was generally interchangeable with "disposition," even "temper" or "temperament." I generally use the word disposition because it avoids the connotation with "moody."

[31] In this dissertation, I am not overly preoccupied with the invention, modification, and propagation of individual forms because in my research I found, as Hacking pointed out, in many cases those forms were pragmatic hodgepodges for which nobody in particular had ever argued; "Nobody argued for this style; they merely found themselves practicing it" (1991:192).

[32] This point was made amply clear to me when I (twice) assessed one particular application for a medicine containing garlic. The first time, I recommended it for licencing. The second time, I noticed and flagged a serious safety concern. Each time, I assessed exactly the same file, in exactly the same cubicle, in exactly the same overall context of pre-market review. The only difference was that, during my first examination of the file, the application was apparently an unexceptional file, like the hundred other files I had assessed, and one of the handful I was supposed to assess on any given day; the second examination was after the file had been made into a puzzle, made exceptional. It was the change in the context of the activity, which interpellated me into a different emotional state, social position – way of noticing and reasoning. I argue this simple observation is indicative, symptomatic of a larger dynamic in scientists' reasoning. The way in which activities were structured, as well as the social dynamics into which the assessor is interpellated in the workplace, encourage certain contextualized choices and noticing. Scientists' notice of safety concerns does not necessarily have anything to do with an entrenched belief or bias of the individual evaluator (although clearly this can have an effect); the structural organization of the activities can be a determinant of the outcome.

[33] See Reed and Lave 1979, Lave et al. 1984 and Lave 1986 for examples pertaining to arithmetic, whose work will be presented in Chapter 13.

[34] Social anthropologists of functionalist persuasions (e.g., Mary Douglas 1986, to some extent Evans Evans-Pritchard 1976), have attributed the existence and persistence of uniform ways of reasoning to their role in maintaining the social structure: "Since it uses the division of labor as a source of metaphors to affirm itself, the community's self-knowledge and knowledge of the world must undergo change when the organization of work changes" (Douglas 1986:102).

While I cannot deny that there was a certain correspondence between the "flexibilized" workforce at the time of my fieldwork and the scientists' reasoning with mantras like *We have to be flexible,* using Douglas' model would not help me answer my main quandary. Furthermore, given that the institution in question (the Directorate) was created by ministerial declaration, a functionalist argument would have to explain the existence of the entire Canadian political-legal system, which is clearly of no interest to my puzzle.

Douglas (1986) states, a satisficing functionalist argument should follow the pattern,

> An institutional or behavioural pattern, X, is explained by its function, Y, for a group, Z, if and only if:
> Y is an effect of X
> Y is beneficial for Z
> Y is unintended by actions producing X;
> Y or the causal relation between X and Y is unrecognized by actors in Z
> Y maintains X by a causal feedback loop passing through Z.

Mary Douglas defines an institution simply, "in the sense of legitimized social grouping," listing possible examples: a family, game or grouping (1987:46).

I think it may be possible to create a functionalist argument, using the style of Mary Douglas, on a smaller scale, focussing on behavioural pattern rather than institution, but the result seems both forced and incorrect. So for instance, in a later chapter, readers may think that I am making a functionalist argument by arguing:

> The backlog (X), is explained by its unrecognized function (the reduction of scientists' notice of safety issues, Y), for a group (the NHPD management, Z), if an only if:
> The reduction of scientists' notice of safety issues is an effect of the backlog
> The reduction of scientists' notice of safety issues is beneficial for NHPD management
> The reduction of scientists' notice of safety issues is unintended by actions producing the backlog
> The reduction of scientists' notice of safety issues is unrecognized by actors in the NHPD management
> The reduction of scientists' notice of safety issues maintains the backlog, by a causal feedback loop passing through NHPD management.

But this argument is both forced and, I believe, incorrect (esp. the issue of benefits).

[35] Job names classifications will be explained in more detail in Chapter 17. I use the term "scientific staff" to denote all staff in positions requiring, at a minimum, an undergraduate degree in science. The science was generally related to chemistry, biology or human health.

[36] My collection of evidence is modelled on the methodological precepts of Evans-Pritchard who advocated long-term, flexible participant observation (1976:240-254) as well as the alliance of anthropological and historical methods (1950). It is also modelled on the configuration of methods reported in Hayden 2003, Petryna 2002, Rapp 2000, Young 1995.

[37] Additional fieldwork in Canada but outside the Directorate – at conferences, trade shows, research and development sites, and private homes – investigated the measures used in the evaluation of herbal and traditional medicines in Canada, and helped to contextualize the evaluation activities of the Directorate itself. In addition to the 13 months in the Directorate, I spent the equivalent of an additional five months of fieldwork outside the Directorate doing archival research, observation, participant-observation and interviews (during the period 2002-2008). For instance, between 2002 and 2007, I attended 18 Canadian events in which measures of traditional medicine's or herbal medicine's efficacy and side effects were discussed. These were one- to four-day events and included symposia, workshops, information sessions, trade shows and conferences. With maybe one exception, NHPD officials attended each of these events. These conferences were an opportunity for many informal discussions, putting the measures and standards used by the NHPD in a different perspective. I also conducted formal history interviews with key researchers, industry members, and the politician who was Minister of Health when the category "natural health product" emerged. Although this and other additional fieldwork outside Health Canada complements my fieldwork within Health Canada, it has ended up featuring in this dissertation only in passing.

[38] Several modifications were also approved during that four-year period. Two were minor. Because some industry-based interviewees had wished to be interviewed via e-mail, I requested the possibility of e-mailed consent (approved June 15, 2006). (I abandoned this line of research in industry, part of my original multi-sited fieldwork plan, when I became employed in government.) To improve confidentiality, I requested the possibility that public servants be allowed to sign the informed consent form with an X, rather than their signature (approved January 29, 2007). One modification was more substantial, occurring when I took paid employment at the NHPD (approved September 7, 2006).I also received permission to conduct a survey in August 2007.

[39] I suspect that getting permission to do anthropological participant-observation in any large, government institution with tight security is a challenge. In my case, getting permission was indeed a challenge, but at least insofar as I was told, the challenge was unrelated to hesitation on anyone's part regarding the permissibility of my research.

Rather, neither I nor the officials whom I approached had a clue who would be responsible for permitting participant-observation, nor how permission would or should be given. Furthermore, I did not really understand who in the bureaucracy could appropriately give permission for research within the fieldsite until I had significant experience within the public service of Canada, and had access to organizational charts. Because of the particular arrangements of my participant-observation, and the evolving nature of my research permissions, I outline them in more detail than is usual in an anthropological dissertation.

In November 2005, I began approaching NHPD officials at conferences and other research meetings, asking whether and how best I might do anthropological fieldwork in the directorate. I said I hoped to pursue this research as an independent anthropologist, but I also suggested that I might be eligible for an internship if that would assist the process of getting permission (including security clearance). After eight months of approaching various officials for research access, and getting nowhere despite proffered statements of general support that served to brush me off,* I was offered the only concrete suggestion for research access: one manager offered to hire me into her work unit. This manager explained that the Directorate was extremely short-staffed, and that because of the confidentiality of industry's pre-market applications, visitors and interns had to be chaperoned while on NHPD premises – and that devoting a chaperone, for a full year, to accompany an anthropologist was clearly not feasible. I accepted her offer of employment with the explicit understanding that I did so as a way to do my anthropological fieldwork.

* This experience was similar to that of Kevin Karpiak, who, after 18 months into his ethnographic research into reforms of the French police, and after many (failed) research requests, decided that "no one seemed in either a position to, or have the will to, offer much aid in moving forward" (2010:8).

[40] My position, with Group and Level SG-SRE-04, was officially entitled "Submission Screening Officer" in the Monograph Management Unit. Although this position was classified as scientific regulation (SG) not applied biological sciences (BI) or applied chemistry (CH), the workers in this unit referred to themselves as "assessment officers," a term generally reserved for workers in positions classified as BI or CH.

[41] As Stanley Tambiah points out, the use of the term "commensurability" in anthropological discussions of cross-cultural comparisons is a post-Kuhnian phenomenon (1990:124).

[42] Stacy Leigh Pigg, in her discussion of science moving through various environments worldwide, frames the questions as:

> Attention to the social production of commensurability raises the following questions: What are the practices through which actors forge, provisionally or lastingly, common measures, standards, and frames? How are perceived differences bridged or mediated? What are the consequences of the routinization of certain conceptual paths of connection? (2001:483).

Whereas, Elizabeth Povinelli argues that "anthropology has now complemented and complicated classical social questions about how actual social worlds are reproduced and ruptured," in part by asking:

> How do incommensurate worlds emerge and how are they sustained in their incommensurability? In other words, how is the inconceivable conceived? (2001:320).

[43] Taken from my research proposal, I had planned to investigate:

> (1) What standards, procedures, measures, statistical techniques, etc. are used at Health Canada to evaluate herbal and traditional medicines
> (2) How Health Canada arrived at these standards etc. (including the involvement of industry, research, and social groups, and the influence of the evidence-based medicine movement on policy)
> (3) How the Natural Health Products Directorate at Health Canada arrived at its commitment to "philosophical and cultural diversity"
> (4) What the implications of these standards etc. are for the commensurability or incommensurability of:
>
> a) various medicines, and
> b) various medical traditions
>
> (5) What conceptions of "efficacy" are manifest in numbers 1-4.
> (6) Conceptions and practices of 'objectivity' manifest in number 1-4 above.

[44] The term genealogy in the social studies of science immediately calls to mind the work of Michel Foucault; it is not in this sense I am using it as I am not discussing subject formation in this dissertation (cf. Schied 2002a:138).

Chapter 2
Scientists' reasoning in a Canadian government directorate, 2006-2007 (A thesis and chapter overview)

The puzzle: the remarkable uniformity of reason, judgement

My puzzle was how a hundred very different people reasoned in a relatively uniform manner. These scientists were hired as professionals, expected to bring their varied expertise and knowledge to their on-the-job reasoning – why, then, was their reasoning not as varied as their expertise and knowledge? Even more puzzling was that very few of these scientists claimed to reason in this way prior to their employ in government; yet, within a relatively short time after their acquaintance, without even a formal period of training,[1] their reasoning was normalized. As I will explain, had there been some common denominator among these hundred scientists, this relative uniformity might have been unsurprising, but this was an extremely diverse group – born and raised in varying circumstances around the globe, trained in a motley of disciplines, experienced in a variety of professions, and expressing very different attitudes towards the medications being regulated. Yet newcomers into the environment voluntarily adopted the style of reasoning, as a competence within the organization. While scientists debated, declared differences of opinion, and so on, their reasoning in assessment and their regulatory judgements about the safety and efficacy of medicines became uniform.

My surprise (and to some extent annoyance) was aggravated by my own participant-observer experience, finding myself reasoning with remarkable alacrity

in precisely this style, even when I did not exactly agree with certain of its features.[2] As I will explain in the dissertation, this was not about duplicity, misplaced intentions, or false consciousness, even though I, as well as other scientists, reasoned in very different ways outside work activities.

Uniformity in reasoning is relative. As a regulatory scientist, I saw troublesome inter- and intra-scientist inconsistencies nearly every day. To take but a small example, in one of my work projects, I surveyed other scientists' evaluations of the safety and efficacy of an extract of the tomato, lycopene. I found striking and troublesome inconsistencies in different scientists' consideration of the same evidence. For instance, two scientists reasoned with the results of the same published clinical trial in near-opposite ways: one scientist concluded that the trial supported the safety of lycopene consumption for the duration of the trial, whereas the other scientist reasoned that the trial could not be used to support the safety of lycopene consumption because safety was not an endpoint of the trial.[3] Many, if not most, scientific staff were very concerned about "inconsistencies" such as these, in part because the success of regulatory project depended on the absence of glaring inconsistencies, or at least glaring inconsistencies that could not be rationalized. Such inconsistencies often became issues or even Issues. Individually and in groups, these scientists often went to great lengths to reduce such inconsistencies, as I will describe throughout the dissertation's third section, Textual Standards in Practice.

Some inconsistencies were by design. Scientific staff also frequently distinguished the reasoning used in the pre-market evaluation of *traditional* medicines, versus that used in the evaluation of *non-traditional* medicines. This second type of inconsistency was not problematic to scientists, in that the procedures for reasoning in the Directorate about traditional and non-traditional medicines had been designed to be segregated. Inconsistency-by-design was, I argue, part of a larger, overarching style of reasoning as old as "western science" (Crombie 1994): reasoning through taxonomy and comparison.

What was the uniformity, then, that I found so surprising? As an anthropologist, I found certain ubiquitous features of scientists' reasoning particularly odd. These ubiquitous features did not seem related to an extant and entrenched scientific style of reasoning previously described by authors in the social studies of science. For instance, why did so many scientists declare, in moments of indecision, *We have to be flexible!,* with this declaration becoming a sensible and integral part of reason in the directorate? There were also features I found particularly counter-intuitive. For instance, why did scientists consistently not "see" certain elements of the scientific evidence and files that, to me as an anthropologist – but not so much when I was in my role as scientific regulator – seemed glaringly obvious? There were many features of scientists' reasoning that begged some explanation. Or to be more precise, the way in which scientists reasoned with surprising uniformity *in a way that did not correspond to my prior expectations of scientists engaged in public health protection* is what begged some analysis.[4] Because I was also a

scientific regulator myself, this includes explaining my own reasoning in precisely this style, during my work as scientific regulator.[5]

Features of the surprisingly uniform way of reasoning

Features of this uniform style of reasoning, as observed in the Natural Health Products Directorate between August 2006 and September 2007, included:

(1) Recursive reference to textual standards, regardless of the scientists' personal opinion of the text's validity

(2) Ready incorporation of other scientists' reasoning and judgements

(3) Repetition of mantras such as "we have to be flexible" and "if it doesn't have to do with safety, we have to let it go," especially in moments of uncertainty

(4) Acute, explicit awareness of the limits of scientists' own authority

(5) Acute, explicit sensitivity to "fairness"

(6) Common affective disposition in evidence towards certain file traits such as their easiness or messiness

(7) Selective notice of certain, but not other, issues with files

(8) Inseparability of reasoning from a plethora of electronic databases

(9) Explicit consideration of the backlog.

The features of this style of reasoning will be described throughout the dissertation; the explanation of scientists' uniform style of reasoning, will largely consist of descriptions of the most salient (to me as an anthropologist) features of this relatively uniform reasoning and judgement, as well as observations of how these

features nestled together, mutually supporting each other in the style of reasoning of this particular thought collective. I argue that scientists' immediate environment (social and office) and evaluation activities interpellated scientists into this particular style of reasoning.[6]

Causes and consequences mixed up

The dissertation is an anthropological ethnography; as such the arguments are brought in only when I feel arguments can sufficiently account for field observations. From time to time, when possible, causes will be posited. I do not presume, however, that a framework of cause and consequence is the most useful way – or even a possible way – of approaching collective human phenomena such as reasoning. Furthermore, I do not intend to diagnose causal relationships with an eye for change; without interventionist purpose my goal remains to try and articulate the relationships within the web.

Uniformity of reason, not accounted by some common pre-existing factor

But let me immediately dispose of one possible cause of this uniform reasoning. Readers unfamiliar with this particular government department may justifiably ask: Can the remarkably standard style of reason that I observed be the result of a common personality trait, predilection, or training experience selected for by virtue of becoming employed as scientific staff at Health Canada? Despite a year of participant-observation and over fifty interviews, I found no such commonality.

Is the explanation that all these scientists are, well, scientists is the reason? This, I concur, is hypothetically possible. But this would presume some commonality among sciences, scientific training programmes, and scientific labour that is rather a stretch for anyone familiar with a wide range of sciences. These scientists were previously trained in a wide variety of disciplines whose practices sometimes mutually negate each other's perspectives with respect to the evaluation of medicines (e.g., pharmacodynamics and homeopathy; toxicology and traditional Chinese medicine). Even if one is to examine only the scientists' scientific, as opposed to medical, training, the scientists' training ranged widely in: levels of education (ranging from a bachelors to multiple post-docs); type of institution providing education (with respect to prestige, location, intensity of scientific research); disciplines (from biochemistry to ethnobotany, from kinesthesiology to environmental science, from biophysics to food microbiology, from plant science to immunology and so on); and laboratory experience (from none, to years of experience guillotining rats in academic laboratories or growing cell cultures in Health Canada laboratories, to the pursuit of multiple independent projects). A list of scientists' volunteered "specialties" in only two work units, contained a hundred entries: in addition to the general "biology" and "phytochemistry" and "microbiology," the listed specialties ranged from "earthworm enzyme" to "estrogen and estrogen receptors" to "conservation biology," "ginseng and relatives" to "Vitamin E, including conversion factors" to "pediatric issues" to analytical methods and instrumentation such as "TLC", "HPLC", "ELISA", "NMR", "IR", "GC", "PCR", "pUC19 plasmid manipulation" to "pharmacognosy" to "access to information act"

to “neurodegenerative diseases: clinical treatment and experimental research.” They learned about natural health products in a variety of languages.[7] Some of the directorate’s scientific staff – I refer to them as “scientific staff” because they must have qualifications in science (see Chapter 17 for details) – did not even self-identify as *scientists*, and many had other educational qualifications or work experience with which they self-identified. Among the scientists, there was also an ex-teacher, an ex-pharmaceutical representative, an ex-environmental field researcher, a few MBAs, community garden advocates, a self-declared “witch” or two as well as other healers of various stripes, and of course, an anthropologist.[8]

Perhaps then, argues the reader, the fact that these scientists chose to enter the public service and become ‘bureaucrats’, selects for some common personality trait? I believe this could be a contributing factor in more homogenous organizational divisions in the Canadian public service. Among scientists in the NHPD, I do not believe this was a contributing factor, at least not in the sense that the choice to work for government reliably indicates some trait predating the scientists’ employment as public servants. But come on, continues the reader, does not becoming a bureaucrat indicate a conformist tendency? The real impediment to working with the stereotype of bureaucrats – at least in a relatively diverse work environment – is that it does not reflect the varying representations of work as a public servant across social classes and nationalities, among other things. According to a voluntary, anonymous survey I conducted among scientists, roughly forty percent of the hundred or so scientists were born outside Canada, in

one of at least 25 other countries. I learned in interviews that several scientists felt that the public service is a high-prestige and desirable vocation. One must also consider the limited professionally-relevant employment opportunities for some foreign-trained professionals. Among foreign-trained professionals, there were health practitioners whose qualifications were not recognized for the purpose of practice in Canada, and scientists who found that opportunities for tenure-track appointments in Canadian universities were limited for scientists who had received their PhDs outside Europe or North America. In interviews, I learned that, for several amply educated scientists who moved to Canada as adults, their appointment as public servants might not have been their first career choice but, given impediments to their first career choice in Canada, public service employment represented satisfactory, reasonably interesting, relevant, sufficiently prestigious or well-paid professional work. Given the different employment opportunities for foreign-trained professionals when compared with their Canadian-trained analogues, I believe there is little ground on which to work with Canadian middle-class stereotypes assuming that work as a public servant selects for those with conformist tendencies, with no drive, and so on. Finally, as a point of fact, many of the scientists working in the Directorate were employed by hiring or staffing agencies on short-term contracts, and therefore were not technically public servants (discussed in Chapter 17).

Any explanation must emerge from fieldsite itself

Because we can dispose of the uniformity in reason stemming from some common trait predating the scientists' employment in the Directorate, the uniformity in reason must be explained by something occurring within the Directorate.

Like many social anthropologists and historians of science have done, I approach these scientists' style of reasoning and judgement as collective, situated endeavours, embedded in local material and social arrangements: as inextricable from thought collectives. Let me begin with two straightforward ways in which they are inextricable. First, social structure: the uniformity in the scientists' style of reasoning was facilitated by the hierarchical organization of the scientists in the Directorate. Second, standards: the uniformity in scientists' reasoning was also in no small part attributable to the Directorate's (many) documentary standards, which were simultaneously the trigger for evaluation activities and prescriptions for how regulatory scientists must reason.

Sociability and social organization as one explanation

"If we're unsure, you know we talk to each other, and come to agreement! What is mysterious about that? And our Assessment Reports have to be signed off by no fewer than two other scientists: our direct and indirect supervisors – so if our judgement is problematically inconsistent with another scientists' judgement, the managers will notice, and may send the file back down to us! We have to respect

decisions taken at a higher level. But anyways, we're not all that consistent, as you should know."

This paraphrased, local explanation of uniformity, entwines two causal factors having nothing to do with science in particular. These causal factors are: 1. general sociability (chatting, talking) and 2. social organization. Just because these factors are not specific to science does not lessen their import in scientists' reasoning.

General sociability and the informal distribution of reason and judgement

As Louise explained to me in interview, "When you don't know, you go see people – *anybody* – above, below, side, etcetera." Learning to consult with one's peers in situations of uncertainty was part of becoming a properly socialized regulatory scientist at the Directorate; one had to learn to attune one's reason and judgement to that of others. This was not only a social imperative, but a practical one – even the most arrogant could not consider him or herself an expert in all the domains involved in the pre-market evaluation of such a wide range of medicines.

The limits of *general* sociability in normalizing the reasoning and judgements of a group of more than one hundred scientists was evident in day-to-day work, especially given the high rates of staff turnover that I will describe in Chapter 17. Management's imposition of a quota system for judgements (see Chapter 14), one that did not valorise consistency as achieved through general sociability or the

more structured discussion of issues at meetings,[9] also limited the impact of general sociability in reaching uniform judgement.

Targeted consultation of one's peers came into play regardless. Scientific staff learned to seek out and consult informally recognized experts in reasoning on particular topics. The informally recognized expert's reasoning often became the norm for reasoning related to the particular topic of their expertise. For instance, for each of the traditional medicinal "paradigms" recognized by the NHPD, there were at most a few, and often only one, expert whom any other competent assessment officer would consult if she was the least bit unsure regarding appropriate reasoning. In Chapter 8, I present the case of Terry's reasoning about whether the efficacy of a proposed traditional Chinese medicine was sufficiently supported by the evidence; Terry's reasoning included consulting a resident expert on traditional Chinese medicine, and appropriating this expert's judgement into Terry's own – literally cutting and pasting the expert's reasoning from an e-mail into Terry's assessment report. Expertise could be recognized because of a scientist's previous work or training, and or because of experience the scientist had accumulated at the NHPD.[10]

This distribution of expert reasoning tasks among scientists was sometimes formalized. Files could be formally transferred: instead of appropriating an expert's judgement into the scientists' own, the scientist would simply transfer the entire file (and responsibility for the judgement) to the expert. Sometimes entire batches of

files of a certain type (e.g., complex traditional Chinese medicines, or medicines containing MSM) would be directed to one individual, because of recognized or expected expertise. The reasoning and judgements of experts could be formalized by its textual inclusion in the Directorate's documentary standards, which would then be available for cutting and pasting for all other scientists from that point onwards.[11]

Formal division of labour

Divisions in the organizational structure also divided responsibilities for the creation of norms for reasoning on particular topics. In the premarket evaluation of medicines, the Directorate conceptualized distinct Assessment Streams, which were mapped onto different Assessment Units. Through this distinction, and concomitant division of labour, scientists assessing similar files according to similar evidence were more likely to be proximate (in cubicles, in meetings) and thereby normalize their reason and judgement through general sociability and through their common oversight by one Unit Head. As Marie, a Unit Head, stated blandly in response to my interview question about consistency: "Consistency. That takes a lot of meetings." Through the creation of work units, inconsistencies-by-design were kept separate. Scientists did not expect, for instance, that colleagues in the Traditional Medicines Unit would use the same evidentiary standards, in their reasoning, as colleagues in the Synthetic Duplicates Unit, or as those in the Monograph Management Unit.

Each unit to some extent had the responsibility of establishing and perpetuating norms for reasoning in one Assessment Steam (or type of medicine). To use Herzfeld's characterization, the unit needed to create and maintain "various taxonomic devices with which to regulate their small sections of a civic universe" (1992:181). At the NHPD, many differences in scientists' reasoning, in their use of the evidence, were not understood as inconsistencies, but as the purposeful use of different evidentiary standards in the reasoning and judgements, or the existence of different evidence: different units, different standards (in many cases). Norms for reasoning about particular types of medicines were determined by pockets of expert scientists and organizational units.

Pyramidal, hierarchical organizational structure

This creation of expert pockets could be counter to the government task of speaking as one. To some degree reason was normalized through social interaction (chatting). The creation of expert pockets was also counterbalanced by the NHPD's formalized hierarchical organizational structure, typical of the Canadian Public Service. The pyramidal structure of the Service also allowed those higher in the hierarchy to establish and dictate norms.[12] Most scientists in the Directorate worked as "assessment officers" (evaluators) or "scientific regulators." They were grouped into units of three to twelve scientists, under the supervision of a Unit Head who was also a scientist. Units were grouped together under the supervision of a Manager or a Director, who themselves were usually, but not always, scientists. When a full pre-market evaluation of a medicine's safety and

efficacy was required, every judgement (i.e., Safety and Efficacy Assessment Report) written by an evaluator had to be signed off by his or her Unit head as well as his or her Manager.[13] Because scientists' judgements in the pre-market evaluations were eventually funnelled through a few scientists in upper management, the latter could notice and address inconsistent judgements among scientists. The latter could also order underlings to follow a decision taken by superiors.[14] It is fair to say that this particular formalized organizational structure, a pyramidal hierarchy, explains the relative absence of inconsistent final judgements. The recursive, but socially contextualized and stabilized, movement between normalization and norms, is an important source of uniformity in judgement and, to some extent, scientists' reasoning.[15]

I have described some informal and formal divisions of labour that fostered uniformity in the directorate's scientists' reasoning. These mechanisms for normalizing reason and judgement, however, are to some extent predicated on the continuity provided by individuals in their (informally or formally) recognized positions. At the time of my fieldwork, this continuity was not always present because of turnover in personnel. For instance, in the mere year I worked as a scientific regulator, the person appointed as my supervisor changed three times (four separate individuals working as my direct supervisor), my manager at least once, my director twice, and the director general at least once.

I now turn to the way in which experts' and managers' judgements were formalized through the organization's many textual standards, thereby increasing the chance that these norms survive staff turnover. But because textual standards played such an important role in scientists' reasoning, I turn to the topic of textual standards more broadly.

The raison-d'être of the organization – regulation – is another explanation

On my first morning of work as a scientific regulator, my supervisor sat me down in my cubicle with a mountain of documentation and instructed me to read through it. "The Regulations", I was told by a well-meaning colleague appearing in the door of my cubicle later in the day, "are your friends; learn them well." And thus began my bleary-eyed entrance into the world of scientific regulation, which, in this particular Directorate, was a world of documentation. If you were to ask any of the Directorate's scientific staff what makes their judgements so uniform, I have no doubt that you would be immediately pointed towards regulations, guidance documents, standard operating procedures, standard lines, document templates, records of decisions, compendia of monographs, communiqués, and so on: the Directorate's textual standards. This is perhaps unsurprising given that the raison-d'être of the organization, in the mindset of these regulators, were the regulations and affiliated texts.[16]

Textual standards: Regulations, Guidance Documents, SOPs, and so on

The plethora of documents I used in the regulatory evaluation of medicines is quite overwhelming. There were the regulations. There were guidance documents instructing how to interpret the regulations. Additional textual standards such as pharmacopoeia and databases were incorporated into those regulations and guidance documents. There were also documents instructing scientists how to interpret the documents interpreting the regulations (communiqués, records of decision, standard line spreadsheets). There were documents with algorithms instructing when to use which other document, instructions for how to file the documents one creates in the evaluation process so it becomes part of the overall algorithm, and so on. Textual standards and materials were central to the scientists' style of reasoning, constraining, but never fully determining, scientists' reasoning activities. Chapter 4 summarizes these written rules and standards, and in conjunction with the remainder of the chapters in the section Textual Standards in Practice, provides an overview of how scientists navigated and used these documents in mundane evaluation activities.[17]

Reasoning and ordering of variety by comparison and taxonomy

The moment a Product Licence Application entered the Directorate, scientists decided whether the medicine proposed in the Application was a "natural health product". If it were not, staff determined they were unable to provide market authorization, and the evaluation process ended there. The definition of "natural health product" was a crucial standard in scientists' premarket evaluation of medicines in the Directorate, described in Chapter 3.

If the proposed medicine were deemed a natural health product, scientists had to make the next decision, regarding in which Assessment Stream the proposed medicine should be evaluated. Once the Assessment Stream was determined, scientists decided which types of evidence were required, and so on. In a way, scientists' reasoning was embedded and structured by a large, complex algorithm that I characterize in Chapter 6.[18] At each stage in this algorithm, scientists made decisions (definitional, evidentiary) that determined the subsequent reasoning activity and dictated the range of appropriate textual standards to guide their evaluation. This algorithmic approach to evaluation, has much in common with one of the six core "styles of scientific thinking in the European tradition," as outlined by A. C. Crombie (1994): the "ordering of variety by comparison and taxonomy."[19]

The more comparative the reasoning, the more ideal the judgement

In the Directorate, the most favoured (most efficient) assessment processes were the algorithmic paths ending in the comparison of the proposed medicine with one clear regulatory standard.[20] When possible, new standards were created to increase the number of applications for which this type of reasoning through comparison could be applied. There was a feeling (or more accurately, a hope) that applications were coming into the Directorate "cleaner" as the years progressed, as industry learned how to complete Application Forms in ways that facilitated scientists' comparison activities in general. Reasoning with algorithms, and via

comparison, is the focus of the first part of the dissertation: textual standards in practice.

The remainder, judged on the "totality of evidence"

Any application not clearly attesting to a singular regulatory standard as evidence of safety and efficacy was generally deemed *non-traditional*. ("Non-traditional" was the catch-all "other" category in the Directorate's classification of medicines.) Scientists' reasoning about the safety and efficacy of these non-traditional applications was to be based on "the totality of evidence" that was submitted with the file. What constituted sufficient or a totality of evidence was determined on a "case-by-case basis." Nevertheless, even in the Non-Traditional Assessment Stream, with its focus on case-by-case considerations, scientists brought textual standards headlong into reasoning whenever possible. The dissertation addresses the scientists' work in these fields, focussing especially on moments of uncertainty in Chapter 12 onwards. It is in these later parts of the dissertation that I most explicitly draw from Fleck's characterization of the thought collective.

But comparison is predicated on thorough enculturation

Comparison, as Mary Douglas (1966) and other anthropologists have pointed out, is never self-evident except to the thoroughly enculturated, and the use of "this or that" reasoning inevitably creates those pesky entities that refuse to be either "this or that." Scientists had to learn to determine: (1) which standard to use in the comparison, as well as (2) whether the application matched, or did not match a

particular standard, and (3) whether the matching endeavor was made irrelevant by some other factor. As Fleck observes, the "formulation of a problem already contains half its solution" (1979:37).

Textual directions for algorithmic decision-making were never complete. I argue that competent assessment officers, were expected to discern the most appropriate standard(s) among the many available for the most appropriate comparison. There was no way to develop this skill other than with experience. The dissertation presents several cases of scientists' *faux pas*, and of complaints regarding certain colleagues "just not getting it," as windows onto right, wrong, and incomprehensible judgements regarding the safety and efficacy of medicines in the Directorate.[21] In Chapters 9 and 12, I will argue that this ability to discern, use and apply the correct standard in a particular instance, had very little, if anything, to do with belief.

Decisions on the line

No matter how fine-grained the algorithm, there were invariably files in which the scientists were unsure if a medicine should fall into one category or another, and thus unsure what the appropriate comparison would be. These cases were often referred to as "the messy" files or, by one less politically-correct scientist, "the freak files." In these instances, scientists had to: (1) reshape the files so a comparison could be made, (2) reshape the procedural algorithm so a comparison could be made or (3) obviate the need for a comparison.

Reshaping the file by asking for more information

Often, the evaluators threw the problem of comparison back into the applicant's court, by pointing to information or clarification that was required according to regulations (or other textual standards), but that the applicant had not clearly included in the application. Sometimes this resulted in the applicant's reshaping of the file in a way that allowed the scientist to make a comparison and judgement; sometimes it just obviated the need for a comparison, because the applicant did not respond within 30 days and therefore the Product Licence Application was refused on administrative grounds. (A classic way of making the problem go away).

Reshaping or extending internal textual standards

In other instances, evaluators could make the particular issue of questionable classification an Issue, perhaps bringing the Issue to a weekly "PLA Issues meeting," to get an appropriate decision on the Issue (see Chapter 7 for an example of this). The decision would then be incorporated into the collection of textual standards via a revision, communiqué, record of decision, and so on. This extension of the guiding documentation meant that, in principle, any evaluator coming across a similar file in the future would be able to smoothly continue the algorithmic reasoning, because a Decision would be available (in principle) for comparison and order.

Recurring recourse to ever-proliferating documentation

As an entire literature in sociology has shown: while written rules and standards shape practice, written instructions never fully determine practice, whether in law, science, or other fields.

So my puzzle, the uniformity in scientists' reasoning, cannot be fully explained by documentary standards. As I already explained, general sociability among scientists at the directorate can explain some of the uniformity in interpreting written rules and standards, but with over a hundred scientists on staff and a significant rate of staff turnover, informal discussions were not the sole source of normalizing interpretations of the plethora of guiding documentation. Creating more written rules and standards to guide interpretation was another strategy taken by scientists at the NHPD.

But endless proliferation of documentation not possible

The perennial bureaucratic solution to incompatible or inconsistent multiple written rules is: more paperwork (Herzfeld 1992:121). There are de facto limits on the expansion of written rules and standards, even within a large government bureaucracy. One only needed to begin a short exploration of the Directorate's shared computer drive to be overwhelmed by the number of unfinished or unused standards, sometimes I suspect simply because current staff were unaware of the previous standards' existence. Furthermore, I was struck by the absence of written rules and procedures as to how the precise moment of judgement regarding the safety and efficacy of medications premarket was to occur.

Consideration of other features of scientists' reasoning

Clearly uniformity in judgement and, to some extent, reason, can be attributed to general sociability, and the use of textual standards. They do not by themselves help me answer two questions, though. (1) Why was scientists' apparent *notice* of certain features of files so uniform? (2) In moments of uncertainty, why did scientists make so many decisions that were the opposite of what their 1960s predecessors would have made (or so I conjecture)?

The second and third parts of the dissertation focus on factors that I observed came into these moments of judgement regarding the safety and efficacy of medicines, especially in moments of uncertainty, moments in which uniformity derived from common textual guidance was less significant. I describe the way in which these factors, along with general sociability, pyramidal organizational structure, and textual standards, were inseparable from one another.

Striking features of reason and judgement in moments of uncertainty

This dissertation could be titled, with a nod to Kahneman, Slovic and Tversky (1982): *Judgement under uncertainty: heuristics and biases in public health protection, from an ethnographic perspective.* In a way, this dissertation is an anthropological analogue to their classic psychological text; the dissertation is not premised on the existence of feral scientists, nor is it presenting artificial scenarios

in a laboratory environment, or heuristics inferred by the researcher. The heuristics described below were observable entities, recognizable to anyone in the fieldsite. Although scientists might argue they were peripheral to reasoning, I argue they were central to reasoning.

Never underestimate consultation

In moments of uncertainty, when needing to come to a decision of yes, no, or irrelevant, I should remind the reader that most scientists' first, second, and third strategies appeared to be: consult [documents], consult [colleagues], consult [again].[22]

Mantras refocusing scientists' attention on what mattered in context

I repeatedly observed scientists, in moments of indecision, reasoning with the phrases: *We have to be flexible*; *If it doesn't affect safety, we have to let it go*; *We have to ensure safety.* I characterize these phrases as mantras to emphasize the way in which these phrases were used as "instruments of reason," the repetition of which aided concentration on that which mattered.[23] Although scientists did not sequentially repeat the same mantra, scientists' frequent use of these mantras should not be dismissed as peripheral to reason by virtue of being interchangeable slogans or catchphrases.[24] In moments of uncertainty, scientists spoke these imperative phrases as a way of transforming their affect, disposition, and orientation into that required for reason in the Directorate.

At a conference occurring prior to my fieldwork inside the NHPD, an official from the Directorate answered a question regarding requirements for Clinical Trial Applications, saying something to the effect of "As we say at the NHPD: *We're here to help*." What struck me was not *hearing* the phrase, *We're here to help*, but *seeing* the change in the official's physical stance as she said the phrase.[25] The speaker literally transformed herself, embodying a disposition that was apparently required for the correct reasoning in her reply.

Scientists I observed in the Directorate reasoned with what I call mantras in a an embodied, not mentalistic, way, in at least three senses. One, scientists' physical stance, bearing, posture sometimes changed when reasoning with phrases such as *We're here to help*. Second, these phrases often encapsulated scientists' perception of their social role and status, including an acute awareness of their impotence as regulators in 2006-2007, for example with: *We have to be flexible*. Third, these phrases were sometimes used as tools to interpellate the evaluator to the correct starting point, or bottom line, for proper reasoning in the Directorate, as in the mantra *We have to ensure the safety of clinical trial participants*, which articulated the fundamental purpose and bottom line of one unit's work.

Mantras brought justification into reason

With mantras, one cannot clearly distinguish reason (pre-decision) from rationale (post-decision), as mantras are a means by which recurring or mandatory rationales are brought into the reasoning process.[26] (I am not arguing implicitly or

explicitly that it is possible to speak of reasoning that is entirely independent from context, including its possible justificatory uses; I only wish to point out that reason and justification are not always the same thing, and that mantras are used as tools for bringing rationales into the reasoning process). Because of this, I believe that attention to mantras is of relevance to any ethnographic study of reason: they are a mechanism by which diffuse social imperatives and rationales are brought into reason and thereby shape individuals' judgement. In the specific case of the pre-market evaluation of medicines, attention to mantras is of utmost relevance because, mantras were a way of interpellating oneself into different versions of the public interest in the assessment process, of scientists' compromise reasoning with rationales from different worlds of *common good* (formulation from Boltanski and Thévenot 2006), and of cultivating the only feasible disposition in the style of reasoning of the thought collective.

Mantras were especially useful in obviating the need for a decision, judgement

Several mantras were precisely about excluding certain considerations from the ambit of the scientists' assessment, such as the mantra: *If it doesn't affect safety, we have to let it go*. This mantra was not about avoiding work; in most cases in which I heard this mantra, it was primarily a reminder of scientists' lack of authority, of management's interventions encouraging file completion, and of the constant interventions of various applicants and trade groups who were quick to state that scientists had no legal right to judge on particular issues.

Mantras helped to bring about the required socially-situated, affective disposition

Attention to mantras may be useful for many empirical, sociological studies of reason because of the way mantras collapsed justification, reason, and social position. In my fieldsite, mantras' embodied repetition seemed to have the effect of facilitation or even enacting the required affective disposition of scientists for them to reason, recognizably, in the Directorate. For instance, in Chapter 13, I will describe how, in the case of the Clinical Trial Unit, the mantra *We can't be against research* collapsed the following: (1) a political imperative for research, (2) a standard justification for activities in scientific regulation (*We can only regulate what is in the Regs*), and (3) a position of relative impotence.

Scientists' acute awareness of their (lack of) authority

Scientists' uncertainty regarding their own appointments, as well as scientists' acute awareness of their limited authority as regulators, were other striking features of scientists' reason and judgement in moments of uncertainty.

Scientists in precarious or tenuous appointments

In Chapter 17, I will describe the impact of tenuous appointments during the period of my fieldwork, when nearly half the Directorate's scientific staff members were temporarily (rather than permanently) appointed to their positions. I note that a tenuous appointment, in some cases, caused scientists to (explicitly) reason and judge in a way that they anticipated would be pleasing to supervisors.

Scientists perceive Directorate's existence to be precarious or tenuous

Many scientists also perceived the entire Directorate to have a tenuous existence. The Directorate apparently had no permanent budget, and, at the time of my fieldwork, was the black sheep among Directorates in the Health Products and Foods Branch because it had the regulatorily impossible: a backlog. The backlog, described in Chapter 15, consisted of the roughly twenty thousand (the number varied) Product Licence Applications submitted to the Directorate, that had yet to be evaluated. Upper management predicated the continued existence of the Directorate and its regulatory project on the disappearance of the backlog.

The backlog: the imaginary redirecting scientists' attentions and affect

In Chapter 14, I describe the extent that concern with backlog was brought into the daily evaluation activities of assessment officers through the introduction of productivity quotas (e.g., some evaluators had to produce seven or eight judgements, or Safety and Efficacy Assessment Reports, weekly). Evaluators continually and extensively 'tracked' their reasoning and judgements in a variety of computerized managerial databases. This system of quotas emphasized file completion (completed judgements), and, I felt, lessened the chance that scientists noticed safety concerns, because the structure of their evaluation activities directed their attention and desires elsewhere. What was of most interest to many upper managers in the public service, to judge from their statements to their underlings,

was the backlog. Backlogs have been salient phenomena in the pre-market review of drugs for several decades and in several countries.[27]

At the time of my fieldwork, there was little or no market enforcement of the Regulations, because with the backlog, general enforcement of the regulations was deemed unfeasible. This contributed to scientists' perception of their lack of authority as regulators – not only did they have little authority themselves in many cases, they had very little by their association to the state, which could enforce the scientists' judgements, but did not. This particular social positioning reverberated with several of the mantras repeated by scientists. Thus, while one might assume managerial origins to the mantra *We have to be flexible,* (and I suspect its origins may indeed have been managerial in intent), the use of this mantra primarily and pragmatically focussed the scientists' attention on what could potentially be enforced, encouraging scientists to turn a blind eye to the rest, as irrelevant: *If it is not about safety, we have to let it go.*

Values, affects and moral economies

Fairness was an important value in my fieldsite, and unfairness was the subject of many moral outbursts among scientists. Chapter 18 details the specific and robust meaning of *fairness* in the Directorate, whether it pertained to internal promotions, or to product licencing; this robust and specific meaning was indistinguishable from a more general Canadian "being nice." To be fair, one had to act with empathy at

all times and be partial to one's acquaintances, but impartial among acquaintances. In practice, the limits of acquaintances to whom fairness applied was essentially determined by the limits of reasonable complaint. Fairness was irrelevant for unknown or hypothetical persons.

Fairness can be usefully analyzed as a moral economy as outlined by Daston (1995) – as an "organized system" with clear and observable regularities that can be described but not necessarily predicted. It is the odd regularities in effect that I found disturbing. Using this formulation, I will argue that scientists' concern with fairness, in the context of managerialism, displayed certain regularities such as a positive affective disposition to easy files and a lack of notice of certain safety issues, regularities that were explicable but not always predictable.[28] Several mantras used by scientists in their reasoning – "we have to be flexible," "if it doesn't affect safety or efficacy, we have to let it go" – can be viewed as indicator's of the moral economy's particular equilibrium points and constraints; as tools for maintaining balance. While these mantras all directed scientists to take (in)actions of particular bents, they are simultaneously emotional imperatives – reminding scientists what should be held dear to the heart, and what should be ignored, to properly reason and judge.

I observed scientists' reasoning regarding the safety and efficacy of drugs in moments of uncertainty, and I argue that a constellation of sundry elements in the local moral worlds of the evaluators had significant impacts *especially* in these

moments of uncertainty. These sundry elements are those I have already mentioned: managerialism, mantras, and affective dispositions. While these three terms may at first seem nebulous, this dissertation discusses the effects of very tangible cultural phenomena: performance standards, databases, phrases like “we have to be flexible.” These sundry elements were understood, by many of my scientist colleagues, to be in the public interest – and while I originally disagreed with this interpretation, I had to revise my interpretation after interviewing those scientist and other colleagues whom I had initially believed were not working towards public health protection. After speaking with these individuals in interview I realized they were no less committed to public health protection, although their understanding of “the public good” and concomitant appropriate means and ends were not the same as mine. As Boltanski and Thévenot point out (2006), there are several different common goods. I would argue certain goods were enacted by the backlog and managerial tools.

The harmony of the mantras, conditions of labour, affects, measure

I am unsure whether this style of reasoning, this complex of features would have been relatively stable and so uniformly used by scientists, if any one of the following had not been the case: implementation of productivity quotas, high rates of tenuous appointments, the backlog, absence of permanent funding and inspectorate support for the Directorate’s activities, mantras like *We have to be flexible* and *If it doesn’t affect safety, we have to let it go*. While I suspect that many

styles of reasoning requiring decisions involve mantras, and that many regulatory decisions are constrained by budget concerns, there is a way in which the particular mantra *We have to be flexible* jived with an utter absence of permanent funding, the imaginary of the backlog, and many scientists' expressed feelings of tenuousness and (regulatory) impotence.[29]

While the reason for the particular equilibrium is speculative, I do not speculate when I observe these sundry features, affects, situations, comfortably nested among each other, supported each other, harmonized with one another, even accentuated each other.

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[1] An approach to the uniformity of reasoning among a group of scientists, compatible with what can be empirically observed by the anthropologist, is the "becoming a scientist" exposition featured in several ethnographies of science. For instance, Sharon Traweek presents physicists' "developmental cycle" in *Beamtimes and Lifetimes* (1988). Traweek describes how neophyte physicists, through their training activities and career trajectory, come to think, act, and value relatively uniformly like established physicists. Hugh Gusterson, in *Nuclear Rites* (1996) describes the socialisation of weapons scientists, noting how nuclear weapons become as unremarkable as vacuum cleaners to the scientists living and working with nuclear weapons on a daily basis. These anthropologists' descriptions of observable socialization of neophytes into a group, provides a wonderful structure to ethnographies, especially when there is a clear and distinguishable training period or career trajectory.

Unfortunately this approach is less useful for an analysis in my fieldsite, because there was preciously little formal training (often none) provided on the job. The government scientists I studied also lacked a common career path before and during their work in the Directorate. Clearly, in my fieldsite, there were manners and social etiquette specific to the Directorate (and likely the Canadian Public Service in general) that needed to be learned for scientists to become properly socialized. (I will not neglect to describe the learning process I and my colleagues went through, however, in our first year as regulatory scientists. I will discuss some of our *faux pas*, and the learning experiences involved, but these are used to bring *expected* reasoning and affective stances into relief.) In this fieldsite, though, the 'becoming a scientist' approach does not yield an explanation of uniformity in reasoning. The key factor in this uniformity was less scientists' formal on-the-job or prior training, I argue, than the structured activity itself.

[2] Formulation inspired by Young interviewed in Duclos (2009). Cf. Herzfeld's remarK:

> For ordinary people, then, including bureaucrats bewildered by the apparent ineluctability of forces that compel them to deny their own moral judgement [although here I quibble with Herzfeld, because I never lost my moral judgement, I just discovered it was incredibly socially embedded], some sort of explanation is needed. Such explanations are not necessarily believed by those to whom they are offered. But it is not at all clear that belief is the issue (1992:7).

[3] When I read this published study, I found no mention of adverse reactions, but also no mention of the absence of adverse reactions.

[4] There is one experience that I believe had overriding influence on my expectations of scientists engaged in public health protection, and thus overriding influence on my fieldwork experience and analysis thereof: a period of historical and archival research. In the course of this research, I believe I normalized to a certain degree, what I imagined to be the mindset of a food and drug inspector from the 1950s.

Had I spent those months in a natural health products business instead of in the archives, I believe a very different dissertation would have resulted, if only because very different things would have appeared strange, and worthy of analysis.

[5] This characterization is taken in spirit from Allan Young who states his:

> reality in the world is through the lens of science. That's the way that I see it. But again, that doesn't mean that one is uncritical or unknowing about what science is and what science does. The job is not to discredit science. Hacking says this very nicely, he said: 'I'm not interested in deconstructing what science does, I'm interested in knowing how science constructs knowledge, because that's my knowledge as well.' To talk about the contingencies that shape technology doesn't make that knowledge any less science. Because we don't have any other option! This is the human condition, this is how we live in the world, and our job is not to purify science because that truly would be a very mistaken enterprise with all sorts of unforeseen consequences. Our obligation [as anthropologists] is, to the extent that we can, to make the process transparent, and that's it. (in Duclos 2009)

[6] This formulation has the disadvantage of seeming self-referential – I approach reasoning as an observable activity, and analyze uniformity in reasoning in terms of the common structuring of evaluation activities. This disadvantage, however, is a feature of many empirical approaches to scientific reasoning and may be unavoidable. There is no escape from human activity.

[7] Each scientist could read or speak about natural health products in English, and according to a survey, about half could also do so on French. Among the scientific staff there was someone who could read about natural health products in each of an additional 23 languages. In order of number of times mentioned in the survey: Arabic (8), German (8), Farsi (5), Mandarin (5), Spanish (5), Hindi (4), Italian (4), Punjabi (4), Portuguese (2), Russian (2), Urdu (2); and one mention each of: Amharic, Cantonese, Fon, Marathi, Polish, Romanian, Sanskrit, Sinhala, Tigre, Vietnamese, and one more language for which I could not decipher the handwriting. From other conversations I also know that there was at least one scientist who could 'do' Latin. I am presuming there were 69 scientists who answered that question in the kitchen survey because this was the number of tallies for "English." There were 34 tallies for French.

[8] As Tola Olu Pearce demonstrated (1989), the expressed beliefs of university-educated civil servants do not (often) conform to Weberian (1947) expectations of those beliefs.

[9] In the early days of the NHPD, when there were only a dozen or two scientific staff, there were Weekly Health Assessment Meetings (WHAM) off all scientific staff and that served as a place for all scientists to get on the same page through a discussion of issues encountered by some scientists. Several scientists recalled these meetings with nostalgia, but also noted that as the Directorate grew the meetings became so unwieldy (because of the number of attendees) that they ended.

[10] Experts included the "fish oil queen," the multi-vitamin-multi-mineral go-to, a labelling policy guy, the black cohosh aficionado, the assessment officer who had dealt with dozens of gingko Product Licence Applications, the one Ayurvedic doctor, the toxicologist, the scientist on various Branch-level cosmetics working groups, the chemist who politely fielded all assessment officers' questions about manufacturing processes, and so on. When scientists could not otherwise find an answer, they often went to consult a de facto science guru in his abode on the north face of the building.

[11] In government and in academia, there is a significantly different approach to norms of writing – specifically the moral valence attributed to cutting and pasting from others' electronic documents into one's own. In government, cutting and pasting is expected so need not always be cited; in academia, cutting and pasting is plagiarism and taboo. In government, hundreds of individuals are trying to speak as one, and consistency is a virtue; in academia, hundreds of individuals are trying to speak uniquely.

[12] The day-to-day metaphors from military action used by various levels of management at the Directorate belied how the origins of British-style civil services shape current understandings of the organization and purpose of scientific staff (cf Lakoff and Johnson 1980:3-6). Middle management, only half in jest, would regularly ask entry-level staff how things were going "on the front lines" or "in the trenches" or "among the troops."

[13] In the case of clinical trials, his or her Director, not Manager.

[14] The reporting structure of the NHPD also entailed that, at some level, scientists were supervised by non-scientists. NHPD's upper management oversaw scientific assessment staff and sometimes had the final say in product authorizations and licences. Two of these positions were classified as "executive" positions, and thus the incumbents were not required to have any background in science. During my year at the NHPD, one of the Directors and one of the Director Generals (as already mentioned, there was turnover) had no background in science to my knowledge. The third position was classified as biologist position (BI-5), requiring substantial qualifications in science, but apparently that classification and level did not hold sufficient sway at the level of the Branch; at one point during the turnover of upper-level management at the NHPD, the NHPD reportedly "had a credibility problem" at Branch meetings because there were no executives (although there were senior scientists) to defend its interests and decisions. The sometimes uneasy relationship between scientists and non-scientist executives will be discussed in Chapter 16.

[15] I follow Canguilhem in his distinction between normalization and standardization; he argues that normalization is not immutable like standardization (1989). This distinction, along with his remark that the 1930s preference in France for the former (Canguilhem 1989:247) may provide a key in a genealogy of the differential attention to evidence-based medicine (with its standards) and other broader phenomena of 'transparency' via textual standards in Anglophone countries.

[16] Herzfeld: "precision is not merely a perverse bureaucratic pleasure. On the contrary, it is vital to professional survival. The bureaucrat always wants to be in a position to point to a legitimating text" (1992:124). While this much is similar, Herzfeld's discussion immediately surrounding this observation pertains more to situations in which the bureaucrat is not supported by superiors; in the case of scientists at the NHPD, the imagined challenge, rather than from superiors, was ultimately from applicants taking legal action. So perhaps it is better to contextualize this interpretation of regulatory activity as text within a broader tendency to *textualize**, as:

> (1) interpreting statements abstractly, as simultaneously objects in themselves and elements in a system of statements (the text), (2) evaluating and interpreting statements in terms of the technical procedures used to produce them, and (3) treating a corpus of statements, the text, as an object about which other statements (i.e., commentaries) can be produced. (Young 1981:324-325)

*****Young notes that textualization, in the manner he is using the term, is not restricted to literate communities, because similar effects may occur in juridical, rhetorical and narrative traditions in all communities. He characterizes the tendency to textualize to make a methodological point: that when anthropologists textualize the oral statements of those they are studying, "these three tendencies are carried over as a set of expectations, i.e., expectations that speakers can discourse abstractly, produce utterances that mirror prior internal statements ('thinking'), and self-consciously monitor the trajectory of their oral statements."

[17] The section Textual Standards in Practice builds from, and adds to a body of literature in sociology on the contextualized way in which written rules and standards are part of professionals' reasoning and judgement in various public services. There is an entire body of "institutional ethnographies" following the work of Dorothy Smith focussing on textual standards in government, because "texts do something rather special as coordinators of people's activities" (Smith 2006:65). There is another entire body of literature in the sociology of science on this topic, focussed on protocols as textual standards; one of the more memorable case studies is that of Timmermans and Berg's study of protocols in emergency situations. While a protocol such as that for CPR, for instance, or a diagnosis may be standardized internationally, it can only be local in its performance and thus "universality is always 'local universality'" (Timmermans and Berg 1997:273, Mol 2003). While these authors see standardization as a "distributed activity," they note that a successful standard crystallizes the activities of various actors like patients, pharmaceuticals, support staff, instruments, etc. (Timmermans and Berg 1997:276; cf. *routines* in Verran 2001).

[18] The Oxford English Dictionary (2010) provides three definitions of algorithm. The first is as arithmethic (e.g., Arabic, decimal numeration). My use of the term combines the second two definitions, from math and medicine respectively: (2) "a process, or a set of rules," (3) "a step-by-step procedure for reaching a clinical decision or diagnosis, often set out in the form of a flow chart, in which the answer to each question determines the next question to be asked."

[19] The difference between the science-based reasoning in the Directorate and the taxonomic reasoning pertaining to plants and animals, as described by Crombie from antiquity to the 19th century (1994:1245-1292), is, I would argue, inseparable from the development of the computer with its series of 1 or nought – this or that – communications (and which involves time differently than the taxonomic reasoning of Aristotle, Linneaus, or even Darwin). While the style of thought described by Crombie is not exactly the style of reasoning used by NHPD scientists – nor is the purpose nor object of thought or reasoning the same – there is a strong genealogical relationship.

[20] Compendial applications attested to the NHPD's Compendium of Monographs for safety and efficacy; Trans-DINs attested to a previous market authorization; most homeopathic applications attested to one of the foreign homeopathic pharmacopoeia formally recognized by the NHPD; TPD-Cat-V applications attested to labelling standards produced by another part of Health Canada; vitamin and mineral supplements were often compared with a standard produced by the NHPD; traditional medicine applications attested to one or two published descriptions of the traditional medicine's use; and so on.

[21] For a discussion of committing *faux pas* while learning the proper manners for the audience of a genre of storytelling, see Verran (2004). The relationship between reasoning and etiquette will be expanded in Chapter 9, on the evaluation of homeopathic medicines.

[22] Because of regulatory scientists' perpetual reliance on underlying documentation (regulation, guidance documents), the comparison to practitioners' use of evidence is difficult. Regulatory scientists' engagement with the regulations and the guidelines were not "informed by a brief reading" only, as Gabbay & le May (2004) characterize the activity of reading in physicians' thought collective. I cannot use this for scientific regulators, because there was no "brief reading" of the regulatory documentation or documentary evidence – it was thorough for its purposes.

[23] To draw from the original Sanskrit meaning from the *Concise Oxford English Dictionary* (2008).

[24] As reads the general definition for "mantra" in the *Oxford English Dictionary Online* (2010).

[25] I believe this to be a mantra used in a pre-2006 era of scientists' reason at the NHPD.

[26] There are many other possible means; for a more general formulation of the issue, see Young 1981.

[27] For instance in Germany in the 1980s:

> Drug manufacturers began complaining in the late 1980s of an 'approval jam' (Zulassungsstau), comparable to the [US] American 'drug lag' critique of the early 1970s. [But in Germany] Despite their best efforts to publicize bureaucratic inefficiency, the issue attracted little public attention beyond the Bundestag's Health Commission and the trade press (Daemmrich 2003b: 38).

[28] One could imagine a world, still managerial in its organization of activities, but where the items measured are adverse reactions in the general population, and that would result in different regularities than those I observed.

[29] An utter lack of "A-base funding" for readers conversant with funding in Canadian government.

Part II. Official standards

regulations, definitions and processes

It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. For the reformer has enemies in all those who profit by the old order, and only lukewarm defenders in all those who would profit by the new order, this lukewarmness rising partly from fear of their adversaries, who have the laws in their favour; and partly from the incredulity of mankind, who do not truly believe in anything new until they have had actual experience of it.

Niccolo Machiavelli (1469 – 1527)

> As cited as epigraph in the *Report of the Expert Advisory Committee on Herbs and Botanical Preparations to the Health Protection Branch, Health and Welfare Canada* published in January 1986 by authority of the Minister of National Health and Welfare.

One of the things that I think was *extremely* prophetic is, in this first report, in '86, they preface it with a quote from Niccolò Machiavelli. It fits *so* well.

> Robin Marles, Director, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate, Health Canada, in interview in September 2007.

Chapter 3
Natural health products as standard
'A New Vision,' 'A Fresh Start,' a new order

A new order of things

In a random telephone survey, nearly half (45%) of Canadians reported being unfamiliar with "natural health products"; 36% reported being familiar and the remaining 19% were neutral. These statistics exist despite 71% of those surveyed Canadians declaring, upon prompting, that they had used medicines now classified as "natural health products" (Ipsos-Reid 2005).[1]

The category *natural health products* is the result of an explicit attempt to create a new regulatory order of consumables in Canada in the last two decades of the twentieth century. The category is in use on a national scale, even if this use is largely restricted to Canadian regulatory and pararegulatory activities. Canadian researchers and industry are now frequently using the term, and Canadian non-governmental organizations have been created or renamed in relation to this new category: the Natural Health Product Research Society of Canada, the Canadian Herb, Spice, and Natural Health Product Coalition, and the Western Canadian Functional Food & Natural Health Product Network. Nevertheless, the phrase "natural health products" is not entirely recognizable to the general Canadian public, nor is it oft used in the scientific literature by authors outside of Canada,[2] nor, by the regulators of other countries.[3] It is a phrase that is ridiculed (e.g., CMAJ 2001:613) as well as used to evoke nationalistic pride – for instance, at a conference in Ottawa in 2003, an official's statement "We Canadians are the world leaders in natural health product regulation," was a statement greeted with a round of applause.[4]

This category, this new order of medicines, is not without causes nor consequences,[5] even without its large-scale 'naturalization' in Canada or internationally.[6][7] I include this discussion of the category "natural health products" at the beginning of the dissertation, because this category is both prior to the work of the scientists I observed, and *the* first and most important standard in the assessment of traditional and herbal medicines' safety and efficacy at Health

Canada in 2006-2007. One of the first, and most important activities in the Natural Health Products Directorate's regulatory evaluation of medicines is to ensure that the product in question is really a natural health product, rather than a drug, food or cosmetic, for instance. As such, the first standard used in the Natural Health Products Directorate in the pre-market evaluation of traditional and herbal medicines is the regulatory definition of *natural health product*.

Whence the new order

The development of the category of natural health products was neither self-evident nor arbitrary, as will become evident later in the dissertation. This category was developed as part of a solution to a perceived regulatory dilemma. I provide but a brief overview of the category's development here, asking the reader to note the ever-increasing ambit of the categories proposed as solutions to the perceived regulatory dilemma.

Since the early 1980s, Canadian federal regulators had sought assistance regarding the classification of various traditional herbal medicines into one of the two legal categories available in Canada's *Food and Drugs Act* and *Food and Drug Regulations*: food or drugs. Between 1984 and 1997, no fewer than *six* official committees advised the federal department of health on the regulatory classification of herbal medicines. Figure 3-1 provides a list and overview of seven committees.

Figure 3-1: Canadian government committees considering the regulation of traditional herbal medicines by the federal department of health, 1980- 2000

Committee Name	Reporting to	From date	To date	Listed member affiliation, primary	# of members	Final report
Expert Advisory Committee on Herbs and Botanical Preparations	Health Protection Branch	[1984] 1985	1986	University, medicine or pharmacy (4); industry (2); practitioners/ health training (3)	~9	*Report of the Expert Advisory Committee on Herbs and Botanical Preparations to the Health Protection Branch, Health and Welfare Canada* (January 1986)
(above, reconvened)	Health Protection Branch	1993	1993	University, medicine or pharmacy (3); Industry (3); Practitioners (4)	~10	*Second Report of the Expert Advisory Committee on Herbs and Botanical Preparations, to the Health Protection Branch, Health Canada* (October 1993)
Expert Advisory Committee on Complementary Medicines	Therapeutic Products Programme	1997-	? ~2000	University (6); Practitioners (3)	~ 9	n/a

Advisory Panel on Herbal Remedies. Renamed later in 1997: the Advisory Panel on Natural Health Products.	Unclear. Variously declared: Therapeutic Products Programme; Minister of Health; Standing Committee on Health	1997	1998	"Represent-ative of Stakeholders" Industry (9); University, pharmacy (2); practitioners/ health training (5); First Nations (1); Consumer group (2)	~19	*Final Report of the Advisory Panel on Natural Health Products: Regulatory Framework for Natural Health Products*. (May 13, 1998)
Standing Committee on Health, tasked by Minister of Health to examine the issue of Natural Health Products	Minister of Health, Parliament	1997	1998	Elected officials (Ministers of Parliament)	~16	*Natural Health Products: A New Vision* (November 1998)
Transition Team of the Office of Natural Health Products	Minister of Health	1999	2000	14 "from the consumer and natural health private sector" Industry (9); health consultant/ practitioner (4); consumer group (1); & government (3)	~17	*A Fresh Start: Final Report of the ONHP Transition Team* (March 31, 2000)
Expert Advisory Committee on Natural Health Products	NHPD management	2000		Current location of employment not listed	~14	n/a

Initially, the categories proposed by regulators and their advisory committees varied. The first official committee was struck to advise on the suitability of certain plants with medicinal uses, being sold as foods. Machiavelli's statement regarding "initiating a new order," used as epigraph in the first report of the Expert Advisory Committee on Herbs and Botanical Preparations, likely alluded to the committee's proposal that a regulatory category of "Folklore Medicines" be created. This category was not much subsequently used by the federal regulators, however, who instead used categories like ethnic herbal preparations, herb and botanical drug products, herbal remedies, and herbal medicines somewhat interchangeably for many years. By the early 1990s, the category "traditional herbal medicines" enjoyed some stability, being used by the Expert Advisory Committee in its second report, and even entering into official government policy in 1995. This temporary stability ended in 1997.

On the receiving end of various letter-writing campaigns, two successive Ministers of Health were brought into the discussion. In the spring of 1997, Minister David Dingwall called for the creation of an Expert Advisory Committee on Complementary Medicine, as well as an Advisory Panel on Herbal Remedies. The Advisory Panel on Herbal Remedies was clearly instructed to exclude, from its considerations, homeopathic medicines, vitamins, and nutraceuticals.[8]

The major shift from a focus on herbal medicine, to a focus on a wide range of medicines, happened later in 1997, officially in November 1997, although it is

difficult if not impossible to give a precise date.[9] On November 14, 1997, Minister Allan Rock renamed the Advisory Panel on Herbal Remedies, the Advisory Panel on Natural Health Products at the Advisory Panel's own request. This administrative change was the public debut for the category "natural health product" in official government recognition. Also in 1997, Minister Allan Rock also tasked the House of Commons Standing Committee on Health to examine the issue of "natural health products," specifically "the legislative and regulatory regime governing traditional medicines (including, but not limited to, traditional herbal remedies, traditional Chinese, Ayurvedic and Native North American medicines), homeopathic preparations and vitamin and mineral supplements" (in Volpe 1998).[10] When I briefly interviewed Allan Rock a decade later, he stated he did not remember whence the category natural health products came.[11] Nevertheless, this renaming, I wish to underscore, extended the ambit of discussion from Herbal Remedies to the much larger category of medicines: Natural Health Products. Based on contemporary estimates by lobby groups, this renaming shifted the annual gross from medicines under the committee's ambit a full order of magnitude, from an estimated $150-200 million to $1.5-2 billion or more.[12]

The parliamentary Standing Committee on Health managed to examine the issue of natural health products, hearing from hundreds of witnesses, and making 53 recommendations in a report entitled *Natural health products: A new vision* (1998), without further defining what natural health products were (because

"members fe[lt] they do not have the adequate expertise.") Instead, the Committee's first recommendation was that another expert advisory committee develop the definition of natural health products. In March 1999, the Canadian Parliament accepted all the recommendations in the report, and an Office of Natural Health Products was created to licence these products deemed neither food nor drug. The committee helping to set up the office, the Transition Team, also managed to release its final report *A Fresh Start* in 2000 without defining "natural health products," although the report did provide what it called 'guiding principles' for the definition:

> Natural health products (NHPs) are composed of substances or combinations of substances found in nature, and energetically-potentized preparations, used for the purpose of maintaining or improving health or treating or preventing diseases/conditions (2000:18-19)

These guiding principles again expanded the ambit of the category, with the Transition Team stating that the new category should be inclusive of, but not limited to:

> homeopathic preparations; vitamins; minerals; enzymes; co-enzymes; co-factors; herbs or botanicals; naturally-occurring animal, plant and micro-organism substances; and a variety of molecules extracted from natural sources, such as amino acids, polysaccharides, peptides, naturally occurring hormones and biochemical intermediates, as well as naturally occurring molecules synthesized by chemical or biological means. (2000:19).

As far as I can determine from the historical record, the (actual) regulatory definition was developed by government officials in conjunction with the Expert Advisory Committee of the Office of Natural Health Products in 2000-2001. Although this Committee had considered a "grid or matrix system, with which any

product could be put through an algorithm to determine where or how a product should be regulated, including consideration of its risk or safety," the grid or matrix system was later relegated to the sidelines, as a possible administrative tool (Health Canada - NHPD 2000). The committee was steered towards a list-based system. The Expert Advisory Committee members used exemplar medicines that members believed should be included in the new category, medicines such as SAM-e, to think through draft inclusion and exclusion lists. The draft definitional lists were first published in the *Canada Gazette I* on December 22, 2001, and remained largely unchanged in the final version published in the *Canada Gazette II* in June 2003. When the *Natural Health Products Regulations* came into force on January 1, 2004, "natural health products" became a category with the force of law in Canada, a regulatory category distinct from both food and drugs.[13]

Natural health product, defined in regulation (text)

The regulatory category "natural health product" includes commodified medicines that are one of three types of medicines:

1. traditional medicines
2. homeopathic medicines, or
3. medicines whose medicinal ingredient(s) *can* (all) be naturally-sourced;

provided that no medicinal ingredient in the medicine is otherwise regulated as a prescription-only drug, a poison, a radiopharmaceutical, a biologic (e.g., blood,

interferon, vaccines), an antibiotic, an injectable, or a narcotic or other psychoactive.

The exact regulatory definition, as an important standard in the evaluation of traditional and herbal medicines, is sufficiently important to this dissertation that the complete definition from the *Natural Health Products Regulations* is reproduced below. In the reproduction, I have underlined the part of the definition that is taken, nearly verbatim, from the definition of *drug* in Canada's *Food and Drugs Act*, to emphasize the difference is largely in terms of medicinal ingredient:

> "natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in
>
> (*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
> (*b*) restoring or correcting organic functions in humans; or
> (*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.
>
> However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Because Schedules 1 and 2 are essential to the definition, I have reproduced these schedules as Figures 3-2 and 3-3. The regulatory definition essentially divided medicines into two categories: those included in the definition and that would become regulated as natural health products, and those, excluded from the definition, that would continue being regulated as drugs under various Acts.

Figure 3-2: The Natural Health Products Regulations' SCHEDULE 1: INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2.	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3.	Any of the following vitamins:
	biotin
	folate
	niacin
	pantothenic acid
	riboflavin
	thiamine
	vitamin A
	vitamin B6
	vitamin B12
	vitamin C
	vitamin D
	vitamin E
4.	An amino acid
5.	An essential fatty acid
6.	A synthetic duplicate of a substance described in any of items 2 to 5
7.	A mineral
8.	A probiotic

Figure 3-3: The Natural Health Products Regulations' SCHEDULE 2: EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A substance set out in Schedule C to the [Food and Drugs] Act [radiopharmaceuticals]
2.	A substance set out in Schedule D to the Act [biologicals such as blood and interferon], except for the following: (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3.	A substance regulated under the Tobacco Act
4.	A substance set out in any of Schedules I to V of the Controlled Drugs and Substances Act [psychotropics]
5.	A substance that is administered by puncturing the dermis
6.	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

Natural Health Product, defined in regulation (activity)

Long lists of inclusion and exclusion like in Schedules 1 and 2 of the *Natural Health Products Regulations* are not easy to "think with" (cf. Lévi-Strauss' remark that animals are good to think with.) Alongside the official regulatory definition, there was an informal rule for determining whether a medicine should be classified as a drug or a natural health product, a rule stated explicitly by government officials in public information sessions: "If it is found in nature, it's natural," and thus a natural health product. This rule follows the Office of Natural Health Products' Transition Team's guiding principle for the definition of natural health products.

Science and the great divide: Nature gets ethanol, Man gets activated charcoal

With the creation of the Natural Health Products Directorate, there was a need for certain medicines previously regulated as nonprescription drugs, to become regulated as natural health products. The question was, which medicines? A working group of government scientists proceeded to sort out the 'natural' non-prescription medicines from the rest.

No amount of anthropological and philosophical reflection on the nature::culture dichotomy obviates bureaucrats' pragmatic classificatory activity. They worked with the advanced principle Me, Nature; You, Man (or culture, artifice, and so on). Although I jest, this was no simple work; one scientist found the classificatory

work to be one of the most intellectually-engaging activities with which s/he had been involved in the workplace, because the naturalness of many chemicals was not self-evident, and so the work, this scientist felt, bettered one's "understanding" of the chemicals. Among antidandruff products, salicylic acid was classified as a natural health product, and coal tar as a drug; among bulk forming laxatives, cellulose a natural health product, but methylcellulose a drug; among medicated skin care products, glycerine a natural health product, mineral oil a drug. A full list of the results of the divorce of certain drugs into the natural and the non-natural – the work of a classification working group – is posted on Health Canada's website.[14]

Nevertheless, another scientist with whom I spoke found these classification activities to be a very messy separation indeed, perhaps one without resolution. Numerous complications emerged in the working groups. To take but a basic example: isolates from plants and animals often need to be stabilized, for instance as salts or esters. This chemical intervention led to debates, over, to use the words of one scientist:

> What criteria do we accept to be natural?
>
> One example is salicylic acid, which can be converted to ASA [aspirin]. By doing so, something with no blood thinning effects is converted into something with blood thinning effects. The decision at the time was that if the modification rendered additional pharmacological activity, it was not an NHP. If the modification was to stabilize the product, it was an NHP.
>
> But it is a big black hole. For instance there is the question whether making an [isolate into an] ester or a salt also makes the body absorb it differently, split[s] it in the stomach versus elsewhere. There is no real evidence in

> literature to know. And in any event, can one really use lab results *in vitro* to say where it would split? (Ommy)

Another complication involved the synthesized duplicates of naturally-occurring chemicals. Many synthesized duplicates – most notably synthesized vitamins – are synthesized in a raecemic mixture, whereas "in nature" the chemical only exists in one stereoisomer.

> So things like dl-alpha-tocopheryl acetate don't occur in nature, but they provide the body with the natural compound. They act as a source [for the natural compound].
>
> So, there has been a considerable degree of *interpretation* of "natural" in our product classification. So, it's not as simple as we thought it might be [laughs], in the first place.
>
> And, we do a lot of literature searching. Some things that we all thought were synthetic, turned out to be natural.[15] (Robin Marles)

(That the Nature:Culture divide can be created and overcome through such mundane activities as developing criteria and searching the literature is a recurring theme through this dissertation.) Given the scientists' particular way of reasoning the Nature: Culture divide, "nature" did not always correspond to a particular imaginary of "natural" as "safe." While criteria were developed and literature was searched, as Ommy observed, "Simple things can screw you up." There was much that was unanticipated and, apparently, undesired. According to one scientist's memory of the first few years of operation of the Natural Health Products Directorate, there were regular exclamations of scientists' surprise and dismay, as Product Licence and Clinical Trial Applications came into the Directorate featuring products that the scientists had not anticipated would be

included in the ambit of natural health products – antiperspirants, toothpaste with fluoride, sunscreen, hand sanitizers, and gum to aid smoking cessation. (Oxygen gas was rejected "by policy interpretation.") These products' medicinal ingredients could be 'found in nature,' but the products did not always correspond to what the scientists considered natural. One scientist recounted:

> It was just overwhelming. It was like NHPD was suddenly responsible for everything like from foods to drugs. Like *true* drugs. The sort of stuff that we're getting in [applications ….] Aside from the source, they're a drug, you know like the way we think in our head of it as a drug. (Alma)

At least one scientist held out hope that regulatory amendments could hone in on a more anticipated group of medicines:

> We wanted to capture … as a broad category, these natural substances. If we, with all of our 20/20 hindsight, we see there were certain things we should have captured and didn't, and other things we did capture and probably shouldn't have. And those can be resolved later by specific [regulatory] amendments. (Robin Marles)

The informal rule of "if it's found in nature, it's natural" proved to be not so simple. It was nevertheless in operation. In 2006, after a few years of operation, the Natural Health Products Directorate was fielding Product Licence Applications for nature's bounty of medicines including: vitamins and minerals, traditional medicines, antiperspirants, whole plants packaged with health claims, plant extracts and isolates, fungi, sunscreens, bacterial cultures, medicines that would normally be excluded from being natural health products because of other laws but were actually included in the classification because they were homeopathic medicines, medicines that from a long way off look like bottled chemicals, et cetera, natural health products having just been synthesized, bits of proteins…

The order of natural health products

Michel Foucault begins *The order of things* (2002 [1970]) with mention of his laughter at reading Jorge Luis Borges' presentation of a passage in an unnamed Chinese encyclopedia, in which animals are reportedly categorized as follows:

> (a) belonging to the Emperor,
> (b) embalmed,
> (c) tame,
> (d) suckling pigs,
> (e) sirens,
> (f) fabulous,
> (g) stray dogs,
> (h) included in the present classification,
> (i) frenzied,
> (j) innumerable,
> (k) drawn with a very fine camelhair brush,
> (l) et cetera,
> (m) having just broken the water pitcher,
> (n) that from a long way off look like flies.

This fable, argues Foucault, causes the reader to "apprehend in one great leap, the thing that, by means of the fable, is demonstrated as the exotic charm of another system of thought, is the limitation of our own, the stark impossibility of thinking that" (2002:xvi).

But Foucault was not a bureaucrat. I believe that if he had worked as a bureaucrat he might not have laughed. I say this because my instinct upon reading the list is now distinctly humorless, after my year's experience as a bureaucrat, despite my prior delight in the list. After this experience as a bureaucrat, I immediately make sense of how such "charming" divisions are a rather stark possibility, whether one had grown up reading Chinese or French encyclopedias or Borges' fabulous

renditions thereof. I have been retrained to read enumerations, categories – representation – as inseparable from messy worlds of practical intervention (cf. Hacking 1983) rather than, say, as part of a smooth world of hypothetical orderings or, in Bruno Latour's (1990) terminology of science, immutable mobiles, even though the regulatory definition itself is textual and such an immutable mobile. This dissertation is a reflection of my retraining. The apprehension in one great leap is no longer possible.

How to read the unnamed encyclopedia's list as a bureaucrat, the reader asks? Try and imagine oneself as a cog in the wheels of an arcane regulatory machine, whose daily activities orient one only to practical action. The list is perfectly thinkable if one is to read it as an animal control officer having to complete very practical tasks for her Emperor – these practical tasks being dictated by an uneven hodgepodge of political imperatives, tasks requiring her acting in relation to animals differently depending on their qualification. I would imagine, she would be required to act very differently in response to reports of stray dogs, sirens, embalmed animals, and – horror of horrors – animals having just broken the (Emperor's) water pitcher. (A category borne of a discrete and frightening event, whose repetition is to be avoided at all costs). Likewise, scientists, as I will describe in Section I, were required to reason somewhat differently regarding different categories of medicines.

This is not to say such an animal control officer would expect others to think in such “charming” divisions. I can imagine she would recognize that her classification is of very little use to someone investigating the evolution of the cuttlefish, or to someone acquiring a family pet. In other words, the animal control officer could recognize the stark impossibility of such a classification being self-evident outside her regulatory world, yet, in her daily work, need to think and live in precisely in those categories.

Likewise, with the category of, and categorization of, natural health products, I believe that one can overcome ‘the stark impossibility of thinking’ with a very bizarre categorization *even when*, for all intents and purposes, the categorization is not otherwise naturalized in general Canadian life, as indicated by the random telephone survey mentioned at the beginning of this chapter.

I should point out that the definition of natural health products also did not appear to be normalized even among the NHPD’s scientific staff in their lives outside the directorate. In nearly all of the 40 interviews I conducted with the NHPD’s scientific staff, I asked them which natural health products they used; only four mentioned toothpaste, antiperspirant, sunscreen – any so-called “personal care product.” (And one of those four mentions was not even during the interview, but via a hurried e-mail the day following the interview, with the scientist clearly abashed at herself, saying she had forgotten to mention toothpaste.)[16] Because there was no lack of oral hygiene in evidence among these 40 scientists, and I do

not believe they *all* used baking soda or neem sticks, I take this as an indication that toothpaste is not top-of-mind in response to a question about natural health products, even among regulators of natural health products.

At the NHPD, the classification exists in daily work activities, rather than as a tool for reflection or everyday life outside the Directorate. Thus item (h) in the unnamed encyclopedia's list, "included in the present classification" – an item that Foucault finds particularly telling – is no longer ironic to my newly acquired bureaucrat sensibilities. Indeed, I read the determination of item (h) as a specific work task, one that could be listed in the animal control officer's ten-page job description, because surely, the overall category of animal is only of interest to her when she is unsure whether a particular entity requires action on her part, i.e. is an animal to be controlled.

At the NHPD, scientists' entire style of reasoning was inseparable from the order of natural health products. But the order was never complete, with new circumstances or finer-tuned boundaries requiring re-ordering, a process that was often unpredictable, as I will describe in Part III Textual Standards in Practice. An upper manager in the Health Products and Foods Branch declared, at a branch-wide meeting, "the entire issue of classification" to be somewhat of a "bugbear," presumably attempting to lessen the salience of the classification, because, according to the *Oxford English Dictionary*, bugbear is an "object of dread, *esp. of needless* dread; an *imaginary* terror. In weakened senses: an annoyance, bane,

thorn in the flesh" (2010, emphasis added). But from the regulatory scientists' perspective, the terror was not imaginary, as the entire regulatory order could be threatened by misclassifications; "all margins are dangerous…. Any structure of ideas is vulnerable at its margins" (Douglas 1966:122). The same classificatory terrors occur internationally among regulatory agencies.[17] The classificatory terrors are also not restricted to those in the regulatory agencies themselves, as the effects of such classificatory moves also may have significant effects on the legal status and preservation of medicines in the wild or in cultivation,[18] and in some cases the legality or feasibility of people's livelihoods by association.[19]

Remarks on the regulatory classification's co-production with that of drugs

> Why not call modern medicine "alternative"? Because we can't. It has already become the name for the other side of the coin (Bates 2002:27).[20]

"Alternative" and "complementary" medicine are clearly defined in contrast to a non-qualified, (mainstream) medicine. As Roberta Bivins notes, "to have medical systems, theories, and practices that can properly be regarded as 'alternative,' one must have a recognized, definable, and at least relatively stable orthodoxy to which they oppose themselves" (2007:171). The coproduction of alternative medicine (or complementary medicine) with mainstream medicine is analytically given a priori. The same observation may be made for the qualifiers "evidence-based" and "bio-" (as in biomedicine), which, although they change the valence given to unqualified medicine (in these cases, plain old medicine is implicitly derided as non-"evidence-based", non-scientific, and so on), presuppose an a

priori, unqualified, medicine. Other ways of qualifying a group of medicines do not immediately bring to mind an implied counterpart. “Homeopathy” or “Homeopathic medicine”, for instance, can be understood as it was in the Natural Health Products Directorate as a stand-alone tradition, with its own standards and so on: fully independent. (Indeed, the term *allopathy* was first coined to distinguish it from homeopathy, according to the etymology entry for allopathy in the *Oxford English Dictionary* (2010)). “Traditional, Ethnic” medicines were likewise treated as independent traditions in the Directorate. But even though the qualifiers “homeopathic,” “traditional,” and “ethnic” do not highlight a medicine’s co-production with an unqualified (Western, allopathic, mainstream) medicine, the presumed *sui generis* origins of “homeopathic medicine,” “traditional medicine,” and “ethnic medicine,” lumps a range of medicines with few similarities together and obfuscates the complex relationships among these and other forms of medicines through time, as anthropologists and historians have so elegantly described for traditional Chinese medicine (see Chapter 8 for a summary). All these qualified medicines are coproduced with a presumed unqualified medicine, whether this co-production is more or less evident. But a change in the ambit of the qualified medicine changes the ambit of the unqualified medicine.

I am not concerned with medicines as much as medications, but the same principles of the coproduction of categories apply. “Natural Health Products” is another category that appears to stand alone. A brief examination of the regulatory definition of this category, however, underscores the category’s

coproduction and codefinition with other categories of medicines in Canadian regulation. (Readers may wish to review the list of exclusions in Figure 3-3). Although the committees and government officials drawing up the definition, were focused exclusively on the new category *natural health product*, much of the definitional work implied redrawing the boundaries of the regulatory category *drug*. Many medicines previously regulated as drugs under the *Food and Drug Regulations*, became regulated as natural health products.[21] Therefore, development of the regulatory category of natural health products has effected a regulatory redefinition of drugs, even if the textual regulations of the latter have not explicitly changed in this regard.[22] I assert that the current categories of *natural health products* and *drugs* are co-produced in this very straight-forward way, although the shaping of one category (natural health products) holds all the attention, and with the other category (drugs) (falsely) presumed to have remained the same.

I wish to make three brief (rather conceptual) arguments regarding this co-production of the regulatory categories drug and natural health product. These are remarks on the (political, marketing) work done by this new order. There is no denying that classifications, orders, often do political work, whether or not this was intended when the classifications were developed. What is the political work in the regulatory division of *drugs* into *drugs* and *natural health products*?

One: there is a way in which the cultural association of nature with gentleness (in effect, and as safety) has become a self-fulfilling prophecy, because most naturally-sourced drugs with immediately or strongly noticeable effects (positive or negative) are excluded from the category of natural health product by regulatory and policy definition. Because, to some extent, natural health products have been repeatedly and explicitly defined as safe, drugs have implicitly been made stronger and riskier. While I will not revisit this argument in the dissertation, it nevertheless important background for my descriptions of scientists' mundane regulatory evaluation of natural health products. The second argument is less argument than observation: the name of the new classification, "natural health product," is a (short-term?) marketing boon for the manufacturers of these medicines, given this cultural association of nature with safety. I suggest the boon may be short-term, because *nature* and *natural*, as long-standing polysemic symbols, may just as easily be associated by Canadians with danger, rather than safety – or possibly both simultaneously, as one must never underestimate the power of polysemic symbols. But I will begin with a third argument, one which I feel it is important to sketch because it is persuasive conceptually and rhetorically, and because it must be partially disposed on empirical (historical) grounds. This is the argument that the new regulatory category of *natural health products* emerged because certain medicines had been excluded from the mainstream regulatory category of *drugs*, but, enjoying substantial sales, needed to be corralled back into regulation.

A rhetorical argument with questionable relevance

Conventional accounts of the formation of the Natural Health Products Directorate include reference to increasing interest in, or use of, variously qualified medicines (e.g., complementary, alternative, traditional, ethnic, natural medicines). These increases are claimed to have occurred in the 1980s, 1990s, or the 2000s.[23] These conventional accounts also often imply that these medicines had been effectively written out of the regulatory regime; new regulatory measures were therefore required.

Was there an increase in the use of the medicines now deemed natural?

There is, quite likely, no way of knowing to what extent the use of natural health products increased in the late twentieth century. This is not only because reliable numbers are simply unavailable, even if one were to restrict one's interest to the sale of commodified, packaged natural health products. The more fundamental problem is how to meaningfully project the category "natural health product" backwards in time. Would one include vitamins when they represented the pinnacle of advances in laboratory science and chemistry – in biomedicine? Would one include Coca-Cola when its advertising contained what would now be considered health claims, similar to those of the now-licenced natural health product Red Bull?[24] One could probably get reasonable numbers for fluorinated toothpaste over a long period of time, because of the limited number of manufacturers. But my point is that to even think about speaking of increases in

the sale or use of natural health products requires thinking in terms of subsets of the regulatory category.

So let me consider only the most salient subcategories, those of packaged ethnic, complementary, and herbal medicines, to which I think it is fair to say that conventional accounts claiming an increase in the use of natural health products are by and large referring. These categories are, nevertheless, still difficult to meaningfully project back in time. Ukrainian medicines are not of frequent concern among regulators today as “ethnic” medicines, but they were between world wars. The definition of complementary medicines is quite clearly a function of whatever is considered mainstream medicine, which has radically changed through the twentieth century with the development of biomedicine (Keating and Cambrosio 2003). Many herbal medicines were not qualified medicines at the start of the twentieth century but rather considered drugs, tout court; they only became marginalized or qualified, I will argue, by the middle of the century with the rise of biomedicines. So instead of using a current or past category, let me work with a contrived category – plant-based medicines – that has little relevance in any time period since the establishment of Canada, and whose inclusion criterion is independent of changing ideas of the natural.

A short history of commodified plant-based medicines on the Canadian market through the twentieth century, from the perspective of regulators

At the inception of Canada's "food and drug patrol" in the late 19th century, crude herbs *were* drugs, tout-court, with many a synthetic chemical yet to make its appearance as drug; vitamins were not yet extant. (Arguably, the first synthetic chemical drug was Aspirin, a patented medicine first marketed in Germany in 1899 [Select Committee on Science and Technology 2000]).The description *natural* was neither here not there – crude herbs and their extracts and products were simply "medicines," "drugs," "chemicals," or, occasionally, "drugs of vegetable origin." Drugs based on plants, including witch hazel and ginger, were subject to the scrutiny of the Dominion Analyst in Canada like any other drug, in fact indistinguishably from other drugs. The drug standards with the force of law in Canada at the time – the *British Pharmacopoeia*, the French Codex, and the *United States Pharmacopoeia*, included many plant-based products.

The importance of plant-based medicines in these drug standards apparently corresponded to practice. In a study of prescriptions filled in an important Montreal pharmacy of the late 19th century, researchers find that plant-based medicines represent an important percentage of the prescriptions filled by pharmacists (Collin 1999); a pharmacy textbook for medical students at the University of Toronto was grouped by plant part (Henderson 1919). A source of medicines for the largely rural population of Canada at the time – the mail order catalogue, taking as an example the 1901 Eaton's mail order catalogue published out of Toronto – lists a wide range of plant-based medicinal substances, for instance, entries under the letter "C" included: caffeine, cocoa butter, caustic

points, currie powder, chloroform. The list under “herbs, barks, roots, etc.” only lists the company’s ‘principal’ coverage, yet includes a hundred or so herbs. This is in addition to the fluid extracts, gums, lozenges, oils, and pills; and in addition to the “patent medicines” of the time, listed separately, featuring various branded nerve pills, cod-liver oils, Beef Iron & Wine preparations, “Datura Tatula asthma cure,” olive oil, mustard plasters, “South American rheumatic cure”, and various (literal) horse pills. Sales of herbs must have continued to some extent to the middle of the century, as a commemorative news clipping in the Eaton’s files from 1945 features a photograph of two men in white coats in the Toronto store’s drug dispensary, with the caption:

> These two druggists makes [sic] up the “home recipes” or formulas which customers bring in. The man in the foreground has made an intensive study of herbs and their medicinal value. Probably no one in Canada is better informed on this subject.[25]

The ousting of herbal medicines from unqualified category drugs, as I see it through the statements of regulators in the federal department of health, happened after 1930, but before the 1960s; it would be difficult to pinpoint an exact date. In the annual reports of the federal department of health in the 1930s, the categories of drugs tested included (original terminology maintained in list): crude drugs, pharmaceutical chemicals (including valerianate, quinine bromide), remedies (including Chinese medicines, stimulants, Hindoo medicines, and Japanese medicines), and other pharmaceuticals or pharmaceutical specialties (including digitalin, digitalis, glycerine of thymol). So to some extent plant-based medicines were still central in the regulatory evaluation of drugs. Nevertheless,

the number of drugs of vegetable origin in contemporary pharmacopoeias and other drug standards were dropping the drastically by this time: the *Canadian Formulary* in 1935 was organized around chemicals. Sixty crude drugs of vegetable origin were dropped from the 1932 edition of the *British Pharmacopoeia* in comparison with the 1914 edition. By the late 1950s and early 1960s, drugs of plant origin represented only a very small percentage of entries in the official pharmacopoeias in Canada. Furthermore these books of standards were becoming altogether obsolete in the eyes of the regulators, with an early 1940s regulator noting that "the traditional expensive printing and binding of pharmacopoeias is hardly warranted at the present time in books which are so rapidly outdated." This was related to the changing nature of the medicines on the market. In 1941, Dominion Analyst A. Linton Davidson predicted "with the great increase in the use of synthetics and the development of chemotherapy which is growing apace at the present time, the demand for herbs is likely to decrease rather than increase." The Canadian Committee on Pharmacopoeial Standards was disbanded in 1953; in its place a Drug Advisory Committee, no longer focused on pharmacopoieal standards, was formed. In the words of the retiring director of the Food and Drug Division in 1965, Clarence Allison Morrell, "now the active principles have been isolated and sy[n]thesized. The chemicals have taken over." By 1967, the synthetic chemical had risen to such great heights that a Food and Drug Division research chemist had to state, at a conference, that "it is erroneous to condemn all natural products out of hand as inferior drugs." (Hughes 1967:297)

It was not until “the chemicals had taken over,” that many plant-based medicines were no longer discussed as unqualified medicines or drugs, but, by the 1980s and 1990s, rather as: herbal remedies, traditional medicines, ethnic medicines, complementary medicines, alternative medicines, and eventually, natural health products. This particular range of qualifiers would not have been possible until there was a very clear archetype in the imaginary, for the unqualified medicines or drugs: namely the synthetic pharmaceutical.[26]

The difficulty with this line of reasoning is that many plant-based medicines remained archetypal “drugs.” Many plant-based medicines required no qualification in the 1980s and 1990s because they had been squarely written into laws and regulations during the twentieth century, and so were still drugs without necessarily being synthetic pharmaceuticals. First opium, and later coca, cannabis, peyote and khat were covered by the *Opium Act* and its successors, now the *Controlled Substances Act*. In the 1920s, one focus of the federal department of health’s laboratory was other plant-derived medicines with clear, immediate effects, such as digitalis and ergot, for which special “biological assay” (animal testing) was required to produce a standardize dose. Many of these “biologicals” became subject to additional requirements for pre-market testing. If plant-based medicines with strong, noticeable effects were not regulated in-and-of-themselves, strong claims made on their behalf were; legislation in the 1930s that forbade marketers from making claims for ‘serious ailments’ directly to the public. Many additional plant-based medicines became regulated as

prescription-only drugs in the 1940s, lists of them included in regulation. My point in this last paragraph is that many plant-based medicines with strong or immediate effects, whether these were desired effects or undesired effects, were given special regulatory attention in a way that entrenched them as drugs in regulatory texts, as well as in the later part of the twentieth century, in the work of the Bureau of Drug Research until it was cut.[27]

There were of course many other plant-based medicines without a strong, immediate effect, or associated with a strong claim. Some of them also received regulatory attention through the twentieth century. In addition to the *Food and Drugs Act* – in fact, predating that *Act* – there was the *Proprietary or Patent Medicine Act*, which enabled the registration (licensing) of many plant-based medicines.[28] A significant proportion of medicines registered under the Act, even in the late 1960s, contained botanicals for internal use.

The Proprietary and Patent Medicines Act was repealed in the late 1970s, declared obsolete. One could argue that the dissolution of that Act, along with the "chemicals' takeover" of drug regulation under the *Food and Drugs Act*, effectively excluded plant-based medicines without strong or immediate effects, from regulatory practice by 1980; and that this regulatory exclusion was what led to the series of committees described above in this chapter's section.

But old (institutional) habits die hard

The difficulty with these arguments, is that the Health Protection Branch licenced "self-medications" with GP numbers (as opposed to DIN numbers) beginning in 1977, according to the annual reports for the department; it also licenced herbal medicines as drugs in the early 1980s, in a manner that is not so different from the way these medicines were assessed at the beginning of the twentieth century, and the way these medicines were assessed at the beginning of the twenty-first century: via comparison with textual standards, most notably pharmacopoeia. Applicants were provided with instructions on how to make an application for a Drug Identification Number in the 1980s (Morrison 1984); provided a medicine was not deemed a "new drug," no clinical trials were ever required.[29] Through the 1980s, the Health Protection Branch's Bureau of Drug Research employed scientists working in a natural products laboratory on the standardization of herbs such as devil's claw, feverfew, and so on. The *Drugs Directorate Guidelines: Preparation of Drug Identification Number Submissions* (Health Canada – HPB 1995a) included homeopathic and traditional herbal medicines like other categories of medicines; the sections of the guidelines covering a wide range of submissions read:

I. Change in Manufacturer's Name and/or Address…
II. Homeopathic Preparations
III. Traditional Herbal Medicines
IV. Disinfectant Drugs
V. Nonprescription Products Subject to a Category IV Monograph [e.g., toothpaste]
VI. Nonprescription Drugs Subject to a Labelling Standard (LS)
VII. Solid Oral Dosage Forms….

For Homeopathic Preparations and Traditional Herbal Medicines, all that was required was the applicant send in a *Drug Submission Application* form, a *DIN*

Submission Certification, and the proposed product labels. (Granted, certain manufacturers were refused such registration. Most notably for this dissertation, importers of traditional Chinese medicines were told that both ginseng and artemesia were considered "New Drugs," and therefore human clinical testing would be required before a licence could be issued. But this is a consideration of a specific decision, not an overall regulatory framework). Thus whether in 1921 or 1981 or 2011, the federal department of health has licenced many drugs on the basis of pharmacopoeial standards, without evidence from scientific clinical trials.

The argument that the *Natural Health Products Regulations* filled a problematic regulatory void – problematic because Canadians were eating these medicines, but the medicines could never meet regulatory requirements – is rhetorically compelling on some level. It also conveniently plays into the justification and rhetoric of all sorts of manufacturing lobbies: that drugs require scientific evidence like randomized clinical trials to be on the Canadian market (Pharma lobby), conveniently eliding the myriad drugs that are bestowed a Drug Identification Number without nary a clinical trial; and that "natural medicines" were excluded from the regulatory process because their lack of patentability precluded the huge profits required to fund clinical testing, especially when the medicine is 'known' to work (natural health product lobby).

But this argument also needs to be disposed on empirical grounds. An administrative unit within the nonprescription drugs bureau registered these

herbal medicines through the 1980s, drawing from phamacopoiea as evidence -- strikingly consistent with regulatory practice more than thirty years prior, and up to thirty years later. This is not to deny that certain decisions (regarding the use of ginseng in traditional Chinese medicines, for instance) are very different than the decisions taken by comparable regulators thirty years prior, or thirty years later.

To conclude this first argument: there was a way in which the use of pharmacopoeial and other textual standards in the mundane regulatory assessment of many plant-based medicines (of less immediate, obvious effect across a range of doses compared to, say, digitalis or opium) has remained remarkably stable through the twentieth century; the way in which these medicines were rhetorically included in various textual and regulatory imaginaries of *drugs* or *medicines*, has changed.

The safety of natural health products, a self-fulfilling prophesy

The safety of natural medicines is to some extent a self-fulfilling prophesy. *Even before official committees were clear what medicines would be considered natural health products*, the committees' final reports categorically state that natural health products are safe:

> *Because of the inherent safety of natural health products*, it is unnecessarily burdensome to subject them to the rigours of double-blind clinical studies. In other words, the burden of evidence required for pharmaceuticals is excessive and unjustified if applied to NHPs. (May 13th, 1998, from Final Report of the Advisory Panel on Natural Health Products, emphasis added)

> Throughout its deliberations the Transition Team has recognized *the inherent safety of NHPs*. (Transition Team 2000, emphasis added)

This categorical safety was, and continues to be, in tension with a relative safety. For instance, the Transition Team's statement (above) was immediately followed by proposals to mitigate NHPs' riskiness:

> It is the consensus of the Transition Team that products of lower risk require lower regulatory barriers to the market. On the other hand, *any NHPs which pose significant risk* should require more stringent regulatory control. Regulatory stringency should reflect the level of risk, whether inherent in the product, the growing, harvesting or manufacturing process, or through product claims. (Transition Team 2000, emphasis added)

I believe this tension between absolute and relative safety, while uneasy analytically, has been unimportant pragmatically. The problem of "inherently safe" NHPs posing "significant risk" has been repeatedly solved by excluding risker NHPs from the regulatory category of NHP, in both formal and informal ways.

Making risky natural health products oxymorons, formally

The categorical exclusion of riskier medicines as NHPs is evident in Schedule 2 of the *Natural Health Products Regulations*, the table of exclusions. Prescription medicines, like those with digitalis, quinine, adrenaline, dicoumarol remained regulated as drugs.[30] Psychoactive drugs, like cocaine, remained regulated as controlled substances. The categorical exclusion is also evident in policy decisions on how to interpret the regulations. Snake venoms, along with maggots and leeches, were deemed biologics and thus regulated by the Biologics and Genetics Therapies Directorate, rather than by the NHPD.

Judgements on whether medicines were natural, were not easily separated from judgements on whether medicines were safe. The classification of a medicine as a natural health product, drug, or biologic often changed the standards used in the evaluation of the medicine's safety (sometimes drastically, sometimes rhetorically.) One self-described "hard-core scientist" at the NHPD recalled interdirectorate meetings being:

> very contentious, because they [in another directorate] were really hard-core when it comes to a lot about requirements for evidence, and safety measures and things like that …. The hardcore science-types just were not speaking the same language [as scientists from the NHPD] …. The [committee's] work, it wasn't going anywhere: there was no agreement on products that should go to one [Directorate] or the other, or how to deal with the risk.

Regulatory scientists' judgements regarding a medicine's classification were, to some extent, initial judgements regarding the medicine's safety.

Making risky NHPs oxymorons, informally

The "risky NHP" was also somewhat of an oxymoron in regulatory practice within the NHPD. As I will describe, I frequently heard evaluators reasoning using the mantra *We have to ensure safety*. (I am sure, nevertheless, that if questioned directly, any scientist would have declared absolute safety as an impossibility.[31]) I noted very little or no use of reasoning with "risk-benefit ratios," even though I was looking for such reasoning. I do not believe anyone consciously decided to reason in one way rather than the other, or that it was anything but pragmatic; I asked the

Director of the Bureau of Clinical Trials and Health Sciences about this precise issue:

> Anthropologist: *I have a question about benefits and risks. Here at the NHPD, I most often hear safety and efficacy. These are either met or not met, as opposed to benefits and risks, which are usually conceived of in relation to one another; you balance one off the other. Was there any discussion about using one or the other—safety and efficacy, versus risk-benefit? Is the reason why safety and efficacy are really the buzzwords, because they are in the Regulations*?
>
> Director: They're in the regulations, and they are terms that the consumer is very familiar with, whereas a, a risk-benefit analysis tends to be a more technical term. Certainly risks and benefits are taken into consideration in licensing, because it's recognized that there's really no such thing as a product without risks. Sometimes the risks may be intrinsic to the product, where it has a certain toxicity at a particular dose, for particular people. There's also the risk of omitting some other treatment, using [the product] instead of something that's actually better. But we strive to mitigate risks through cautionary labeling, because we have our cautions, warnings, contraindications, known adverse reactions, and having mandatory labeling requirements allows us, then, to mitigate certain risks that we feel aren't so severe that they should require the product to have a prescription …

This reasoning does not, rhetorically or otherwise, balance risk with benefit, but rather requires that risks are disappeared ("are mitigated") to ensure safety.

Natural : chemical :: safe : risky

To conclude: defining natural health products as safe is inseparable from making drugs risky, if only because, in many cases, risky natural health products (oxymorons) must be recognized as drugs. This argument I have been making is on a conceptual, rhetorical level, as opposed to the more ethnographic level on which the dissertation's other chapters will proceed.

A note on the usefulness of nature *and* natural *in marketing*

Presumably to bring an aura of safety or wholesomeness or some such thing, the marketers of medicines have long wanted to use the term “natural” in Canada. My final argument is less an argument than an observation in this regard. Based on historical evidence of regulators’ restrictions on manufacturer’s use of the term “natural” in the advertising of medicines: the name of this new category of natural health products, is an advertising boon to those who profit from the sale of medicines so classified. This is one of the reasons why I stated the development of the category was not arbitrary.

Yes, marketers of medicines have long used the terms ‘natural’ and ‘nature’ in their Canadian advertising and labelling. But federal regulators (in the departments of health; health and welfare; and consumer and corporate affairs[32]) have been on their case for years – at least sixty years, to be exact. The *Guide for Manufacturers and Advertisers* issued by the Food and Drug Divisions devoted entries for these terms, which I include in full:

> 55. Nature. “Nature”, “Mother Nature”, “Nature’s Way” are terms generally misused in that actually Nature is impersonal and does not especially favour human above other living or dead components of the universe. The most complicated chemical processes follow Nature’s laws. Animals, plants and minerals were not placed on Earth for the sole use of man and their composition is not specially designed to be exactly right for man.
>
> 56. Natural. Whether there is justification or not the public seems to regard a “natural” article as of greater worth than a processed one. There are few foods or drugs which are so devoid of processing as strictly to justify the description “natural”. Many, however, are obtained from natural sources alone with a minimum of processing, so as to retain most of the useful constituents. At the present time it is considered that such articles can be

> described as natural, but this conception cannot be extended indefinitely. (1950:23-24).

The regulators who composed that guide would be chagrined to learn of that the conception "natural" was extended at least half a century. By 1995, the *Drugs Directorate Guideline on Traditional Herbal Medicines (Revised)*, read:

> The term "natural" may only be used to describe a THM [Traditional Herbal Medicine] when it is sold in its <u>original</u> state without processing or refinement by humans. Where the original state of an ingredient is altered or changed the use of the term would be considered misleading. Herbal ingredients that have undergone a minimum of processing in order to retain most of the original constituents (e.g., drying), may be described as "natural source". However, use of the term "natural source" is considered misleading and unacceptable where chemically-defined substances have been added as medicinal ingredients" (1995:12).

During my participant-observation at the NHPD, another policy decree was issued: the *Consumer Advertising Guidelines for Marketed Health Products* (Health Canada – HPFB 2006). As a scientific regulator, I was expected to use these guidelines in my verification of proposed medicines' labels. Section 2.14 of those guidelines addresses the use of *natural*: "An advertisement [including a label] must not mislead a consumer to believe that a nonprescription drug or a natural health product is "natural" or "natural source(d)" if it is synthetically derived." According to the guidelines, the qualifier "natural" was permissible if the medicine were: 1. naturally sourced, 2. in a form found in nature, and 3. been subjected to an absolute minimum of processing, such as chopping, drying, or encapsulating. Marketers could use the qualifier "natural sourced" on the label if the medicinal ingredients came from nature via extraction, isolation, boiling, steaming, and so on, provided there no chemical alteration was involved (e.g.,

forming salts, raecemic mixtures). The document also declared (in Section 2.15) that it was misleading for an advertisement to claim "that a product acts "naturally" since all nonprescription drugs, including natural health products, modify the body's physiological processes."

Thinking with (my interpretation of) the mindset of a 1950s scientific regulator, I was happy to require applicants to meet these stipulations of the *Guidelines*. At an internal meeting, however, my fellow regulators pointed out the obvious: "Well, what are we supposed to do, ask *Natural Factors*™ and *Nature Source* and *Santé naturelle* and *Nature's Sunshine* and *Au Naturel Inc.* and *Nature's Way* and *Natures Formulae* and *Nature's Cure* and to change their company names?"[33] "But we've licenced tons of products with 'natural' in the brand name." "But they get a *natural* product number, for heaven's sake!" Needless to say, the guidelines' sections regarding "natural" were deemed rather unenforceable for natural health products.

In sum: Canadian regulators have often tried to restrict the use of the terms "natural" and "nature" in the advertising and labeling of medicines, but with the regulatory category of "natural health products," the term can now be used pell-mell. Whether intentionally or otherwise, the regulatory category of natural health products reconfigured the regulatory environment for advertising in a way that was increasingly permissive for the use of these two descriptors. The ability to use the word "natural" on labels and advertising may seem semantic and inane but, as far as I can tell from the historical record and the frequency with which companies

now use this word: it sells.[34] "As herbs and botanical preparations are of natural origin, there is widespread belief that they are non-toxic" (Expert Advisory Committee 1986:2). So perhaps we can read this story as one in which regulators – by creating, with the order of Natural Health Products – a group of medicines declared (relatively, absolutely) safe, have managed to render the use of the term "natural" in advertising less misleading. Herbs and botanical preparations conjured up by the regulatory category of Natural Health Products are not concentrated extracts of, say, foxglove, poppy, rauwolfia, or oil of rue. With the new Canadian regulatory order of medicines created at the close of the twentieth century – natural health products – the devil, so to speak, is in the details of the definition.[35]

Conclusion

Nature, as Raymond Williams remarks, "is perhaps the most complex word in the language" (1976:184). This word, in its qualifier form "natural," was used to transform various qualified medicines (alternative, complementary, traditional medicines) into a new regulatory category, standard. This transformation, however, is not self-evident in practice.

I would like to end this chapter with am image, representing natural health products, from an issue of *Profiles in Progress,* a publication of the Health Products and Food Branch intended for its employees, for its irony. I am not

entirely sure what medicines regulators were expecting in Product Licence Applications for natural health products; but for the most part, what they got, was definitely not recognizable plant matter packaged in darkened glass, which might enable the marketer to use *natural* and *naturally-sourced* according to the *Consumer Advertising Guidelines for Marketed Health Products*.

Figure 3-4: Representation of natural health products (Health Canada – Health Products and Food Branch 2004).

[1] Health Canada had commissioned this random telephone survey of 2004 adults; the results reportedly have "an associated margin of error of ± 2.19 percentage points nineteen times out of twenty."

[2] A Web of Science search revealed only about a dozen uses of the phrase "natural health product" in titles of publications by non-Canadians. A few of these uses appear to be interchangeable with other phrases, for instance Mukherjee, Kumar & Heinrich (2008) use "natural health products" in the title but "plant-based pharmaceuticals" in the body of their abstract; likewise, Menniti-Ippolito et al. (2009) use the term in the title of their presentation, but use this phrase in their abstract apparently interchangeably with "non-conventional medicine", "alternative medicine", "complementary and alternative medicine", and "natural health products."

[3] During my writing-up period, the Italian National Institute of Health has used the term "natural health product" in English-language presentations describing a new form for reporting adverse events related to medicines other than conventional pharmaceuticals. The ambit of these medicines mirrors the NHPD's definition of NHP, essentially anything of natural origin not already regulated as a drug: "any kind of natural health product (raw medicinal plants, dietary supplements, animal-derived products, minerals, homeopathic preparations, etc.), which is not included in the pharmacovigilance system" (Menniti-Ippolito et al. 2008:628). Their webpage on the issue, however, does not use an exact Italian equivalent; entitled *fitosorveglianza* [phytovigilance, presumably opposed to pharmavigilance], refers to *prodotti di origine naturale*, and the adverse events reporting form declares its ambit to be *prodotti a base di pialte officinali e a integratori alimentari*. (http://www.epicentro.iss.it/focus/erbe/fitosorveglianza.asp; accessed February 1, 2010).

[4] Conference entitled "Biodiversity & Health: Focusing Research to Policy."

[5] I do not have space in the dissertation to develop a detailed history of the development of this natural health products. Because nearly all the assessment officers were ignorant of the origins of the category and previous regulation of traditional and herbal medicines by the Health Protection Branch, these causes and consequences are not imperative for this dissertation focusing on the assessment officers and their work and judgements.

[6] Over the past two decades, several countries have set high-level committees to address regulatory quandaries pertaining to traditional, complementary, alternative, unconventional, or dietary medicines. Examples from the UK and US (the most frequent countries of comparison used by officials in the NHPD other than Australia) include: the British Medical Association's study *Complementary medicine: new approaches to good practice* (1993) which uses the term "unconventional therapies," the House of Lords' Select Committee on Science and Technology's *Sixth Report* on Complementary and Alternative Medicine (2001), and, at the request of the Prince of Wales who is the President of the Foundation for Integrated Medicine, Smallwood (2005); the White House Commission on Complementary and Alternative Medicine Policy's Final Report (2002), US National Academies' Institute of Medicine's *Complementary and Alternative Medicine in the United States* (2005), in addition to various position pieces by the National Center for Complementary and Alternative Medicine.

There is little international standardization of national regulators' evaluation of *herbal* medicines to date. The little international harmonization there is with respect to herbal medicines (see, for instance, WHO 2005) is mostly traceable to local geographic consortiums, notably the evaluation of all medicines, including herbal medicines, in the countries of the European Union (see http://www.ema.europa.eu and select the headings Regulatory, then Human Medicines, then Herbal Products) and incorporation of those standards in other countries such as Australia (see http://www.tga.gov.au/docs/html/euguideh.htm). While I was at the NHPD, there was the expectation that Australia and New Zealand were going to create a joint pre-market review of medicines including complementary medicines; I do not believe this has come to pass.

([7] continued from above) As I will argue later in this chapter, regulatory agencies regulate medicines through taxonomy, and the taxonomies used vary but usually depend on some prior judgement of safety. This makes comparison difficult. Prior to the general EU requirements, a study of "health foods" by the Nordic Council of Ministers, released in 1991, revealed a range of practices in Nordic countries.*At that time, in general, many products that were generally considered harmless were exempt from drug regulations, and could be sold as foods – although the government agency in question often had the power to determine whether a product was harmless (Denmark, Norway). Finland had a system of deeming a preparation a medicine, food, or semi-medicinal product – the latter of which could bear claims, but was required to be harmless. In Iceland and Sweden, such products required pre-market authorization for safety and efficacy from the government agency, although in Iceland some doses of vitamins could be sold as foods. (*As summarized in: Agenda Item No. 12 (CX/NASWP 94/12) "Sale of potentially harmful herbs and botanical preparations as foods" of the Joint FAO/WHO Food Standards Programme's Codex Co-ordinating Committee for North America and the South-West Pacific's Third Session, in Vancouver, BC May 31-June 3 1994. Allison McCutcheon Collection)

The World Health Organization (WHO) has a traditional medicines strategy, and because of that strategy WHO is involved with a few initiatives related to traditional herbal medicines (WHO 2005). One such initiative is the recent formation of the International Regulatory Cooperation of Herbal Medicines (IRCHM), which will address the safety and quality – but not efficacy – of herbal medicines, and to which approximately 16 countries are signatory (Health Canada - NHPD 2006). It is also important to note that despite geographic proximity, the legislation pertaining to herbal medicines in Canada is quite different from that in the US, where herbal medicines are largely regulated as a subset of foods. In the EU, Australia, and Canada, herbal medicines are more akin to pharmaceuticals in that regulators assess evidence for the efficacy of the herbal medicines, however the evidence required can be quite different that that required for pharmaceuticals. That said, Australia has a system whereby some medicines may be exempted from being listed (for low risk products) or registered (for high risk products) – this is a model that many regulators at the NHPD mentioned as an interesting model (see http://www.tga.gov.au/cm/cm.html for links to the Australian model; the regulatory guidelines for complementary medicines are available at: http://www.tga.gov.au/docs/html/argcm.htm).

In terms of the international standardization of national regulation, herbal medicines are quite different than pharmaceuticals. There is more international standardization of pharmaceutical regulations than there is of herbal medicine regulation. Canada is an observer with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and a signatory to the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS).

[8] The Director General of the Therapeutic Products Programme clearly delineated the original mandate of the Advisory Panel on Herbal Medicines:

> For the purposes of this initiative [the advisory panel], herbal remedies are considered to encompass therapeutic products derived from herbs, botanicals and other natural substances. Vitamins and minerals, homeopathic pharmaceuticals and nutraceuticals are the subject of similar policy and regulatory initiatives in the Therapeutic Products Directorate and these initiatives will be linked.

(Dann M. Michols, Director General, Therapeutic Products Directorate. Health Canada. May 16, 1997. “Therapeutic Products Programme. Advisory Panel on Herbal Remedies.” 3pp document later given to members of the Expert Advisory Committee on Complementary Medicine.) [documents from Allison McCutcheon Collection]

I should note that Dann Michols stated, when speaking to the Standing Committee on Health on February 26th 1998, that he did not believe the change in name changed the ambit of the committee’s focus:

> Secondly, with regard to the panel's mandate, it has not changed. When it was originally set up, it was called the advisory panel on herbal remedies, but we said at the time that we wanted it to deal with a wide range of products. The problem was that there was not a commonly accepted collector for that wide range of products. In their deliberations they said they would rather be called the advisory panel on natural health products. We said, fine, if that helps you in your deliberations. The panel was still dealing with the products that we call therapeutic products. (Canada. Parliament)

While I do agree that the Advisory Panel was always addressing medicines that the regulators called therapeutic products, the directions he gave to the Advisory Panel the previous May belie a change in scope of mandate.

[9] One date, November 14th, 2007 is taken from page included in "Background Material" package for the Expert Advisory Committee on Complementary Medicines' inaugural meeting on December 17, 1997. Page entitled "Advisory Panel on Natural Health Products", dated November, 1997, from the Therapeutic Products Programme. (Allison McCutcheon Collection). Note that this date varies slightly from that published by Health Canada online in a document entitled "Information. Natural Health Products in Canada – A History" and dated 2003-06-18; that document dates the Minister's announcement of "a full public review by the House of Commons Standing Committee on Health (SCOH) of the legal regime governing natural health products" to *October* 1997 (Health Canada – NHPD 2003). The final report of that Standing Committee on Health dates its acceptance of the terms of reference on natural health products to November 13, 1997 (Volpe 1998). That report also stated that a survey by the Canada Health Monitor in June and July of 1997 investigated Canadians' use of natural health products, although perhaps the use of the term in that context is a neologism. Nevertheless, the term was floating around before November 1997 in government. MP Svend Robinson, on a Motion on the Order Paper dated March 19, 1997, called for a "Moratorium on the enforcement of newly-imposed restrictions and user fees on natural health products." Svend Robinson's motion read:

> That, in the opinion of this House: (a) the federal Health Protection Branch should immediately impose a moratorium on the enforcement of newly-imposed restrictions and user fees on natural health products, which include traditional Chinese herbs; should not proceed with the proposed implementation of additional such restrictions and user fees; and should strongly oppose the attempts by multinational pharmaceutical corporations and the Codex Commission to restrict access to nutritional supplements in Canada and around the world and (b) the Standing Committee on Health should conduct public hearings across Canada to review these important health issues.
> (document from Robin Marles Collection)

[10] Again (cf. previous endnote), the point of this chapter is not to establish exact dates. According to an Issue sheet obtained through an Access to Information Request (Health Canada A-2008-00195), as of November 25th, 1997 officials in TPD expressed the issue as "The Standing Committee on Health, reviewing the Natural Health Products file, met for the 1st session on Thursday, November 20, 1997." A briefing written by the Parliamentary Research Branch on "Herb Regulation In Canada: Background and Issues" (Lafrenière and Chenier 1997) states "On 4 October 1997, Health Minister Allan Rock announced that the House of Commons Standing Committee on Health would be asked to conduct a review of *herbal regulation*" (emphasis added). I can only conclude that the change in ambit happened in either October or November 1997.

[11] From a five-minute phone interview May 20, 2008. Later in the interview, he queried *Didn't I form an Advisory Panel on this?* And when I replied, yes, you renamed the Advisory Panel on Herbal Remedies, the Advisory Panel on Natural Health Products, he remarked (not verbatim): Yes, that was to broaden it, because of need to deal with stuff that is not pharmaceuticals, but has a health impact; that way, can sit down at one big table for all those not-pharmaceuticals. While this remark highlights the term's salience from a ministerial perspective (the use of lumping problems together), it still does not explain from whence the term came. In interview, a member of a practitioner and industry lobby group claimed he introduced the term; I have not pursued verifying or triangulating this statement.

[12] Estimates of various industries always seem a little haphazard, but in 1996 an industry-herbalist lobby group estimated that herbal medicines represented ten percent of the overall gross income of the Canadian "natural foods and supplements industry," an overall gross income pegged at $1.5-2 billion. Draft of "A Proposal for the Rational Regulation of Therapeutic Botanicals" prepared for the Therapeutic Botanicals Advisory Committee by the Central Canadian Herbal Practitioners Association, undated. [1996]. The report had been circulated to the Canadian Health Food Association (then, the Canadian Natural Health Products Association) for comment. (Allison McCutcheon Collection)

That estimate for herbal medicine is more than, but on the same order of magnitude as, estimates of the market size of traditional Chinese medicines (TCM) in Canada, delivered by industry representatives to the Canadian Parliamentary Standing Committee on Health on February 19, 1998. Three estimates were:

Mr. Andy Shih (Vice-President, Chamber of Chinese Herbal Medicine of Canada):

> Chinese traditional herbal medicine has been in Canada more than 50 years, if not 100, and 90% of the products still consumed by the Chinese community come from Chinatown. The market size is less than $50 million. According to government research, it's about $20 million. So we're not talking about a big business, but in terms of culture and tradition, it is very important to the Chinese community.

Mr. Albert Fok, (President, Kiu Shun Trading Company Ltd.):

> According to a recent survey done by Health Canada involving stakeholders of Ontario and B.C., statistical results yielded that the total monetary value of TCM in Canada is about $35 million, in which there are 5,000 directly employed and many more indirect ones such as those in shipping, storage, customs, inspections, regulation and marketing. The net result is substantial sales and tax revenues.

Mr. Lin-Hoi Yu (Chairman of the Canadian Chinese Herbal Professional and Merchants Association):

> The Chinese herbal business generates a volume of up to $100 million annually.

The estimates given by the Therapeutic Botanicals Advisory Committee seem consistent with contemporary estimates of the market size in the US, if one follows the general rule of dividing any US American estimate by ten, the approximate population ratio between the two countries. The Committee's estimate may have been determined by precisely this mechanism. Michael S. Goldstein (2002:52) states that the market for herbs and other botanicals in 1995 was 2.5 billion; but if one includes in an estimate everything from "iced tea spiced with ginseng, chicken soup with echinacea, power pars, and enriched Gatorade," then one needs to add another $15 billion to the annual estimate. It is important to note, however, that between 1995 and 1998 there was an increase in the market for herbal and botanical medicines on the order of fifty percent, so the estimate in 1998 was nearly $4 billion (Goldstein 2002).

[13] Natural health products are no longer regulated under the *Food and Drugs **Regulations***, but rather under the *Natural Health Products Regulations*; as regulations have the force of law, 'natural health product' is nevertheless a legal category in Canada. At the level of the *Food and Drugs **Act***, natural health products are considered a subset of drugs, because the Act was not amended. There is a level of ambiguity, therefore. Both of the following statements have legal validity: (1) Natural health products are a subset of drugs (level of the Act), 2. Natural health products are distinct from both food and drugs (level of the Regulations).

[14] As of February 12, 2010, a list of the classification is available on the NHPD's website at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/list_mono4-eng.php

[15] As well as the reverse – one entry in the *Dictionary of Natural Products* turned out to be synthetic (and the *Dictionary* was notified).

[16] The interviews were explicitly framed as seeking their opinions and experiences. They were in no way framed as a test, or, apparently experienced as a test by interviewees other than this particular interviewee. This interviewee self-identified as a scientific regulator, which was somewhat unusual, and I infer her exactness and clarity was a source of pride in this optic.

[17] Barbara Schneeman, the director of the US Food and Drug Administration's (FDA's) Office of Nutritional Products, labeling, and dietary supplements in the Centre for Food Safety and Applied Nutrition (CFSAN), attributed the then-current US legal regime for so-called dietary supplements (DSHEA, passed in 1994, and the nutrition labelling and education act NLEA, passed in 1990) to "two pervasive challenges in the FDA's efforts to regulate supplements: defining what qualifies as a supplement and determining how to evaluate the nature of the claims that can be used to promote dietary supplements" (2007:113). She continues: "The history of nutritional supplements, particularly in the period between the … 1938 law and NLEA in 1990, is primarily characterized by ambiguity surrounding whether they should be regulated as foods, drugs, or another category entirely" (2007:116). In the US especially, this ambiguity was the subject of focused attention from the public: "Leading up to the passage of DSHEA in 1994, Congress received more mail regarding dietary supplements than on any other issue since the Vietnam War."

[18] Two examples are: of khat (Anderson et al. 2007) and *Taxus brevifolia* (Goodman and Walsh 2001).

[19] The prime examples of people's lives and livelihoods at stake because of the legal classification of a medicine are the opium wars as well as other "wars on drugs." For examples of what now falls under the ambit of natural health product, Pollock discusses the effects of several European countries' classification of kava (2009), and Roland Nigh (2002) and Cori Hayden (2003) write of the effects of international agreements on herbal medicine in Mexico. There are of course worldwide examples of the crimilaliziation of certain types of medical practitioners from sorcerers to shamans, which now may be inextricable from the classification of medicines by regulatory agencies (e.g., Adams 2003 on Tibetan medicines in the US).

[20] As Don Bates (2002) argues, in a larger historical and cultural perspective it is truly twentieth-century "modern medicine" that is the odd one out in terms of its approaches to health, sickness, diagnosis, and therapy. From the quotation above, he continues:

> Besides, in the institutional sense, homeopathy, naturopathy, acupuncture, and all the rest certainly are "alternatives" to the established version of medical care. But none of this should prevent us from noticing that in a broader historical and cultural context, using *alternative* to describe the 20th-century paradigm is warranted, at least in the deeper sense of it being so unlike all the other forms of medicine that have every existed. In some sense, it is incommensurable, not just with the classical paradigm, but more fundamentally with our most basic intuitions about who we are, intuitions which are more clearly reflected in all those other healing traditions across many centuries and cultures (27).

[21] The sheer number of so called "trans-DINs" (medicines previously licenced as drugs and given Drug Identification Numbers, but, after the development of the new regulatory category, the responsibility for their licencing had to be transferred to the NHPD), undergirds the reduced definitional ambit of 'drugs' in Canadian regulation.

[22] A few clauses of the *Food and Drug Regulations* (e.g., that regarding vitamins) were indeed repealed with the enactment of the *Natural Health Products Regulations*. Also, to avert confusion, at the level of the *Food and Drugs Act*, the category of drug is inclusive of natural health products.

[23] For example, see Health Canada. [various versions, 2000-2003]. "Natural Health Products in Canada – A History" (Information sheet). Available at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/history-historique-eng.php. A generic statement regarding the increase in CAM use in the 1990s internationally is made by WHO (2005: iii).

[24] Licenced natural health products can be searched in the Licenced Natural Health Products Database, available on the Health Canada website in the section for natural health products.

According to a database search on August 27, 2010, Red Bull Energy Drink had Natural Product Number 80000012, with the licenced recommended use or purpose "Developed for periods of increased mental and physical exertion, helps temporarily restore mental alertness or wakefulness when experiencing fatigue or drowsiness."

[25] Clipping with indication "Merch. – Drugs" written at top. "Drug Dispensary Having 50th Anniversary. Still Have on File the First Prescription Filled Half a Century Ago." In file of Archives of Ontario, F229-162-0-1134.(Eaton's collection)

[26] The testimony of Dann Michols, then Director General of the Therapeutic Products Direcorate, to the Parliamentary Standing Committee on Health indicates that the norm of medicine as chemical persisted among some staff at least until February 26th, 1998:

> Mr. Lynn Myers (Waterloo—Wellington, Lib.): Mr. Michols, you talked about the 700 [nb he said 750] people in your employ and under your direction, of which 550 had science degrees. One of the things we've heard at this committee is that there's sort of a woeful lack of people who are experts in natural products and herbal medicine.
>
> Is that a fair assessment? Is that something that makes sense?
>
> Mr. Dann Michols: Yes and no, or perhaps no and yes. *These substances and products are chemicals*. We have the biologists, chemists, pharmacologists, and such to deal in many ways with the analysis of these particular products.
>
> We do not have as many as we would like who have experience perhaps in the practice of complementary medicine. We have staffed a couple. We have expertise in homeopathy and such, but we do not have the resources in this area that we would like to have. But I don't think that equates to not having the expertise to be able to evaluate the safety, quality, and effectiveness of these products. In my opinion, *they are chemicals,* and we do have that capacity. (emphasis added).

[27] George A. Neville, a research scientist in the Bureau of Drug Research in the Health Protection Branch for 31 years including as head of its spectroscopy section, told the Standing Committee on Health, on March 12, 1998:

> natural products chemistry was a very integral part of the work of the bureau of drug research right from the beginning, right from the early sixties when I joined, the emphasis at the time being largely, and still continuing, on the drugs of abuse, like morphine and heavier narcotics, essential oils. Later on we got into quite a bit of work with herbals, particularly arising from China, southeast Asia, the subcontinent, and so on.
>
> The other thing I want to emphasize that throughout this roughly 30-year period there was a well-integrated resource of expertise and equipment. The chemistry section, the analytical chemistry section had respectively broad-ranging synthetic capability and analytical capability, the analytical involving resources to do such tings and thin-layer chromatography and high-pressure liquid chromatography, and so on…

(Neville was given his notice of surplus on July 18, 1997. The entire bureau of drug research was cut in 1997, with several other scientific researchers accepting reassignment to the paper-based pre-market evaluation of drugs. The natural products section, however, had already been cut in 1991.)

[28] The title of the *Act*, was a bit of a misnomer. The *Act* did not address medicines under patent, but rather medicines with 'secret' ingredients. The whole point of registering a nostrum under this Act was to legally market a medicine without having to list the ingredients on the label. Now while, in a sense, this is the antithesis of the *Natural Health Products Regulations* and their emergence in the wake of a massive writing letter campaigns demanding "freedom of choice," I suspect that the evaluation of safety and efficacy under the *Proprietary or Patent Medicines Act* and the *Natural Health Products Regulations* (at maturity, e.g., when the NHPD has evaluators with years of experience) would be comparable.

While technically there was no specific, separate requirement in the Act for efficacy, it appears the decision-makers did not feel they could licence a medicine for which it was clear it could not work in the way it was claimed to; I do not have the space in this dissertation to substantiate, based on the archival records, this assertion.

[29] Mary Carman, then Director, Bureau of Pharmaceutical Assessment, explained to the Standing Committee on Health on November 27, 1997:

> When that risk-to-benefit balance favours benefit, a notice of compliance or a DIN is issued. A DIN is a standard regulatory authorization. If you pick up your toothpaste tomorrow morning, look for something that says "GP" or "DIN" and has eight numbers behind it. It's a standard. All products, other than radiopharmaceuticals and whole-blood products, require a DIN prior to market, and they will display that DIN on their labelling.
>
> A product that has a higher level, a new product coming into the Canadian market, will also have issued to the sponsor a notice of compliance saying they have met the requirements of a more detailed set of requirements under the regulations. The vast majority of products on the Canadian market have only a DIN. They do not go through the more elaborate process. Those that are prescribed and used within the medical community generally are new drugs and have a notice of compliance.
>
> As for the traditional medicines, homeopathic medicines, and vitamins and minerals that are the subject of your discussion, those that have gone through the regulatory system go through with a DIN. They have not been subject to the notice of compliance.

[30] An internal NHPD document dated 2003-04-09, entitled "Outstanding Issues with other Directorates: Discussions held on April 7-8, 2003: Therapeutic Products Directorate (TPD)" lists the first "issue" as the margin of safety, and summarizes the concern "that higher risk products may remain as NHPs." NHPD's response to this Issue was to expressly exclude prescription products from the definition of a natural health product, and to use the criteria used by TPD to determine whether a medicine should be prescription only, in "determining margin of safety" at the NHPD.

[31] Links to a website, declaring the deadly effects of a common, natural household substance in certain quantities circulated through internal memos as a joke (the substance in question, potentially toxic when two litres were consumed rapidly, was water).

[32] "On September 1, our office received a communiqué from Consumer & Corporate Affairs Canada suggesting serious changes regarding the use of the term "natural" to describe a food or its ingredients" (From a newsletter of the Canadian Health Food Association, October 1981, cited in Shelton, ed.[2004]:42).

[33] These company names are drawn from the published licenced Natural Health Products database [accessed February 8, 2010], as a substitute for the company names actually mentioned in the unit's discussion because the conditions of my research do not permit me to mention company names I encountered as a public servant, or use other information that may be proprietary.

[34] A search of product names listed in the licenced Natural Health Products database on February 8, 2010 revealed 648 that included "natural," and 307 that included "nature"; clearly there were other derivatives, because a search for "natur" in product names yielded 1325 hits. There were 18297 entries in the database on the date of the search. [The database includes all licenced natural health products].

[35] In a trade journal article on the "whole new ball game: Health Canada is set to play a brand new role in its approach to defining and regulating natural health products in their own environment," the author remarks, that although a definition of natural health products had not been established, "[i]n any case, the impact of the eventual definition of an NHP will be significant" (Gnirss 1999:33).

Chapter 4
NHPD scientists
and their two official explanations of regulatory evaluation

If you were to go among science-based regulators at the NHPD, and ask how traditional or other plant-based medicines are evaluated, pre-market, you would likely get one of two types of answers. The first type of answer would consist of a description of a process with four levels. The second type of answer would be a summary of enabling regulatory texts. Prior to my fieldwork inside the NHPD, I asked NHPD officials exactly that question, and got exactly those answers.

Whether the answer you heard were procedural or legalistic, the answer would characterize evaluation as a linear process. In the case of the process-based answer: medicines are evaluated in four consecutive levels, with the applications sequentially moving through verification (Level 1 = L1), processing (L2), assessment (L3), decision (L4). In the case of the legalistic type of answer, you may be told – perhaps in more graceful terms, perhaps in no uncertain terms – to go read the *Natural Health Products Regulations* and NHPD's guidance documents.

These two rote explanations – the procedural and the legalistic – were those used most frequently by NHPD staff in their presentations to the public and to new scientific staff. Based on my observations of evaluations, these two types of explanations are factual. They are also not the whole story, if one is interested in actual, rather than hypothetical, evaluations, as I am in this dissertation.

Nevertheless a summary of the two rote explanations, along with their relation to everyday regulatory practice, provides an overview of how companies' petitions to market a medicine in Canada are shaped into files, and how these files are shaped before and after they arrive on the desks of the scientists whose reasoning I studied.

The first rote explanation: evaluation as four-level process (L1-L4)

If you go among science-based regulators at the NHPD, and you ask them how the Directorate evaluates traditional or plant-based medicines pre-market, you will likely get an answer in terms of process:

> Any successful application to market a natural health product in Canada must move through four stages, sequentially. These stages are also known as levels:
>
> *Level one (L1): Verification.* The directorate's non-scientific staff acknowledge receipt of the application papers, place the application papers in a file folder, and enter data from the application into the Directorate's electronic systems.
>
> *Level two (L2): Processing.* Staff ensure there is an entry in every relevant field of the Product Licence Application Form, and that all other required

documents are included in the file. This screening is independent of the evidence submitted; it is essentially verifying whether an application is complete. At this level, staff do not determine the appropriateness of entries and supporting documentation, just whether all necessary entries and documents have been provided.

Level three (L3): Assessment. Scientific staff assess whether the medicine proposed in the application form meets the regulatory requirements for market authorization. Assessment, to use the words of a manager at an internal training session, “is a matching exercise.” Scientists document the results of their assessment in an assessment report. The assessment report, when complete, will recommend one of two things: (1) licence issuance or (2) refusal of the application.

Level four (L4): Decision. The Director General, who may or may not have qualifications in the sciences or healing arts, makes the final decision whether to issue a licence. Support staff send the final decision to the applicant.

At any level, NHPD staff can request clarification or more information from the applicant. The applicant generally had thirty days to respond to the regulator’s request for clarification or additional information. During the period of time when the NHPD was waiting for the applicant’s response, the application was considered

“on hold.” (Days on hold did not count towards the “NHPD time” measured for each application in the licencing process.) If the applicant did not respond to the request within thirty days, NHPD staff could recommend the application be refused on administrative grounds. At any level, the applicant could withdraw the application.

Applications cleanly “moved” through the levels, at least conceptually, as tracked in the NHPD’s databases.[1] The applications also literally, and sometimes less cleanly, moved through the hands of many staff at the NHPD. During 2006 to 2007, most successful applications for traditional medicines would have passed through the hands of at least ten separate NHPD staff members.[2] In the first two levels (L1 and L2), the applications would have passed through the hands of: the staff member opening the mail that particular day; a data entry clerk; a filing clerk in the central registry; and a submission co-ordinator. In the assessment level (L3), a submission co-ordinator would have circulated the application to two assessment officers, who in turn would have directed the application to their unit heads and their manager(s). In the final level (decision; L4), an executive assistant would have fielded the application to the Director General, and then sent the application back to various administrative support staff for the application to be properly filed away in paper and electronic media. To use the words of one of the Directorate’s scientists (Olive), this makes the pre-market evaluation of medicines a “rather boring social process”; and it is no wonder that its participants are primarily concerned with processes and organization.

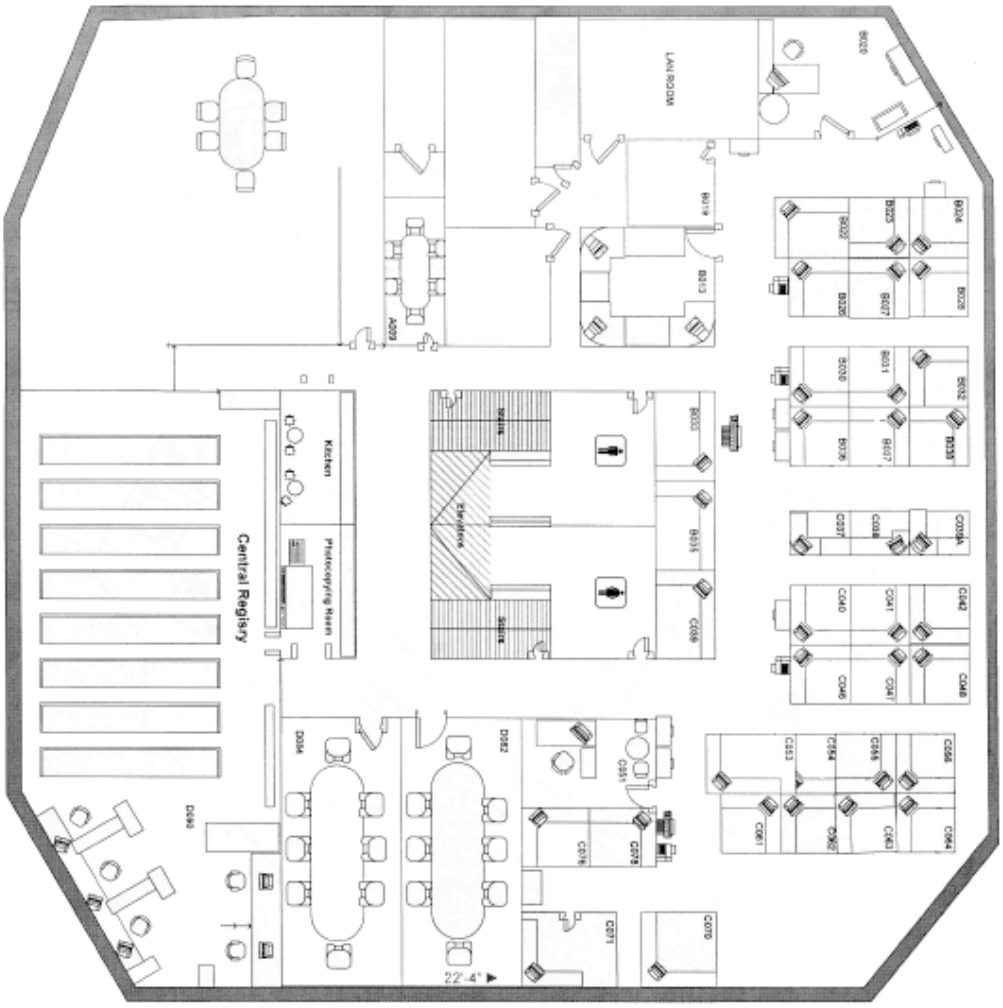
Following the physical application through the four-level process

For many staff, the description of the process given above truly encapsulated the entire, actual process. For the benefit of readers, however, I will describe the entry, into the office building housing the Directorate, of a company's application to market a medicine, and movement of that application through several floors of the office building.[3]

The papers comprising an application to market a natural health product entered the Directorate via the first, ground floor of the building. Applicants, like any member of the public, could not enter the office building unaccompanied beyond the Commissionaire's (security) desk located in the front lobby. No matter their delivery method, the papers comprising application would then end up in the Directorate's mailroom and would get date-stamped. The arrival date was necessary for calculating the "NHPD time" for evaluation. The application was removed from any duo-tangs, binders, boxes in which it was received, and placed in a box in the basement of the Directorate. A scientific regulator from the "Q-Team" would make a decision regarding to which assessment stream the application should be directed.

During the first two levels of the process, L1 (verification) and L2 (processing), the application was generally moving around in the basement of the office building (see Figure 4-1) through cubicles, file drawers, shelving and boxes.

Figure 4-1:
Basement Floor Plan - NHPD (Adapted from Internal Document)
December 21, 2006



The basement of the Directorate was a floor that contained very friendly and sociable staff, the Directorate's central filing registry, as well as air of questionable quality and the occasional dead mouse. The application would rarely move directly from the hands of one staff member into the hands of another; after a staff member finished completing a particular task, she would leave it in a specific box, cart; later,

all the files in that box or cart would be collected by another staff member to complete the subsequent task.

Level 1: Verification

What were the tasks to be completed in the first levels? The papers comprising an application to market a medicine needed to be “dressed” in a file folder and given a tracking number and so on. There was a mandatory style for this dressing: the cover letter was placed on the left side of the open file folder, and the Product Licence Application Form itself and other support materials (animal tissue form, evidence, specifications, label copy, and so on) were pinned to the right hand side of the file folder. Initially, the papers were placed in a simple white and green file folder, essentially filling undergarments. Staff entered a description of the papers received into an electronic tracking database system, and, when they hit “save,” the papers, now a file, received a submission number, which the staff member wrote on the file folder cover. The papers were now a recognized – and registered, tracked – actor in the system. The staff member also created electronic folders named for the new submission and file numbers on the Directorate’s shared electronic drive.[4] Staff also verified the applicant’s company codes and contact information (crucial if there should ever be a recall necessary) in the electronic system and the paper file. Data entry clerks entered, into the NHPD databases, basic information on the application such as brand name, dosage form, and assessment stream. Applications remained in their white and green filing

undergarment until they arrived in central registry; where a clerk fully clothed the file in a yellowish (“legacy”) file folder.

Level 2: Processing

In the second level of the process – L2, Processing – a submission co-ordinator perused the application for “low-level deficiencies,” for instance, whether the applicant had forgotten to include the medicinal ingredient’s proper name and common name, which, according to the *Natural Health Products Regulations*, are required in any Produce Licence Application. In L2, the submission co-ordinator was not evaluating whether the entries and documents were valid, but simply ensuring that there is at least an entry written in every field of the Product Licence Application form required by regulatory texts. There was a system of coding files green, yellow, or red depending on the number of problems, which determined when requests for corrections would be sent to applicants.

In most cases, applicants did not initially submit all the information required, as stipulated by regulatory texts. Thus began the first stage of back-and-forth between the company and the government directorate regarding the medicine. The submission co-ordinator compiled a list of deficiencies in the application into a notice and faxed the notice (called a Processing Deficiency Notice, PDN, in L2) to the applicant;[5] the applicant had thirty days to send modified papers correcting those deficiencies, otherwise, the product licence application could be refused on administrative grounds. If and when the applicant sent the corrected pages or

additional information to the submission co-ordinator, the submission co-ordinator stamped those pages with the date received, and incorporated them into the file, and, with a red pen, crossed out pages previously sent but now replaced.

When the application was deemed, by the submission co-ordinator, to have an entry in each required field of the application, and to contain any required supporting documents, the application's status in the electronic tracking system was changed to "L2 complete." At the time of my fieldwork, any such application would likely have been returned to the central registry, where it would have sat for months, while its electronic avatar in the Directorate's electronic tracking databases advanced in the "L3 queue."

The submission co-ordinators were hired as scientific regulators, as SG-SRE-04s. (Job classification codes will be explained in Chapter 17). They performed many tasks in the co-ordination of the NHPDs regulatory activities that I do not discuss in this dissertation, however, Rose, a submission co-ordinator speaking of the bulk of her work in L2 (and L3), characterized the work as administrative:

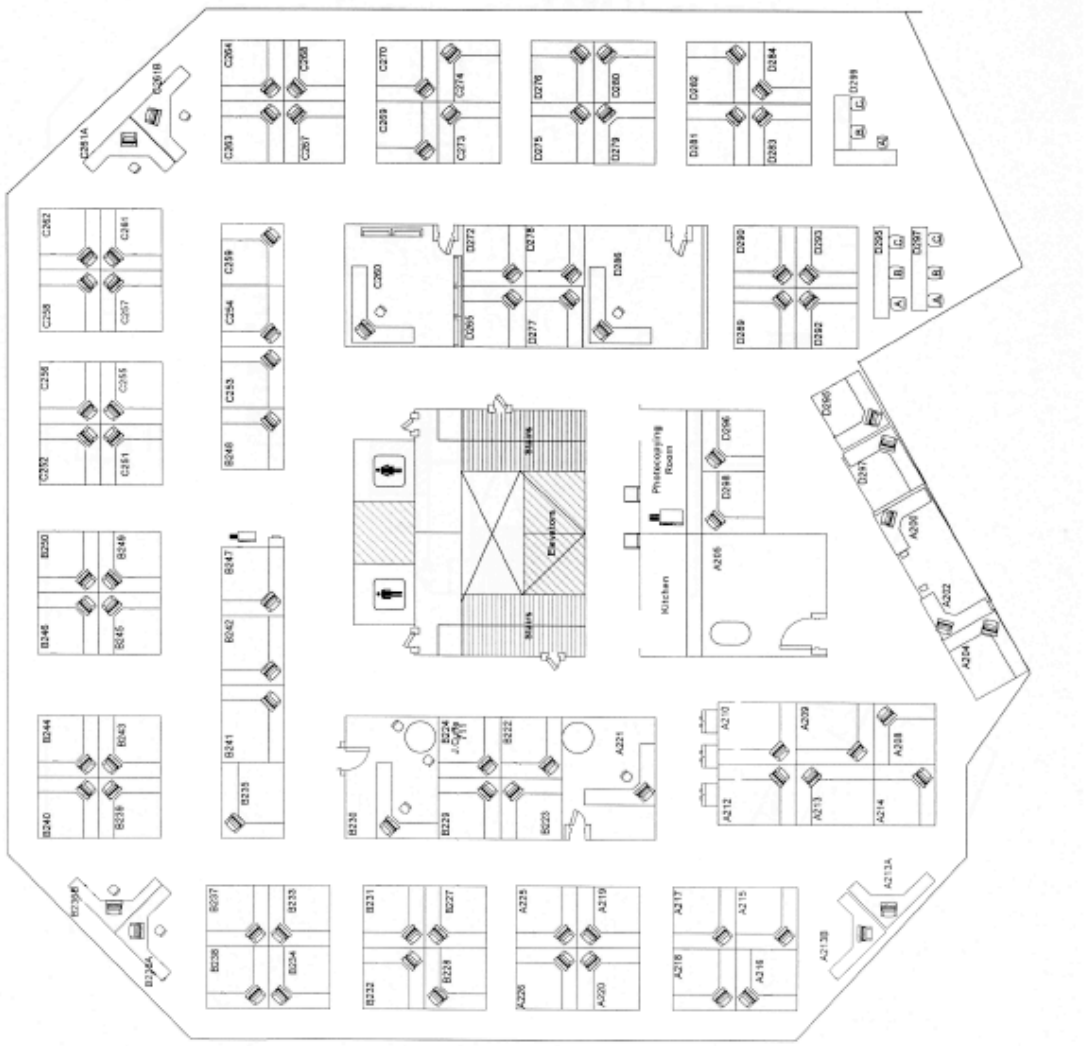
> The bottom line is that it is administrative. It is called scientific regulation, but it's administrative…. I am shocked that one has to have a B.Sc. background for something that is 90% administrative.

Rose joked that, to figure out which documents would be required in the application, "I guess you have to understand "animal tissue."" Despite her opinion on the necessity of a B.Sc., Rose continued:

> However it's a lot of work. The quantity is non-stop. If you go into the cubicles [of the submission co-ordinators], you see files piled up on the floor. It is a lot of work, but in terms of needing a scientific background, I'm not so sure. Most SC's [submission co-ordinators] had no desire to do assessment [L3], because it requires too much research, sitting in an office [cubicle] alone, reading articles, without any social interaction…

When the file's electronic avatar reached the front of the "L3 queue," a submission co-ordinator would pull the paper file from central registry, make two working photocopies, and deliver them to the second floor (see Figure 4-2).[6]

Figure 4-2: Layout of Second Floor - NHPD (Adapted from Internal Document)



One working photocopy of the paper file would be given to a quality assessment officer, and the other working photocopy given to a safety and efficacy assessment officer.[7]

The quality assessment officers all had qualifications in a chemistry. (They worked as chemists, CH-03s). They examined the application and made a

recommendation on the proposed medicine's quality. The quality assessment officers primarily assessed the non-medicinal ingredients, the chemical nomenclature, the processing of animal tissues (especially from animal species that can be infected by BSE/TSE) as well as the results of tests run on the finished medicinal product (e.g., measuring the amount of medicinal ingredient in the final product, and verifying that the product is free from certain noxious substances such as microbial and chemical contaminants). Chemists at the NHPD verified that the company was using appropriate tests, and that the results from the tests would fall within acceptable limits. In pre-market assessment, the NHPD relied entirely on the companies' documents; the chemists at the NHPD did not do any laboratory testing, nor any inspections of process.[8] The chemists wrote up their assessment in a Quality Assessment Report (QAR), an electronic word document saved in the on NHPD's shared electronic drive.

The safety and efficacy assessment officers all had qualifications in a biological science. (They worked as biologists, BI-03s). They assessed everything in the application that the quality assessment officers did not. Emmanuel characterized his work: "assessment mostly involves looking at the public literature and assessing whether the evidence validates the health claim, and whether this meets the regulatory requirements and the product falls within the therapeutic range." The approach to assessment taken by safety and efficacy assessment officers depended on the "assessment stream" into which the application had been directed. On the Product Licence Application Form, companies had to choose one

of seven assessment streams (more on these in Chapter 6): Compendial, Traditional claim, Non-traditional claim, Homeopathic, TPD Catgory IV / Labelling Standard, Homeopathic DIN, Transitional DIN. Safety and efficacy assessment officers wrote up their assessment as a Safety and Efficacy Assessment Report (SEAR).

At the time of my fieldwork, there was a template for this Safety and Efficacy Assessment Report (SEAR). The template's subsections largely mirrored those of the Product Licence Application Form. Assessment officers would enter, into the assessment report, a summary of information provided in the application submitted by the company, and would follow this summary with the assessment officer's comments ("AO comments"). If the assessment officer were new, or had concerns about a particularly difficult file, the SEAR might be "peer reviewed"[9] by a colleague. When the report was deemed complete by the assessment officer, s/he printed off a copy of the SEAR, signed off on the appropriate line, attached the SEAR in the file and delivered the file to the (usually cluttered) desk of his or her unit head. The unit head would review the report and then either send the report back to the assessment officer for revisions, or sign off on the report; once signed by the unit head, depending on the circumstance, the report went up another level, to be reviewed by a manager, who in turn would either send it back down the hierarchy for revisions or who would sign off on the report and its recommendation. With all the necessary signatures in place, the assessment report was delivered to the submission co-ordinator in the basement.

Frequently, the assessment report (QAR or SEAR) would identify deficiencies in the application, recommending that corrections, clarifications or further information be requested of the applicant. This entailed more rounds of back-and-forth between company and Directorate. The requests for corrections or more information would not be sent by the assessment officer him or herself, but by the submission co-ordinator. (There was blinding in many assessment streams, in the sense that the applicant did not know exactly which assessment officer(s) were assessing the files).[10] There was a template used for sending the requests, called an Information Request Notice (IRN) at L3. Rose, a submission co-ordinator, explained that Assessment Officers would bring down their assessment reports (usually on a Friday afternoon), and she would prepare and send the Information Request Notices. She began by saying she "literally cut and pasted" requests from the electronic version of the SEAR and QAR into the Information Request Notice (IRN), but immediately hedged:

> But actually, it is more than that, because you have to read through the IRN. Assessment officers often do not use standard lines, or have great grammar. They may use overly scientific language.[11] Sometimes requests are duplicated by quality and safety & efficacy assessment officers.

As another submission co-ordinator explained, she would take the science issues identified by the assessment officers in the assessment report, and translate them into standard lines if they were not already in standard line format in the report, and ensure that any references to the Regulations were accurate; the ensuing

Information Request Notice would usually be faxed to the applicant, and the application's status in the electronic tracking system would change to L3- on hold.

Applicants, if they responded, would send their reply to the Information Request Notice to the submission co-ordinator. The submission co-ordinators would register the response in the electronic tracking system, stamp the date received on the pages received, place these in the paper "legacy" file, make working photocopies, and send the working copies of the file back to the second floor for another round of assessment.[12] Assessment officers would add to the previous QAR and SEAR, adding into the electronic document whether the applicant's response addressed the deficiencies already identified, and whether the response introduced new deficiencies.

Many applications were refused because the applicant did not supply the required information, because the information supplied did not sufficiently support the quality, safety, or efficacy of the product, or because the proposed medicine would contravene the regulations. If and when the assessment officers and their scientific superiors (unit head and manager) were satisfied that the application met the regulatory requirements for licencing, they would recommend, in the QAR or SEAR, that a licence be issued.

Level four: decision

Once the submission co-ordinator received recommendations in both the application's SEAR and QAR, the file would move to the fourth level (L4), and the submission co-ordinator would prepare the necessary paperwork for the Director General's signature. (The Director General could, of course, point out deficiencies or concerns and send the file back down the hierarchy). Once the licence was signed by the Director General, clerical staff would enter the information on the licence into the tracking databases, mail out the licence to the licensee, and return the paper legacy file to central registry.

This procedural explanation of the pre-market evaluation of medicines at the NHPD does give a flavour of context of science-based evaluation as conceptualized and practiced at the NHPD. The remainder of this dissertation, speaks only to assessment, known as level three (L3).[13]

The second, rote explanation: evaluation as regulatory texts

On my first morning of work as a scientific regulator, even before I was instructed on the four-level process (L1-L4) at the NHPD – that was later in the day – my supervisor directed me to a pile of documents sitting in my cubicle and told me to begin by reading them.[14]

Texts played such an important role in the daily work of assessment officers, that it was nearly impossible to have a work-related conversation until the basic texts were read.

For scientific staff, regulatory texts are in a clear, hierarchical relationship. At the pinnacle, although rarely mentioned in everyday work, is the *Food and Drugs Act*, promulgated by Canadian parliament.[15] Next, and most importantly, comes the *Natural Health Products Regulations*. The regulations were ultimate arbitral text in most day-to-day work. They had the force of law. My first day of work I was well-advised by a colleague to learn the regulations well and to keep them close at hand,

> Because the regulations are your friends. You want them in one of those folders right by your phone, so when you get a call from industry questioning your right to request such-and-such information, you want to grab the regs, look up the clause, and say "Well, as per section 93(1)(a)(v) of the *Regulations*…"

Thirdly, came the wide range of published guidance documents, including *Evidence for Safety and Efficacy of Finished Natural Health Products* (Health Canada – NHPD 2003), and *Evidence for Homeopathic Medicines* (Health Canada – NHPD 2006b).[16] The suite of guidance documents was explicitly based on regulatory requirements. In the everyday assessment the guidance documents were treated as uncontestable rules.[17] Guidance documents do not technically have the force of law like the Regulations; they are merely guides for applicants, explaining to applicants how they *could* meet the regulations.

The Regulations and the suite of guidance documents were used to train applicants and scientific staff. When I asked Richard, in interview, whether there was anything that surprised him when he arrived at the NHPD as a new assessment officer:

> I was surprised there was no support or guidance on how to do the job.
>
> *So how did you learn?*
>
> It seems like some people here [pause…]
> There are certain documents you can read. I can't describe it right. Basically there are work-related documents that you need to know to perform the task. So reading them is step one. Then you have to apply it. And when I would write in the SEAR [Safety and Efficacy Assessment Report] template, I would get feedback from the more experienced colleagues, other assessment officers. And so I learned from my errors. Some people take a while to catch on.
>
> *Did you enjoy that period, or did you find it frustrating?*
>
> It was all right, I guess. It is a learning curve. At the beginning, it was not that difficult. Actually I've been in lots more difficult situations! When I started – it was a good thing – at the time, there was no pressure to meet numbers, to meet a benchmark.

This surprise at being thrown into assessment immediately was expressed by several scientists in interview. For many of us who were hired directly out of graduate programs, being tasked with reading a pile of texts was entirely unremarkable, and there was a degree to which critically summarizing articles in scientific journals was "just second nature …. It was not exactly a big change" to use Namir's words, spoken in an interview.

As a scientific regulator, I had to quickly learn to transform my intuitions into statements linked to specific clauses in the *Natural Health Products Regulations* or

in a guidance document. This transformation was imperative whenever I recommended an application be refused, because if I was not doing so on the basis of a clear regulatory clause, the applicant could appeal the refusal on various technicalities.[18] One of my colleagues, Naavah, recalled that one of the NHPD's "early blunders" (e.g., pre-2006) was allowing its scientific staff to ask applicants for information that the regulations did not authorize the Directorate to ask. At a meeting of all scientific staff in L3 to discuss our operating procedures, we were chastised to not be "picky" –told to "distinguish between what [information] we *need* to have and what we would *like* to have – don't request something just to be picky." Although this channelling of intuition and disposition was framed in various ways, the bottom line was: we could only enquire about facets of the proposed medicines that we were authorized by the *Regulations* to address. The regulations were the raison-d'être of the entire Directorate, at least as regulatory scientists understood it. The regulations were also the only authority one had as regulatory scientists.

Problem: interpretation of legal texts varied; solution: more guiding texts

With more than a hundred staff members interpreting the regulations and the guidance documents, there were a variety of interpretations on what exactly the *Regulations* addressed. Even when staff interpreted the regulations in similar ways, there were many ways in which these interpretations were communicated to applicants. It was incumbent on regulatory scientists, however, to function together as a credible regulatory agency, to speak as one.

The primary approach taken by staff within the NHPD to enable themselves to speak as one, was to standardize interpretations of the regulations in their public reasoning: to create more documentary guidance. Some assessment units kept formal “records of decisions” taken in regulatory reasoning, to maintain consistency across staff and through time; others expected staff to carefully file the barrage of e-mails containing decisions. Standardized interpretations of the regulations were also embedded in the spreadsheet of over five hundred “standard lines” used for external communications. Standard lines were paragraphs designed to be copied directly from the shared spreadsheet, and pasted into individually-tailored deficiency notices.[19] Ideally, each standard line consisted of three sentences, stating: (1) What was wrong with an application, (2) Why it was wrong (e.g., reference to a section of the *Regulations* or other regulatory text), and (3) How the applicant could fix what was wrong.[20] An example of a standard line in use in 2007 is:

> The recommended use or purpose does not reflect the same intent as the recommended use or purpose in the XXX monograph in that the qualifier “traditionally used”\the healing paradim “eg. Traditional Chinese Medicine” has not been specified in the claim regarding XXX. As per Chapter 2 of the NHPD Compendium of Monographs, the recommended use or purpose on the Product Licence Application form must be identical or “statement to the effect of” what appears on the referenced monograph. Revise the recommended use or purpose by including the applicable qualifier(s)\healing paradigm. [The “XXX” would be replaced in each individual case, and one of the options (separated by a \) would be deleted].

These standard lines reflected already-made decisions on how to interpret the Regulations or the Guidance documents.[21]

Standard Operating Procedures

When I began my fieldwork, groups of staff at the NHPD were busy writing standard operating procedures – also known as standard operating protocols, or more frequently as SOPs – for all sorts of scientific regulatory activities. SOPs were written for several purposes, not only accountability. The SOPs contained all sorts of stylistic conventions – such as the requirements that electronic documents feature Times New Roman 11 point font, italics be used only for foreign words including plant binomials, periods be employed after numbers in lists and brackets around letters, and that scientific staff order information requests according to the order of subsections on the Product Licence Application Form. These conventions were crucial tools in speaking as one.[22] (How can 200 individuals speak as one effectively, if each has to reformat and war with autoformatting?) The SOPs also lessened scientists' constant guessing, negotiations, and misunderstandings about who would do what task and when, because those decisions were made explicit as possible in the protocol. For example, one SOP, the 21-page "Level 3 Coordination" SOP, outlined the work of submission co-ordinators, and provided an overview of how product licence applications should move through L3, both conceptually (e.g., the steps to track the file in the electronic system called TWS; electronic file naming and saving protocols) and physically (e.g., to whom the physical file should be given, when, and how).

The SOPs also described the tasks to be performed by scientific staff in their evaluation activities. Of most relevance to this dissertation, is the SOP "How a

Product Assessment Officer evaluates the Safety and Efficacy of a Natural Health Product," which came into effect September 6, 2006.[23] The SOP, like the Directorate's other SOPs, began with standardized headings, reading:

> 1.0 PURPOSE
>
> This SOP outlines how to evaluate a Non-Compendial PLA [Product Licence Application] for safety and efficacy requirements.
>
> 2.0 SCOPE
>
> 2.1 Input
>
> An assessment folder containing a completed PLA form, a proposed label text, a Quality Summary Report, Finished Product Specifications, a Safety Summary Report, an Evidence Summary Report, and Full-Text references.
>
> 2.2 Outputs
>
> 2.21 The possible outputs are:
>
> a. A Safety and Efficacy Assessment Report (SEAR) outlining the deficiencies in the information pertaining to the safety and efficacy of the product, written in Standard Line (SL) format, signed by the Safety and Efficacy Assessment Officer (AO) and Unit Head (UH), indicating that a request for additional information is required.
>
> b. A SEAR signed by the AO, UH, and Safety and Efficacy Manager with recommendation that the PLA be recommended for approval.
>
> c. A SEAR singed by the AO, UH, and Safety and Efficacy Manager with recommendation that the product be refused and a rationale for refusal.

The SOP continued with the section "3.0 ROLES AND RESPONSIBILITIES," "4.0 DEFINITIONS," before detailing the procedures, which (under different section headings) span the remaining 53 pages of the SOP, largely organized according to the section headings of the Product Licence Application Form. For instance, the

entry for Non-medicinal ingredients (NMIs) (section 8.0; note that the quality assessment officer does most of the assessment of non-medicinal ingredients), reads, in its entirety:

> 8.1 The AO [assessment officer] scans the NMIs indicated on page 5 of the PLA [Product Licence Application] form and verifies if any of the NMIs could potentially be an MI [medicinal ingredient] based on the name of the ingredient, the ingredient purpose and/or the quantity (if it is indicated). Additionally the Safety AO can check the QAR [Quality Assessment Report] to see if the Quality AO has documented any deficiencies about some of the NMIs. All issues related to NMIs which may not meet the definition of an NMI must be documented in the "Non-Medicinal Ingredients" section of the SEAR.
>
> Certain NMIs may have NMI and MI [medicinal ingredient] properties depending on the dose (e.g., peppermint oil). In this case the AO will request the quantity of the NMI in order to determine if the ingredient is an MI.
>
> Herbs not having a recognized NMI purpose or herbs which have the purpose "filler" are not acceptable as NMIs.

When the SOP was first introduced -- presented in a large, three-hour (mind-numbing) meeting with all L3 scientific staff -- the manager introducing the SOP began by explaining the SOP was critical for consistency: so that assessment officers, then dispersed throughout ten assessment units, would prepare similar SEARs, and have a consistent "way of looking at things." This was crucial given rates of turnover among scientific staff; it was not unusual for a file to be assessed by a different assessment officer after each reply to an Information Request Notice. As Kayte, an assessment officer, explained, it was difficult to get a file from an assessment officer she considered 'poor,' "because I can't figure out what they've done, and often I can't talk to them because they've left [the NHPD] and I feel I have to start all over again" in the assessment. Whereas, Kayte explained, "If it is

someone I consider a good AO, I'm happy to get their file, because I know our thoughts, and how we built up our assessment report would have been done in a similar way and I feel I can jump in where they jumped off." The SOP, a manager Tiaje argued, would contribute to making assessments: concise, efficient, and consistent. "This is not to say that the SOP might not change two or three months from now; it captures what we are doing today."

The manager Tiaje's arguments were consistent with the rationale presented to me in interview six or seven months later, by one of the scientists who had been involved in the writing of this particular SOP, who explained the rationale behind developing an SOP:

> Everyone comes from a different scientific background, with different interests, and will delve into some files and not others… Writing the SOPs … that was really to target the consistency on our part….
>
> Also, we were hiring very quickly, with assessment officers having to jump in and start evaluating. (Alzien)

The SOPs were immediately used as training tool, to standardize new evaluator's approaches (expanding the documentation that needed to be read by new assessment officers.) After the SOP was developed, new assessment officers were still, according to some, "not given any training," to draw from Zahra's experience as a new assessment officer, "and told to read the SOPs. But I don't want to make mistakes; I like to know stuff ahead of time. But people were too busy."

The standard operating protocols were useful for, but insufficient in, homogenizing the reasoning activities of scientists in the Directorate. Scientists spontaneously acknowledged at least three reasons for this state of affairs. First, the SOP was designed to only cover general cases. As I learned in my third week of work, at the meeting introducing the L3 standard operating procedures, a presenter declared, in response to a question: "They are not literal – you cannot follow SOP literally!" One of the SOP writers explained that the group had originally tried including exceptions in the SOP but it made the SOP completely unwieldy.[24] It was also recognized that even when instructions are as clear as can be expected, the instructions are often insufficient to practice – no matter how detailed the instructions, it is not the same as performing the action.[25] The SOP had been created by generalizing from a few scientists' way of working.[26] Third, scientists attributed moments of confusion about how to follow the SOP to unforeseen circumstances – and these, in the imaginary, could be remedied, in the next version of the SOP, along with any unclear technical writing. Finally, some scientists recognized there were still variations in scientists' use of evidence:

> Unit Heads are very critical, very smart, looking into everything. Everyone doing what she or he thinks consistent, and wants to be consistent.
>
> But everyone has personality. You cannot take away the uniqueness of a person when they come to work. Therefore they are choosing different ways, like they choose different lipstick or hairdyes etc. Some would not change a word [in the assessment reports of their underlings]. There are others who would, and [there are] people in between. (Miel)

The solution, as Miel explained in interview, "is to have a firmer implementation of SOPs, and to make them more detailed, and to make them for Unit Heads."

Scientists recognized the SOP was temporarily imperfect or imperfect in application; deficiencies were, however, (hypothetically) perfectible, through editorial clarification, or “more stringent application” of the SOPs. Through the course of my fieldwork, scientific staff generally felt that the guidance documents and the standard operating protocols *were* their work, in the sense that there was no perceived gap between documents and practice. Scientists framed deficiencies and fogginess in the standard operating protocols or their homogenizing power as imperfections that would be remedied in a later version of the SOP (because, after all, the SOP was a “living document”) or in its implementation. The remainder of this dissertation’s analysis, then, should be read as an anthropologist’s, not a regulatory scientist’s, analysis.

The moment of decision regarding the safety and efficacy of a proposed medicine was strikingly absent from the SOP. Granted, there is a way in which the reasoning activities in the Directorate in some ways skirted around such a decision; as stated in the purpose of the SOP, “This SOP outlines how to evaluate a Non-Compendial **PLA** for safety and efficacy **requirements**” (emphasis added). The Product Licence Application, not the medicine, is the object of the evaluation; safety and efficacy requirements, rather than safety and efficacy tout court, determine the ambit of the evaluation. There were, nevertheless, entire sections of the SOP devoted to efficacy, including sections entitled “Recommended Use or Purpose/ Claim Tips and Hints,” “Assessing the evidence for the claim – determining the

credibility, strength & quality of the evidence," as well as related sections addressing applications in the homeopathic and traditional assessment streams. These sections were largely about which documents and standards the evaluator should or should not consult; or how s/he should summarize evidence in the SEAR depending on his or her decisions regarding the health claim and appropriateness of the evidence. The protocol pertained to things before, after, or around any moment of decision or judgement about efficacy.

"The most complex part of the SEAR," conceded a presenter at the meeting introducing the SOP, "is the evidence." In interview, one of the SOP writers concurred, explaining that the hardest part to write was the "assessing the evidence" part of the SOP:

> As AOs [assessment officers], we have tried, and made a really good attempt, to capture how AOs should evaluate evidence, but yet that is, it is so personal, and so subjective.
>
> We've tried to make an objective, generic attempt at how to look at it. And I guess that this, since its release, has contributed to [AOs] getting through our backlog quicker.
>
> *Do you think it has also contributed to the quality of assessments?*
>
> Oh definitely. Because we have a more standardized, generic way, now, because there are so many different units that [Pause/] Work, regardless of the paradigm, is being completed in a similar fashion. And what we're requesting [of the applicants] and how we're requesting … is a lot more consistent. So I think as a result we're getting better responses from applicants…..
>
> *Was there much debate over the assessing the evidence part, especially from different units?*
>
> No, because in the original contributions most people skipped over the assessing the evidence part and jumped into the, you know, assessing the

> subpopulation and if it is the right route of administration. Most people hadn't made an attempt. There were more issues on do you evaluate all the pieces of evidence the same, do you start to triage them a bit, but [pause] that is where, that is the hardest part to try and get on paper. And that is where most questions and hang-ups come in.

I suspect that part of the reason "evidence" is the hardest part to include in a sequential description of tasks is that assessment, at least as I observed it in cubicles, was anything but a predictable linear process, although this was the ideal.

---

[1] Although the level of any application, in most cases, could probably be deduced from the types of documents in the paper file.

As scientific staff, I was required to extensively track "my" files in various electronic databases. My fieldnotes, after I was (over-?) socialized as scientific regulator are filled with my revelations on the importance or usefulness of pushing certain onscreen buttons in various tracking databases:

> re [NHPD] approach [a tracking database]. Reports. Ass query only do Compendial AR. General queries – find out status of sub in subquery. Work management filter. Special cases (no correcting submission info) to correct status. Only hit reclass when goes back to L2 (if SEAR incomplete).

I experienced these file tracking databases as absolute labyrinths; their navigation required constant attention, and pushing the wrong button could cause a file to get "lost" (conceptually, but then also physically).

[2] This enumeration of staff neglects the many NHPD staff who do not touch the applications, but who create conditions allowing those who do, to do their work (e.g., cleaning, IT, human resources, finance, policy, administrative support staff).

[3] I gleaned this information by "following" three applications: I attached ribbons to three applications entering the Directorate one day. The ribbons held a note asking anyone encountering the application to call me if they were willing to be observed (the project had been described via e-mail circulated to staff). My physical "following" was counter-intuitive for many staff, because they did not understand what would be gleaned from this exercise that could not be gleaned from the tracking databases; "So you want to follow the file, not just the tracking?" My fieldwork was not long enough to follow any individual file through the entire four-step process; however this exercise did let me see what went on in the first two levels, including procedures of which I was unaware as assessment officer.

[4] At the NHPD, officials distinguished between a submission number and a file number. For the purposes of this dissertation, this is irrelevant; I will refer to files as one would conventionally, as that contained within a physical or electronic file.

In case the reader is doing research related to the NHPD: If the NHPD were dealing with a product (e.g., brand name) for the first time, the application would be assigned a submission number and an identical file number would also be produced; the submission would be housed within the file. If that submission were to be licenced, but, the following year, the company headquarters moved and so the company had to send in a notification of the new address to the NHPD, that notification would receive an entirely new submission number, but the submission would be housed within the file number generated for the original submission.

[5] There was some leeway; when submission co-ordinators had a good rapport with the applicant contact, and the deficiencies were minor, it was sometimes more efficient for the submission co-ordinator simply to call the applicant, and get him or her to correct the deficiencies. When this was done, however, there was no legal obligation for the applicant to respond in less than thirty days and so phoning tended to be the exception, rather than the rule.

[6] As a general rule, as the application moved to higher levels, the papers literally moved upstairs in the office building that housed the Directorate's staff. I will not address the extent to which the physical location of offices is of concern to public servants. But for spatially-minded readers, I reproduce text from an e-mail circulated during my fieldwork, describing the assignment of space in the Directorate's building:

> Basement:
>
> Submissions Management Division/[part of] Bureau of Regulatory Assessment
> Records Management [Central filing registry]
>
> Ground Floor:
>
> Bureau of Operations and Planning [general administrative support]
>
> Second Floor:
>
> Director General's Office
> Bureau of Regulatory Assessment
> Bureau of Clinical Trials and Health Sciences
>
> Third Floor:
>
> Bureau of Policy Development and Regulatory Affairs
> Bureau of Research, Outreach and Programs
>
> To maintain fairness and consistency across the Directorate, we are providing you with guidelines for assignment of closed offices and window-adjacent offices….

[7] Note that the exact procedures involved in the photocopying and distribution of files to AOs changed several times during my fieldwork; this description uses the simplest procedure used during that period.

[8] A company's compliance with Good Manufacturing Practices (GMPs) was assessed by an entirely separate group of assessment officers whose work was beyond the ambit of my research project. At the time of fieldwork, however, there were no actual inspections of manufacturing facilities taking place or envisaged in the near future – the assessment of GMP compliance was entirely paper-based.

[9] The meaning of "peer review" at the NHPD was quite different from the usual academic meaning. At the NHPD, "peer review" simply meant a review by a peer, who may or may not go back to source documents – it could entail anything from formatting suggestions, comments from another work perspective, or substantive comments. Usually comments given by the peer reviewer were entered on the electronic document using the "track changes" and "add comment" functions. Because these comments were usually "accepted" or "rejected" electronically by the assessment officer, there was usually no trace of the peer review in the paper file.

[10] Scientists' opinions on this blinding varied. I felt it was indispensable; others felt it was hopelessly inefficient. Abigail, for instance, felt that the blinding was unnecessary; "If the AO [assessment officer] has done the work properly and knows what they want, then they should speak with applicants. *Do you not worry about pressure?* No, I think it will affect the work for good – make the work [assessments] clearer – and that AOs are sufficiently strong that if they disagree, they can say no. SCs [submission co-ordinators] cannot truly give guidance. They can give guidance document aid, but they are not looking at the file." Kayte disagreed that it would be a good idea in the current context: "I think it is important that the AO can assess that evidence and the claim and not be required to defend that position on the phone …. [Applicants] know that the SC will *try* to answer the question…. But we also know that the applicants know that there is no real point of getting into a discussion or debate about a claim or a risk statement because they know that the SC is not involved in assessment. If they do want to engage in a debate or a discussion they do have the right to speak with the unit head. So I think it is ultimately accountability back to the unit head for the file, and the AO is not going to be bugged and feel pressured into allowing a claim because they're being called all the time on the phone."

[11] NHPD officials did not assume the applicants had scientific backgrounds. (Given that many applicants submitted opinion website printouts as "evidence," this was probably a fair assumption). Thus, assessment officers were cajoled: "Using scientific terms is important but please keep in mind there has to be a balance with business language and some things that are obvious to you as an AO [assessment officer] may not be obvious to an applicant with no science background." (From internal document "Guidelines for Refusals," circulated as part of a Safety Assessment Training Session held Friday April 27, 2007).

[12] In the early days of assessment at the NHPD (e.g., pre-2006), it was not unusual for as many as fifteen IRNs be sent to an applicant for one application (e.g., NHPD sends one IRN, and applicant responds, but the application is still deficient so the NHPD sends a second IRN, and applicant responds, and so on thirteen times more). During my fieldwork, three rounds of IRNs was entirely unremarkable although there were initiatives in the Directorate to refuse applications if the applicant did not satisfactorily respond to an IRN. Part of the reason for this extensive, early correspondence is that both the Directorate and the applicants were figuring out what information was required by the Directorate, and how to frame that information.

[13] In the case of certain assessment streams conceptualized as "comparative review," for instance the pharmacopoeial and compendial assessment streams, assessment (L3) was inseparable from processing (L2) (i.e. L2 and L3 are fused). So in certain parts of the dissertation, my comments about "assessment" will refer to both L2 and L3 activities.

[14] The documents I was assigned to read my first day of work were: the *Regulations*, the Product Licencing Guidance Document, the Compendial guidance document, the Product Licence Application form (which contained extensive instructions), and a Monograph Management Unit Compendial Assessment power point. I was also advised to go through my unit's electronic Record of Decisions.

[15] If an interpretation of the *Act* was required, at that point most scientific staff expected that "lawyers [would be] parachuted in to comment," to advise (Naavah). This was rare, and as such, the *Act* was neither required reading nor part of everyday conversation.

[16] These guidance documents can be found at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legistlation/docs/index-eng.php as of August 28, 2010.

[17] I was told that applicants could try and find an alternative way of meeting the regulations, and could take their cases to court if necessary; this was largely neither here nor there in the workaday world of scientists at the NHPD.

[18] At one point the refusal notices began including more than one clause, "so legal has a smorgasbord to choose from." (Naavah).

[19] There was a tab in the standard line spreadsheet for each level and, for L3, for each topic area: Acknowlegement Notice (L1; ~32 lines); PLA completeness & correctness (L2; ~90 lines); Compendial (~50 lines); Quality [Assessment] (L3; ~72 lines); Homeopathic [Assessment] (L3; ~30 lines); Ingredient Specific (L3; ~26 lines); Safety and Efficacy [Assessment not otherwise specified] (L3; ~40 lines]; TPD Cat 4/LS (L3, ~22 lines); Labelling (L3, ~27 lines); Clinical Trials (~43 lines); Refusal (~6 lines); Non-NHP (~100 lines).

[20] This manner of communicating was ubiquitous and standardized, to the extent that it became the premise for an entire genre of joke in at least one unit which I worked. The joke would begin "let's propose a new standard line," and then an utterly unfeasible standard line would be composed. These jokes tended to address elements in applications that were, in the scientists' opinion, so wrong, but in cases when the scientist was unable to address the real issue directly because it only served to highlight the stupidity or moral questionableness of the applicant, or because it really could not be addressed in the current interpretations of scientists' regulatory ambit. (One of the personal suitability characteristics required for our positions, explicitly stated in our job descriptions, was *tact*).

[21] The standard line document could only be changed by its guardian, and even then only for typos unless a change had been approved by an appropriate level of management as well as by the standard lines committee.

[22] Establishing standards for various electronic documents and programs was also, and more often, done orally. In one unit, there reportedly was an hour-long debate over the use of bullet points for formatting. Meetings were devoted to explaining which clicks had to be made in the most recent database (for instance, we had to push the “complete” button,or the “licence” button on one database user screen but not the other). Although this might sound like a parody of bureaucracy, getting 200 staff members to act as one is no joke, no simple matter.

[23] Copy of version 004 dated April 16, 2007 [55pp] available from J. Cuffe.

[24] From an interview with a writer of the SOP:

> *Were you told what should go in the SOP?*
> At the beginning, no. We tried making it applicable to all products, and as you know, there are exceptions applicable to homeopathics, and traditional [medicines]. And then after a while, we learned that an SOP should be general and not capture exceptions. We had a place for exceptions in there, but that was cut out, because we figure that the AO should take initiative. The SOP should not be the repository for RODs [Records of Decisions].
> The stuff with respect to claims and other stuff that has been put in there, is applicable to all the units and paradigms….

[25] For example, to take an utterly mundane example, a colleague, Rosalie, was confused about a new process for refusing applications, and exactly what we, as compendial assessment officers, needed to do to hand the file off to another unit. Her first instinct had been to consult the expert on procedure, but the expert had just told her to read the standard operating procedure. One of our colleagues concurred with the expert, what she thought to be the obvious: “Well, it is in the SOP.” At this point, I piped in the conversation, because I had encountered exactly the same hurdle two days previously – I had thought the directions were clear in the SOP, but when I actually went to follow the directions, it was impossible to do so – “It is so unclear. If you’re reading through the SOP you could think you have to do the whole process yourself – it does not tell you at what point you are supposed to put the file in the box in the basement.” So Rosalie asked what I did for refusals. I said I attached a sticky note describing the reason for refusal to the cover of the file, and put the file in a certain box in the basement.

> Rosalie: so that’s what we’re supposed to do!
> Jennifer: well, I’m not sure
> Rosalie: but that’s what you did
> Jennifer: and I haven’t had any complaints yet
> Rosalie: but these things take time…

Unsatisfied with exactly what she was supposed to do, Rosalie reconsulted the writer of the SOP explaining the problem, and she later reappeared in my cubicle to report back that yes, with a minor modification, that was (going to be the) new process for refusals.

[26] The SOP was developed by an assessment officer in each of the non-Compendial assessment streams writing up how they did assessments; this was compiled into a document, grouped together under the section headings of the Product Licence Application Form. At that point, the group sat down and edited the document down by choosing one of the following: (1) picking one person’s way, (2) combining several people’s way, or (3) coming up with something else. The group was under pressure to get the SOP done.

Part III. Textual standards in practice

Chapter 5
An introduction to cubicle life

In interview, I asked a former evaluator to describe a typical day of work for her at the NHPD. She looked somewhat puzzled, then replied: “A lot of the time I would sit in my cube and work on files and not really have much interaction with anyone.”

The cubicle-bound environment of the scientists I studied fostered a rhythm in their daily work. Assessment officers’ everyday work included hours spent in their individual cubicles interacting with paper and electronic documents; hours punctuated, divided by the moments of social life between and among cubicles, as workers visited each other for questions or pleasure, attended meetings, and so on. While this observation may sound trivial, if one is to take seriously Fleck’s project of examining the sociological basis of all reasoning, this observation is indispensable to any characterization of the thought collective, and thereby any account of NHPD scientists’ style of reasoning in public health protection.

While the description that follows, of an assessment officer at work in her cubicle evaluating a traditional Chinese medicine for safety and efficacy is, by her own avowal, “pretty boring,” it is also useful for bringing the reader’s attention to the embodied world of scientists’ reasoning in public health protection; to begin to move away from the pragmatic rote formulations of evaluation, and Weberian-style rationalized (ideological) descriptions of processes; to prepare the reader for this dissertation’s subsequent discussions of textual standards in practice.

Notes from observing a Health Canada assessment officer evaluating a traditional Chinese medicine for safety and efficacy.

10:00 a.m. I arrive at the entrance of Alex's two metre wide, three metre long, and two metre high cubicle. She is sitting, turned away, facing her computer located in a corner. The cubicle walls to her right and left have 60 centimetre-deep desks running along their length, and are topped by filing cabinets. The filing cabinets are closed and her desk space is rather tidy. On the desk to her left is a stack of green files – the product licence application files that I will observe her assess. In the far left corner of the desk, she has her inbox and outbox. To the right of her computer she has a phone and her pens, pencil, and a few other office supplies. There are textbooks of traditional medicines lying about, as well as a teetering stack of papers that I am later informed is for another project. A free-standing filing cabinet takes up considerable space in the cubicle corner opposite where Alex is sitting. Somehow I will also fit in to this cubicle for a day.

I say good morning from the cubicle opening. She turns around and looks at me incredulously and smiles. Although she'd agreed to be observed, I don't think she believed I'd actually show up, that someone would actually want to spend a day observing her assessing files. She graciously settles me into a chair in the cubicle.

10:02 a.m. "It's pretty boring." She lets me observe her activities and does not provide much narration. Her cubicle neighbours are probably thankful for this quietness: the noise of a pencil writing on paper can be heard in a one-cubicle radius around any given cubicle, and I'm sure our conversations can be heard by at least a dozen other employees, if not twenty, including various supervisors. I am happy to be simply observing, rather than participant-observing; other than the occasional banter, I just observe and write in my notebook, effectively becoming cubicle décor.

Alex stretches and opens up the top green file, titled with its submission number. The file is just over two centimetres thick. Knowing what goes into the file, I know that the first six or so pages of the file consist of the completed Product Licence Application form. Companies must fill out this form should they wish to market in Canada any medicine deemed a “natural health product.” This application form is followed by other forms that are required for specific types of ingredients all dutifully completed by the company making the application. The file also contains the company’s “evidence” for the safety and efficacy of their proposed medicine. For applications for traditional medicines, evidence usually consists of photocopied journal articles or excerpts from pharmacopoeia. The green files appearing in evaluators’ cubicles usually also contain correspondence and other administrative documents, although these are generally ignored by the evaluator.

Alex immediately turns to the fourth page of the Product Licence Application form, the page listing all the medicinal ingredients and their quantities. There are twenty-five medicinal ingredients in this one medicine.

Alex, intensely focussed, flips through the pages of the file. It appears she is comparing the list of medicinal ingredients with “the evidence” the company submitted along with the application form. The company provided monographs as well as articles as evidence. Alex goes through the evidence and underlines key words (common names, diagnoses) and doses.

Alex briefly turns to the computer and opens up an electronic document, a table of medicinal ingredients she has already assessed in other applications for Traditional Chinese medicines. I will call this document TableTCM. The table lists each ingredient’s common name, proper name, part used (if an animal or plant), the reference used as evidence, and a submission number.

10:10 a.m. “About one hour should be enough to see what the company is doing.” More flipping of pages in the file, more scrolling through TableTCM.

After a while, Alex pauses at one of the pieces of evidence appended in the file – “this is a different one,” she says flagging the paper in the file with a sticky note (Post-It note). “There is the question of whether this is original. It seems to be a study, an original study.”

I am amazed at my luck, because I had given up on ever seeing an original study in a Product Licence Application. I exclaim: “How exciting! I’ve never seen an original clinical trial included in an application.” “Neither have I,” she replies.

The inclusion of an original unpublished clinical trial does not slow Alex’s approach to the file. She looks through the study’s method section, and circles the numbers representing the quantity of medicinal ingredient: 14g, 9g. She then quickly flips through several pages of the study: “It’s basic research, characterization of the herbs, so I’m skipping it.” When she reached a page with numbers, she stopped. “This part is toxicology, so you have to read it.”

10:23 a.m. “This is a very well-done study. I’m impressed. Well-done design. Very professionally done.” She continues to flip through the study’s pages.

Just as she finished flipping through the pages of the evidence: thump. “It’s too big.” The file had fallen over and shut from the weight of the pages.

10:26 a.m. I gather that a second phase of assessment activity is beginning, because with a swivel of her chair, Alex turns from the paper file to sit squarely facing the computer. She announces several things she needs to do next:

> “I have to check to see if something similar is in the *Pharmacopoeia* [of the People’s Republic of China].”

While waiting for the computer to get up to speed she declares “This is a huge combination!” perhaps referring to the number of medicinal ingredients.

“I have to see if one animal is an endangered species.”

She opens up an electronic folder containing all her previous assessment reports. She opens an assessment report for a previous application for a traditional Chinese medicine, and saves the assessment report under a new name, the number of the current submission.

10:30 a.m. “Ugh -- this is going to take all day!” she groans as she goes through the list of medicinal ingredients, entering them into her assessment report along with the requisite information. She consults TableTCM for each ingredient. “It makes it faster having my table completed. Anyways, sometimes I do not need to check all [the ingredients for proper name, common name, endangered status, etc.], because I know just by looking it is not OK.”

It turns out the evidence the company appended for each medicinal ingredient is not organized in sequence of the medicinal ingredients listed on the Product Licence Application. She needs to hunt through the pages of evidence for the documented safe and effective dose for each medicinal ingredient, to verify whether the documented dose corresponds to that in the company’s proposed medicine. “That is why I am not happy with this. It’s taking too much time.”

10:34 a.m. On the computer, Alex switches between TableTCM and the growing medicinal ingredient table in her assessment report. It takes a while because the computer is excessively slow. In TableTCM, she adds two entries for medicinal ingredients in the current submission that she had not previously assessed: chicken gizzard lining and flying squirrel faeces.

10:41 a.m. Alex is obviously becoming increasingly frustrated with both the computer's slowness and the company's disorganized compilation of evidence in the file: "They should be more professional!"

10:42 a.m. We leave the cubicle to consult a medical textbook in the NHPD's internal library (a bookcase) for one ingredient. She explains to me that she wanted to verify the recommended use for an ingredient in another source, because some English translations of Chinese documents are neither clear nor precise.

10:46 a.m. The computer is frozen. She uses her pencil as a place marker in the paper file, leans back in her chair, and stretches. "I've never been patient in life. I have learned to wait. I cannot do anything. It is always the same…. If you get agitated you get attitude. I've had to learn to entertain myself." The computer sluggishly shows some activity.

10:54 a.m. She has managed to verify the names, doses, and traditional status of 10 medicinal ingredients, entering the information in her assessment report. "I don't know this one!" She reads avidly about one medicinal ingredient. "Other assessment officers with less experience would take two or three days to do this file, because they'd have to read everything in the file," she explains, just like she is doing for this one ingredient with which she is unfamiliar: a particular species of tree.

[10:57 a.m. still reading.]

11:05 a.m. Alex inserts her pencil as a place marker into the file, and leaves the cubicle to go to see if a meeting is on. It is not.

11:09 a.m. Alex opens a completed assessment report for a similar product, and looks through her personal files. She is trying to establish whether one of the ingredients, *Cervus nippon*, is on an endangered list. She searches the online lists

of the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). There's no Cervus nippon. She shortens the search term to "Cervus", and spends about thirty seconds looking at the results. She sighs, and switches between languages on the website.

11: 14 a.m. "It is difficult to figure out if it is an endangered species." She continues reading.

11: 17 a.m. She google searches to figure out whether Cervus nippon and Cervus elaphus are the same and/ or in CITES.

11: 30 a.m. The computer crashes.

In the seven minutes it takes for the computer to reboot, we have a conversation. She tells me she is passionate about herbal medicines. At my prompting, she says she likes her work, especially the opportunity to use her expertise – but she does not get excited about it. [She also tells me I am too happy: I laugh too much. I try to temper my laughter, if only for her cubicle neighbours.]

11: 37 a.m. Alex re-opens the electronic files.

11: 39 a.m. She opens and looks through an electronic, pharmacopoeial-type list, comparing the quantity of medicinal ingredient listed in that list with the quantity on the Product Licence Application. She sighs.

11:41 a.m. She returns to the clinical trial in the green file, and arranges additional sticky notes on certain pages as place markers.

11:42 a.m. She translates "velvet" [antler velvet], and consults a textbook.

11:44 a.m. She documents a deficiency into her assessment report: there is no animal tissue form for the medicinal ingredient flying squirrel faeces.

[11:49 a.m. Still flipping between the medicinal ingredient list, and TableTCM.]

11:52 a.m. One of the electronic files that she needs to open from NHPD's shared drive, has still not opened. She gives up and says she is going for tea. I say I'll come back after lunch.

[Break in cubicle observation for lunch]

1:10 p.m. When I return, Alex is checking her work e-mail, which she had not done while I was with her all morning. "It makes you feel human again."

She scrolls to the section in her assessment report where she will document the evidence for the medicine's health claims. She turns her attention back to the green file, focussing on the clinical trial. She writes a short summary in the assessment report.

1:16 p.m. She looks closely at the clinical trials' methodology section. In her assessment report, she adds in the word "randomized" to her characterization of the study.

1:19 p.m. She looks at the trial's discussion section. In her assessment report, she writes "There is no statistical difference." "That's a limitation of the study," she remarks.

1:20 p.m. She returns to examining the trial's methodology section.

1:23 p.m. In the assessment report, she documents the limitations of the study: the small number of patients (~ 80) and the lack of placebo control. She writes it is

unclear whether the product that was tested corresponds to the product described in the Product Licence Application.

1:24 p.m. Alex sighs. “All the time, I get tired, there’s too much work.”

1:25 p.m. Back to the methodology section. Reading and stretching simultaneously.

1:27 p.m. Alex writes in her assessment report “Claim different in study and in Product Licence Application.” She starts nodding. I take this to mean she’s made up her mind that the clinical trial is irrelevant to her assessment of the medicine in Product Licence Application form, because the products and the health claims are different. She seems to perk up, which I assume is because she’s made a decision of how to proceed with the file.

1:28 p.m. Alex writes in her assessment report that the daily dose in the Product Licence Application is more than the daily dose in the clinical trial.

1:30 p.m. Alex scrolls to another section of the assessment report, that of Information Requests, which are the exact requests that will be communicated to the company. She also opens another electronic file, the NHPD’s large excel file of various “standard lines.” [Standard lines are the standardized short paragraphs that explain three things to an applicant: 1. What is wrong with the application, 2. Why it is wrong (a regulation or policy is usually cited by number), and 3. How to fix what is wrong. Most standard lines are exactly three sentences long.]

1:34 p.m. In the large Excel file of standard lines, Alex locates the paragraph to be used when an Animal Tissue Form is missing. She cuts and pastes this paragraph into the Information Request Section of her assessment report. She replaces the standard line’s generic notation “[insert animal species here]” with in the animal species in question in the application, “flying squirrel.”

1:36 p.m. In the Information Request section of her assessment report, Alex writes that one medicinal ingredient has been listed twice on the Product Licence Application form, and requests the company corrects the error.

1:39 p.m. In the Information Request section of her report, Alex asks the company to include the qualifier “traditionally used in TCM” in the proposed medicine’s health claim, given that this is an application in the traditional assessment stream. [This will be explained in Chapter 8.]

1:40 p.m. In the Information Request section of her report, Alex writes that the evidence the company provided to support the efficacy of the medicine is insufficient. Although a clinical trial was provided, the number of participants was small and there was no placebo control group. Furthermore, the trial’s endpoint and its quantities of medicinal ingredients and do not correspond to the proposed medicine’s health claim, and quantities of medicinal ingredients, as proposed in the Product Licence Application.

1:47 p.m. “This one’s done!” Alex hits save, then print and goes to the printer room to retrieve the report.

1:50 p.m. Alex attaches her printed Assessment Report in the file and puts the file to the side of her desk.

[Alex will sign the Report and deliver it to her unit head later in the day. If unit head has concerns regarding the file or the assessment, he can send it back to Alex for revisions; otherwise, he will also sign and date the Report. Once the report is signed by these two levels of staff (assessment officer, and her unit head) the file will be delivered to another science-based division, the Submission Management Division. A “scientific regulator” in that Division will verify that each numbered reference to a regulation or policy is the correct reference. S/he will then

communicate the submission's deficiencies, as Alex documented in the "Information Request" section, to the company in an Information Request Notice. (Assessment officers in the Traditional Medicines Unit did not correspond directly with applicants, as a general rule). The company will then have 30 days to respond to the NHPD's request for information. If and when the company responds, the file would go back to Alex or another assessment officer, to assess the material submitted in the company's response.]

Observation versus scientific regulators' two rote explanations

Reading. Flipping through papers in a file. Typing text into an electronic document. Switching to another electronic document. Reading. Flipping through the pages of a textbook. Reading. Cutting text from one electronic document, and pasting the text into another electronic document. Typing. Flipping pages in the paper file.

As could be observed, Alex's activities in the pre-market evaluation of medicines were, above all, comparative. Circuitous, non-linear, even. Requiring intense attention, and perhaps even abductive reasoning. Nevertheless, this is not how the pre-market evaluation of medicines was most frequently described by scientific staff to outsiders, nor how it was primarily conceptualized within the NHPD, as described in Chapter 4.[1]

Assessment as spatialized activity

For some, the assessment process was largely computer-based, and the cubicle rather bare beyond things like lists of French keyboard shortcuts or the occasional

poster; for others, their assessments were obviously a whole-cubicle endeavor. To explain some assessment officers' use of three-dimensional space, I provide another description of my observation of a scientist's assessment of a homeopathic medicine. Because Guineviere was in the homeopathic medicines unit, the "processing" and "assessment" levels (L2 and L3 in the rote explanation outlined in Chapter 4) were fused, along with the quality and safety and efficacy assessments. Because of this, her assessment report is not called a SEAR. Otherwise the procedures are basically the same.

Description of a scientists' assessment of a homeopathic medicine

This was Guineviere's second assessment of the same file. The applicant had just faxed in a response to the Information Request Notice Guineviere had sent at the conclusion of her first assessment. When I observe her assessing the file, she has the papers just faxed in by the applicant loose on her desk, and is comparing the entries on those papers with her concerns documented in the report that she had written as her first assessment.

Next to the loose papers on her desk, the submission's paper file is also open. On the right hand side of the open file, the old material in the file is pinned down: the label, pharmacopoeial monograph, and specifications sheets tabbed by sticky notes. On the left hand side of the open file, the metal clips on the left hand side are open, with the cover letter from the faxed IRN response placed on top.

Her eyes move between the loose pages of the revised Product Licence Application form and the cover letter from the fax; she highlights segments in the cover letter. She flips through pages. From the right hand side of the file, she pulls out the specifications sheet and Animal Tissue Forms submitted with the initial

application. She adds additional comments to the electronic assessment report. Flipping through the pages, Guineviere locates “EHP Method A” in the file.

I get bored and record what is on her computer screen. Among the many documents that are open but minimized I note: two internet searches; three files on shared N:/ drive; seven word documents (“things to remember”, “evidence for non-homeopathic”, and five other assessment reports); Lotus Notes (e-mail); four excel spreadsheets (tracking, time tracking, standard line document, and a spreadsheet specific to her unit); Approach. When she sees me writing down these documents, she states it would be also useful to have several other documents available at glance: standard lines approved by her unit head, standard lines used for the specific company, standard lines previously used for quality concerns in homeopathy.

Guineviere spends well over five minutes on the computer tracking the fact that she has received a response from the applicant, and that the file is now currently being assessed for safety, efficacy and quality.

Then, systematically, she goes through each information request she had written in the original assessment report. She adds a description of the applicant’s response after each information request in the assessment report, writing in complete sentences. This takes a while.

She consults the assessment report for another file, to copy and paste a standard line describing a deficiency in the way the applicant has presented the label. “I copy and paste rationales and explanations from previous, approved assessment reports so that the new assessment report is, in a way, pre-approved by [her unit head].”

She compares the company’s new list of non-medicinal ingredients and the specifications sheet; she summarizes another deficiency in the assessment report.

She continues copying text from the another file's assessment report and pasting it into the current assessment report – "This is great – the files are sort of similar." She repeatedly scrolled up and down the electronic assessment report. "I'm having difficulty with the numbers – I'll do them at the end."

She then spent a large chunk of time trying to figure out an obscure (and possibly unacceptable) test method proposed by the applicant. She decided that she would have to consult a quality expert, because she (nor I) could make heads nor tails of the proposed method. Lunch intervened and, as I had a meeting in the afternoon related to my work duties, my research observation ended there; however later in the day, she reported that the quality expert had never heard of the method earlier, so she was going to have to send another information request, asking the company to provide information on the method. (If I recall correctly, I was later informed the company never responded, so it is possible the method did not even exist).

Managerial tools, such as the Standard Operating Protocol, have little way of including or recognizing this non-linear,[2] spatialized assessment, or, for that matter the extent to which arcane knowledge – ken that can only be amassed through experience – is required (e.g., Guinevere's assessment being stalled because of unfamiliarity with a potential test method, although this is probably due less to inexperience than the applicant's 'creativity').

Assessment Predicated on Arcane Knowledge

The amount of arcane knowledge required for even basic competence was evident in the bevy of lists of standards, processes, documents, keys, and so on compiled by newish assessment officers. To take but a simple example of the required

arcane knowledge, one had to know how to find the templates on the NHPD shared drive, required to do one's work. Although "the SOP has been dummy-proofed by adding in links" that could be opened by holding down the "control" key while clicking on the title –one had to know how to find the SOP in electronic form. With two hundred staff members saving documents with little guidance on the Directorate's shared drive, finding anything on the shared drive required pure memorization, or knowing, among other things, organizational subentities from the previous five years, the history of various projects, and the author of the document. (Using the "find file named…" function for the large shared drive was time-consuming, and, in my experience was often unfruitful because my computer would crash before the search was completed unless I already knew in which general area to search). Scientific staff corralled required work documents onto their "desktop" as files or shortcuts, or into their web browser as links; they pinned directions to find these documents on their cubicle walls; they placed them in file classifiers in arm's reach; they circulated them to their colleagues via e-mail.[3]

Assessment officers collected the numerous standards to be used in assessment in similar ways. For instance, one assessment officer kindly circulated "a few useful websites I have come across and some sent by [another assessment officer] for product licencing" – the "few" websites totalled 25. These were all links to standards: to standards for chemical nomenclature; to standards for botanical nomenclature; to standards for non-medicinal ingredients; to publications or decisions of other regulatory agencies; to common reference textbooks in

electronic format. Some compilations were more widely circulated because of the assessment officer's position or disposition to share with others; some were less widely circulated because they were relevant to only one type of medicinal ingredient (e.g., homeopathic medicines). One assessment officer had two papers, recto-verso, full of links, databases and passwords, instructions, reminders and so on that were required for her assessment work and to help orient new assessment officers. I reproduce the entities in her list below (although I reordered them in list form), because this list indicates the motley range of arcane knowledge required to work as an assessment officer in the directorate:

> [descriptions of the computer drives and their uses];
> [various logins and passwords];
> [her contact info];
> list of desktop shortcuts that should be created; to:
>
> - excel tracking (a tracking database)
> - standard lines
> - SEAR template
> - Workbook (where the SEARs were saved on the shared drive)
> - NHPD Library
> - Submission Co-ordinator
> - NHPSAS (a tracking database)
> - NHPD monographs
> - Monthly communiqués [sent by the NHPD to industry, contains decision summaries]
> - Assessment tools
> - Guidance documents
> - NMI [non-medicinal ingredient] master database
> - Organizational units in assessment
> - Internet explorer;
>
> [How to set e-mail signature]
> Links to:
>
> lists of non-medicinal ingredients.
> List of accepted uses.
> Draft monographs
> Attendance reports for HR [human resources] (for agency staff)
> The regulations;
> Standard operating procedures
>
> [IT contact for computer help]

[How to:
find the submission co-ordinator for a file
sending mass e-mail to bureau
submit a monograph issue sheet
track in NHPSAS]
[File naming protocol for shared workbooks]
List of resources and, where available, web addresses:

- Commission E Monographs
- WHO monographs
- Brinker's Herb CI & Drug interactions
- Herbalgram.org
- NMCD – natural medicines comprehensive database

Summary of relevant legal schedules

- Schedule A = list of conditions or diseases for which claims are prohibited
- Schedule B = international pharmacopoeia
- Schedule C = radiopharmaceuticals
- Schedule D = biologic drugs
- Schedule F = prescription drugs

Notes for assessment, for instance

- "No IRN Req'd" = nothing that would affect safety and efficacy, but notices
- check spelling 7.3, 2
- use health care practitioner rather than provider
- do a NHPSAS to locate a file # for an approved file, get file number, go to workbooks & compare my work to it before submitted SEAR to unit head
- [lists of what needed to be cut and pasted into the SEAR, and under which heading in the template]

For all the lists of useful standards and references, it was impossible to predict what standards would need to be considered in any given file, or what exceptions needed to be considered. Assessment work involved constant learning; one accumulated arcane knowledge with experience, there was no other way to accumulate the relevant standards, they were so uneven in type and unpredictable in relevance. For instance, quality assessment officers just had to learn, that for products with ginseng or nuts one must test for mycotoxins; for products with fish

oil and seal oil one must text for dioxins; that for creatine one must test for specific contaminants, and so on. In the comparative assessment stream (Compendial), assessment officers just had to learn to keep an eye out for certain chemicals (e.g., triclosan) that companies would repeatedly try to 'sneak' in as non-medicinal ingredients, in medicines in which they served a medicinal purpose and therefore the medicine did not meet the definition of a natural health product (and needed to be evaluated by scientists in another Directorate). New, arcane, considerations continually arose. Robin Marles, the Director of the Bureau of Clinical Trials and Health Sciences, explained in interview:

> I've learned a lot, no question about it, with every new file that comes through…. You never quite know where the day is going to take you, because all of the sudden, a new question comes up. Yesterday, it was a herbalist asking us about organic arsenic, as opposed to inorganic arsenic, in herbs, and so I had to try to find out a little bit more about the differences.[4]

A few assessment officers left the directorate, because they were uncomfortable with the level of arcane knowledge or expertise required of them, a level they did not feel they had. In the words of one former NHPD assessment officer:

> I was not comfortable reviewing product that had, until recently, been regulated as drugs, and requiring analysis of the blood uptake of the substance. I'm not an M.D. Other directorates have biostatisticians trying to figure this out, not people with a master's degree in a laboratory science. I could not answer questions like: is six months long enough? What is an appropriate end point? I did not have any guidance or training; it almost felt like I made it up as I went along…. In the end, I felt I did not have signing authority – there's no way. I did not feel comfortable in assessing, so I was not going to sign off.

I believe it was for these reasons that it was so difficult to characterize the evaluation process in the standard operating procedure (SOP) – how to extricate,

from such a multidimensional process based on the types of comparisons most comfortable for the evaluators, a generic, linear, describable process?

More fundamentally an oral culture, rather than textual culture?

At Health Canada, scientific regulators and evaluators are a highly, perhaps one could even say excessively, literate group – many of them spending most of the work day reading and writing. The product licence application is entirely textual. Evaluator's training begins with texts. The basis for assessment activities is textual: the *Regulations* and accompanying suite of policies and guidance documents. Many instructions for assessment activities – Standard Operating Procedures, templates. The "assessment" itself is a written report.

Nevertheless, within any scholarly medical tradition – if I can extend that phrase just a little to include the regulatory side of medical systems – there is the danger that researchers and scholars believe that the plethora of documentation is representative of practice (cf. Young 1995b).

Despite what first seems to be a culture of documents, of texts, many NHPD scientific staff essentially worked in an oral culture. When I observed experienced scientific staff, I was initially puzzled by their lack of interest in procedural documents. For instance, a trainer told me in my first week of work that I should consult my unit's record of decisions, but that it was never kept up to date (at that

point), because everyone in the unit knew the decisions. After many months in the field, however, I noticed myself developing the same disinterest in procedural documents: after six months, I rarely resorted to the procedural documents and lists that were indispensable to me in my first months of work. To some extent, this was because I had learned that documents were "living," and had realized that it was just as much effort to establish a document's credentials as it was to just find the expert and ask my question.[5]

To a larger extent, I believe my eventual neglect of procedural documents occurred because I had internalized the procedures, documents, and lists. Many textual standards, especially SOPs and other procedural documents, are perhaps best approached as learning tools for the uninitiated, as etiquette books – once proficient, and one understands who says what and when, they are of little use. Their contents had became "common sense."

Overview of remaining chapters in Part III

Through the remaining chapters in Part III, I describe the particularities of scientists' reasoning about the safety and efficacy of medicines according to separate procedural standards recognized by the NHPD: the Compendial (comparative) Assessment Stream (Chapter 6), the Traditional Medicine Assessment Stream (Chapter 8), and the Homeopathic Medicine Assessment Stream (Chapter 9). In each of those assessment streams, scientists used

particular types of textual standards as evidence of safety and efficacy. I use my discussion of each assessment stream to develop a cumulative argument. Chapter 6 argues certain sensibilities were developed by activities in comparative assessment. Chapter 7 provides a case study of an Issue arising in comparative assessment, and argues the Issue prevented routine reasoning by taxonomy and comparison and as such involved different sensibilities and affects. In Chapter 8, I detail how “traditional medicines” were, in the practice of assessment, turned into standards called “paradigms”; with this way of approaching traditional medicines, scientists did not bat an eye at medicinal ingredients such as “flying squirrel feces” but were very concerned with how to address change in the practice of traditional medicines. In chapter 9, I explain how ‘belief’ in homeopathy was irrelevant to scientists’ pre-market evaluations of homeopathic medicines; yet how all scientists involved in the evaluation of homeopathic medicines had to *act as if* they believed.

None of the assessment streams discussed here -- the Compendial, Traditional, or Homeopathic Medicine Assessment Stream -- was the imagined norm of assessment at the Directorate. Another assessment stream, called the “Non-traditional Assessment Stream,” was the norm of assessment as I will explain in the next chapter. Scientists reasoned in the Non-Traditional Assessment Stream similarly as they did in the other streams described in chapters 6-8, however, the appropriate standard of evidence was less predetermined than in the other assessment streams. In the Non-Traditional Assessment Stream, scientists were tasked with making a judgement based on “the totality of the evidence.” This

"other" assessment is the subject of the remainder of the dissertation, unless specifically mentioned.

---

1 Assessment in the compendial and pharmacopoeial streams was often presented to the public as comparative, however.

2 Liora Salter makes a similar argument based on her study of risk assessments in Canada, noting that formal organizational structures and process flow diagrams are highly sequential in a way that is often impossible for humans to pursue in practice so sequentially (1988: 176-7).

3 Occasionally documents did not circulate beyond their owners. For instance, one assessment officer I observed, Pink, had compiled issues with the quality specifications, because, she argued, "If I can think of how to organize it, it makes it that much easier." She had circulated it among her colleagues, but, she noted, she did not know if anyone else used the compilation:

> Sometimes you just have to go through the process and boil it down to its elements…. if other people do not understand it [the spreadsheet], then they need to do their own. Because sometimes what's needed is doing the process, so that you trust the document. When I've done it I trust it.

4 For readers interested in those differences, Marles continued:

> Plants can, to *some* extent, convert inorganic arsenic into organic derivatives. There are also organic derivatives that are very common in seawater, so marine organisms tend to have more organic arsenic. Organic arsenic is much less toxic than inorganic. Some organic forms are also used in pesticides, and so if the water or soil is contaminated with those pesticides, then plants will take some of that up as well … something I had to learn about yesterday! I have to answer this person's questions on Thursday in a meeting….

5 Although the procedural documents may seem generic, no activity or document in the Directorate was truly anonymous; it had a story, a pedigree. Electronic files had "guardians," and one had to know who these were if one were to do one's job proficiently (e.g., find out if the document is the most recent one). Tasks required in evaluation were tracked in multiple databases, and tracked by name. Even though there were tens of thousands of product licence applications, there were a limited number of companies, and so scientific staff would frequently speak of applications in terms in the applicant's name and affiliation, for example, "I have this feverfew file from Aiha Bee at Company Cea."

Binta stood in the entrance of my cubicle to ask me a question about a file. At the time she had been an assessment officer for only a few months. Immediately after asking the question, she added:

> There are just so many ways it can go wrong.
>
> It reminds me of childbirth. The more you talk to your friends – which I did after the birth of my daughter – the more ways you find out things can go wrong.
>
> It is the same thing with files. At first you think it is straightforward the licence, but the more you see and the more you talk to people, the more ways you find out that things can go wrong.
>
> So that is why I am asking you.

Chapter 6
Matching sensibilities
Scientists' reasoning through taxonomy and comparison

The Pre-Market Evaluation of Medicines as Conceptual Algorithm

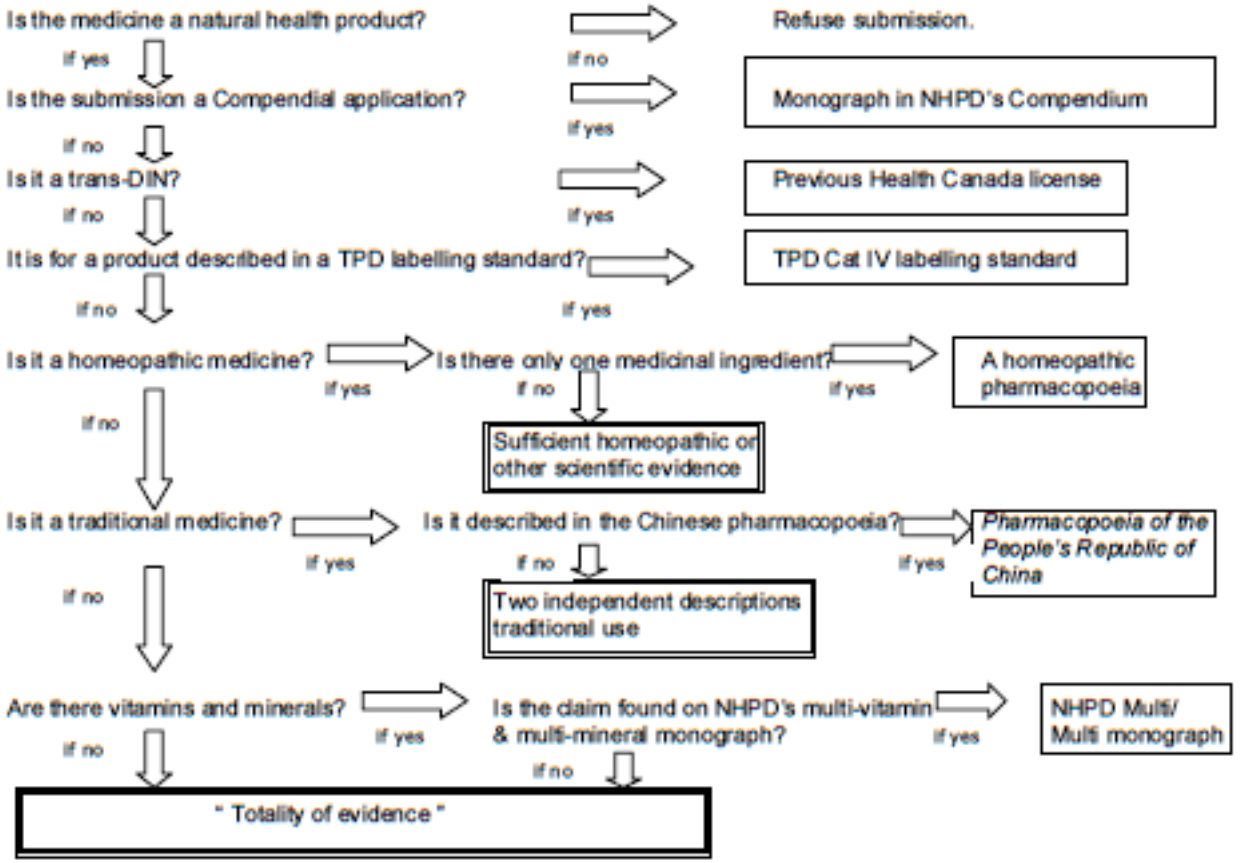
The way in which Health Canada assessed medicines, pre-market, was algorithmic, overall. This is entirely consistent with Weberian-style characterizations of bureaucracy. Health Canada's classification of a proposed medicine – as a natural health product, controlled substance, prescription-only, new chemical entity, or biologic – determined which of Health Canada's Directorates would conduct the pre-market evaluation. The determination of Directorate was simultaneously a determination of which legal regime (regulations and guidance documents) would apply, and as such, classification was not a low-

stakes affair (see Chapter 2). As Herzfeld observes, “much bureaucracy appears to consist of the management of taxonomies” (1992: 39).

Even when a medicine described in a Product Licence Application was classified as a natural health product, the NHPD continued classifying the medicine into subcategories. Based on a series of questions answerable by yes or no, each Product Licence Applications received at the NHPD was channeled into an Assessment Stream. In different Assessment Streams, scientists considered different evidence and standards for the quality, safety and efficacy of proposed natural health products.

I came to visualize a giant flow diagram,[1] in which the files got sorted into finer and finer groups, and then, depending on final grouping, were “assessed” according to the appropriate procedural algorithm.[2] Figure 6-1 provides my characterization of NHPD’s overall diversion of Product Licence Applications into subcategories for the purposes of assessing safety and efficacy. At each stage in this algorithm, the scientists’ decisions determined the evidentiary standards required for subsequent reasoning about a medicine’s safety and efficacy (in Figure 6-1: boxed).

Figure 6-1: Overall algorithm determining standards or totality of evidence to be used in premarket evaluation of medicines, as characterized by anthropologist



The moment a Product Licence Application entered the government directorate, scientists decided whether the medicine described in the Application was a natural health product. If no, the application was refused, because there was no evidentiary standard that the NHPD could apply. If yes, the application had to be channelled into an assessment stream. The first question was: is the application in the Compendial Assessment Stream? If yes, scientific staff needed to begin assessing the file within days because the NHPD was legally required to provide or refuse a licence in 60 days. With Compendial applications, the applicant attested that his or her product met the specifications for a medicine described in the NHPD's *Compendium of Monographs*; safety and efficacy was assumed if the medicine described in the Product Licence Application corresponded to a monograph for a medicine included in the NHPD's *Compendium of Monographs*. The assessment in the Compendial Assessment Stream was characterized internally as a "comparative process" and was a matter of verifying this correspondence between a singular standard (indicated by one box in Figure 6-1) and the proposed medicine. If no – the Application was not Compendial –move onto next question. And so on.

There were six main assessment streams at the NHPD, each with their own evidentiary standards.[3] These streams were formally listed on the Product Licence Application form as: "Compendial," "Traditional claim," "Non-traditional claim," "Homeopathic," "TPD Category IV / Labelling Standard," "Homeopathic DIN," or "Transitional DIN."[4]

Several streams used singular standards created by regulatory bodies. The most comparative of all assessment streams, the Compendial Assessment Stream, used the NHPD's own monographs in the *Compendium of Monographs* as evidentiary standard. Medicines to be "grandparented" were compared to standards previously accepted by Health Canada such as previous licences (DINs, therefore called the trans-DINs), monographs, or labeling standards produced by the Therapeutic Products Directorate (called TPD Category IV / Labelling Standard). Other countries' regulatory standards such as the *Pharmaceopoeia of the People's Republic of China* and the German homeopathic pharmacopoeia were used as evidentiary standards in the Traditional and Homeopathic Streams.[5]

Textual standards created by non-regulatory bodies, such as the *Encyclopedia of Homeopathic Pharmacopoeia*, and certain types of information on vitamins and minerals produced by the US American Institute of Medicine (IOM), were also used by assessment officers as regulatory standards.

The "Non-traditional Assessment Stream," the sixth stream, was the none-of-the above-category. The majority of applications received at the NHPD were assessed in the Non-Traditional Stream, and the majority of assessment officers assessed files in the Non-Traditional Assessment Stream. In general, the evidentiary requirement for Product Licence Applications in this Assessment Stream was the totality of the evidence. During the time of my fieldwork, applicants frequently had

difficulty providing appropriate evidence in this stream. By the end of my fieldwork, there were at least 479 applications that had successfully aligned evidence with their claims in the Non-Traditional Assessment Stream and that had been issued licences.[6] This success, however, was not the rule: more than three thousand other applications in the Non-Traditional Assessment Stream had been withdrawn or refused. I occasionally completed assessments in the Non-Traditional Assessment Stream.[7] My fieldnotes after working on one such application, for a medicine with ashwagandha making the claim "use to rejuvenate," are fairly representative of my experience with many files in the Non-Traditional Assessment Stream:[8]

> There is no evidence in the file; I can see that right away. But then it takes forever to write up. Today's was 2 hours to do the SEAR [Safety and Efficacy Assessment Report], for something that took about 10 minutes to realize there's no evidence.
>
> When I first approached the file, I had paperclipped the Evidence summary report, then the first page of each study [for ease of page flipping]; I read the abstract, and eliminated the study as evidence as soon as I read that the study was
>
> > (1) on animals
> >
> > (2) *in vitro*
> >
> > (3) a crappy publication (e.g., not peer-reviewed; or consisting of reviews or commentary, not actual studies).
>
> But then I ended up having to read the reviews even though they were in [a journal that, supposedly, was the mouthpiece of a business to the extent that *all* the ads were for a certain company and its subsidiaries], because I could not outright say it was unacceptable. And then, because these reviews made mention of human studies, I had to review evidence types 1-3 because while those types of evidence are unacceptable on their own, they can support human data. So I had to skim through the reviews for claims

> pertaining to rejuvenation, which was the label claim for the proposed product. In one review, there was a mention of a human study of 101 men aged 50-59 (Wow! Real live humans, in large quantity, if a little constrained in the demographic) that found increased reported sexual performance. Great! But the leap between enhanced reported sexual performance and rejuvenation is a case that the applicant has to make and support, not me; and I'd need a report or publication of the actual study results themselves, not a review of that report. So off goes an information request notice.

While I was working on the ashwagandha file, a colleague dropped by my cubicle, and listened to me rant about the type of evidence included in the file. In solidarity, my colleague Dorrie expressed a desire to give a presentation to applicants, explaining what 'evidence' was not:

> Dorrie: I want to sit them all down and give them a presentation about what research is … and say, this is not it! No websites! …. But I just don't think they'd care
>
> Jennifer: the one [submission] here [on my desk] actually managed to include some excerpts of reputable journals – like the *Journal of Ethnopharmacology* – but what the applicant included was the "Commentary" [section, which is not peer-reviewed].
>
> Dorrie: [looking at submission number of the file on my desk, which belies date submitted] But I've heard the recent ones are getting better ….
>
> Jennifer: I don't know about that. The one I have here is super recent and from a major company. I mean, they just sent in the evidence last week because they reclassed out of Compendial. And it is the same thing/
>
> Dorrie: Don't tell me that! I had hope, that was sort of the light at the end of the tunnel [that more recent applications, not usually seen by those in Non-Traditional Assessment, included better evidence]
>
> Jennifer: [rubbing it in] And no studies, or at least none relevant to the claim.
>
> Dorrie: I had one [submission] with two binders [of evidence]: it makes me so upset. The most basic matching, you know [was missing]: dose, subpopulation, constituents… even medicinal ingredient!

I hope these accounts convey to the reader why, at the NHPD, the most favored assessment processes were the algorithmic paths ending in the comparison of the proposed medicine with one clear regulatory standard. When possible, new standards were created or incorporated to increase the number of applications for which this type of reasoning by comparison could be applied: new monographs were written, new assessment substreams created, and more internal documentary standards developed. In the Non-Traditional Stream, even if the applicant had not included the following standards in the application, the scientist was able to use, whenever appropriate, regulatory monographs and other textual standards generated by Health Canada (such as NHPD Monographs, TPD LS and CAT IV Monographs) in his or her assessment as a "totality of evidence." For the organization, the more comparative the reasoning, the more ideal (efficient, accurate) the judgement. This algorithmic approach can be considered "the ordering of variety by comparison and taxonomy," one of the "styles of scientific thinking in the European tradition" detailed by A. C. Crombie (1994).

Classification and incommensurability

There was a way in which, for NHPD scientists, there was no "efficacy" outside of the classification of a proposed medicine into a particular Assessment Stream; the classification determined the evidential standard for efficacy (provided the product described in the Product Licence Application matched that described in the

standard). Because there were such clearly different textual standards in use in each assessment stream, there is a way in which the efficacy of differently classified medicines was made incommensurable in a literal sense. While this is true, one could also argue that these medicines were, at the end of the day, made commensurable because they were all the objects of either product licences – and NPN numbers[9] – or refusal notices. These are both, to some extent, theoretical arguments. As I will describe in Chapters 10 and 12, there is a way in which these differently classified medicines were simultaneously maintained as commensurable and incommensurable in the workaday world of scientists. This simultaneous commensurability and incommensurability is indicated by a widely-circulated table in the Directorate; although the number of submissions in each Assessment Stream was counted under separate header, they were all totalled in the end.

Figure 6-2: Product Type Numbers from "Product Details" August 16, 2007[10]

Product Type	Total number of submissions received at NHPD	Total Complete	Total Licenced (already included in "Total complete")
Homeopathic	**1 111**	**343**	**172**
Traditional	**3 619**	**1 274**	**146**
Non-Traditional	12 129	3 770	479
TPD CatIV LS	789	388	241
Transitional DIN	1 330	453	98
Unknown	20	18	0
Compendial	**3 231**	**2 941**	**2 555**
Total	22 229	9 187	3 691
Total possibly involving non-science paradigms	**6 346**	**3 088**	**1 596**

Any commentary by the Directorate's scientists on incommensurability was largely theoretical, and tended to be voiced only *in interview* by scientists, especially when conjecturing about the types of medicines evaluated in Assessment Streams in which the scientists did not work. This commentary also mostly pertained to the NHPD's *processes* not the medicines or efficacies themselves; I will describe most scientists' non-essentialist approaches in Chapters 8, 9, and 12.

The interests of the scientists in their capacity as workaday regulators was primarily practical. The day to day reasoning, as Evans-Pritchard (1976) characterized as similar phenomenon, was "imprisoned in action"; while scientists could and did comment on commensurability (although often not in so many words), this did not necessarily reflect their reasoning-in-action. One activity of practical importance in the regulatory style of scientific reasoning in the Directorate – and that is of relevance to my consideration of incommensurability – was the most appropriate way to group files for assessment.

The remainder of this chapter is as painfully dull as it is crucial to my argument that scientists' activities in the pre-market review of medicines changed their (my) *notice* of safety issues, and interpellated the scientists into certain affective dispositions towards files. Sociologists Bowker and Starr identified barriers to the exploration of classification systems, and

> [n]ot least among them is the barrier of boredom. Delving into someone else's infrastructure [classification systems] has about the entertainment value of reading the yellow pages of the phone book. One does not

> encounter the dramatic stories of battle and victory, of mystery and discovery that make for a good read. (1999:321-322).

Grouping Files

Files: Regulatory Scientists :: Planes: Air traffic controllers

The four-level process (L1-L4, described in Chapter 4) provided conceptual direction for the files moving within and among cubicles. With the exception of the Director General – who, I assume, would only have encountered a file in the final level (Decision, L4) – many other staff, especially scientific staff, had files in various levels in their cubicles. Submission Co-ordinators, for instance, were responsible for processing files in the second level, as well as coordinating files in the third and fourth levels; they also completed other cross-level tasks on a rotating basis such as classifying medicinal ingredients, "troubleshooting," and creating batches at various levels. In the Compendial Stream in which I worked as scientific regulator, it was crucial that scientists keep track of the exact stage of each file because the NHPD only had 60 days in which to make a decision to issue or refuse a licence.[11]

Independent of position and Assessment Stream, all the Directorate's scientists had clearly delineated piles of files in their cubicles – on desks, in filing cabinet drawers, on chairs, in boxes and classifiers, even occasionally on the floor – to keep track of which files were moving from where to where in the conceptual levels and streams. The organization was largely idiosyncratic. One of my supervisors took an archaeological approach to the piles of files around her cubicle – she

always started from the bottom of piles, knowing the files must have been there earliest. When I asked Hildegaard, another Unit Head, *How do you manage so many files?*, she replied:

> I try my best. I divide files by AO [Assessment Officer].
>
> Some [files] are more urgent and go on top, to prioritize what to go through. Sometimes [I do] files I just have to sign off – if they have [been] peer review [ed], it is faster.
>
> I always read every report. For some AOs, I know they do not have major issues, to varying degrees, depending on how much the AO knows. Every IRN going out gets read – even the most senior AO – to maintain consistency.

The specific purpose and manner of organizing files varied widely. These piles were mostly created for one of two general purposes: (1) to serve as an external reminder of the next task required in assessment (the level and stream) to facilitate the smooth flow of files in the assessment stream; and (2) to promote consistency in the assessment of similar files.

Grouping as aid in assessment

For this second purpose, the promotion of consistency in reasoning about similar files, scientists generally created subject-based subgroups to assist them in their assessment (e.g., a pile of ginkgo extract files, or a drawer of files with weight loss claims). Scientists also created applicant-based subgroups (e.g., a pile of applications from the same company).

Sometimes the creation of subject-based subgroups was done formally. In the Non-Traditional Assessment Stream, there was a submission co-ordinator tasked with batching or “triaging” applications for recurring medicinal ingredients. The idea was that this batching would permit an assessment officer to assess all the files together, and then at the end of the assessments, on the basis of the (published)[12] evidence submitted with the files and other research s/he would write a NHPD Monograph for the medicinal ingredient. This not only promised an additional regulatory standard; it also increased the perception of consistency in approaching similar files.

Sometimes this was done informally, with scientists creating their own batches among the files they had been assigned, or two scientists transferring files between one another to create batches. Often this could not be done in terms of physical files, because most assessment officers had little control over the types of files they were assigned to assess. Instead, assessment officers moved the file’s electronic avatars into virtual piles, for instance by organizing files according to colours in file tracking spreadsheets.[13]

Scientists’ assessment-oriented grouping was not limited to applications to be assessed: scientists made piles of textual standards. In the course of my duties and through research-related observation, I had many glimpses into the way other people worked. What never ceased to amaze me were the number of ways scientists appropriated documents and made their own compilation of templates,

standard lines, and so on. For instance, one officer had his own templates on his personal K:/ drive, with different correspondence notices ready-made for different types of products he frequently encountered.[14] These compilations, the scientists felt, not only made them more efficient but also consistent in their assessment of the sort of files they encountered. As I described in my observation of Guineviere's assessment of a homeopathic medicine, by looking through a compilation of files she had previously assessed, she had found a previous assessment she had done for a medicine proposed by the same applicant; she then copied and pasted text from that previous assessment because of the similarity. Sometimes the compilations were centred on medicinal ingredient, other times on company, and other times on substreams of assessment. Some assessment officers created apparently unthemed documents for textual statements they frequently used or that were counter-intuitive and therefore they needed to remind themselves; these documents served solely as fields to be mined for text for subsequent files, the mining conducted using control+F shortcuts to find key words. Some of these idiosyncratic documents were dozens of pages long. Occasionally these variant standard texts were shared among a unit's scientists. Other times they were incorporated into the official standards of the NHPD's science-heavy Bureaux. In any event, I mention these variant standard texts to make clear that the existence of a formal algorithms and classifications do not lessen the need for informal classifications required for everyday action:

> We have certain knowledge of these intimate spaces, classifications that appear to live partly in our hands -- definitely not just in the head or in any formal algorithm. The knowledge about which thing will be useful at any given moment is embodied in a flow of mundane tasks and practices and many

> varied social roles (child, boss, friend, employee). When we need to put our hands on something, it is there. (Bowker and Starr 1999:2).

Flows, groups and directed perception

This description of the omnipresence of mundane and insignificant grouping is crucial to my later discussions of scientists' directed perception or notice. Even though this grouping was often idiosyncratic, the omnipresence of the grouping is the crucial point. Any individual file (Product Licence Application) was only one among many in the flow of files through the process, as a (temporary) member of a group, rather than primarily perceived a unique entity.

Scientific staff tended to give a file to unique consideration to an application only when some mitigating circumstance or "issue" ejected the file from the regular flow of files.[15] Even then, however, it was not the file itself that was the focus of scrutiny. Scientists' attention was directed towards the issue that precluded the file's smooth sailing through the appropriate levels in an Assessment Stream, rather than the file itself. I will return to Issues below.

Assessment in the Compendial Assessment Stream

Scientists' reasoning was, overall, predicated on a comparison, although in the assessment of safety and efficacy the baseline standard in the comparison varied. Throughout Part III Textual Standards, I move from NHPD's original comparative approach – Compendial Assessment, described in this chapter –through other

comparative approaches in Traditional and Homeopathic Assessment Streams, to the Non-Traditional Assessment Stream that was conceptualized as non-Comparative although scientists readily brought in a variety of textual standards. In each case, for comparison to be possible, much had to be standardized.

Assessment in the Compendial Assessment Stream was the most straight-forward "comparative assessment." In the Compendial Assessment Steam, there was only one possible standard for safety and efficacy: a monograph published by the Directorate itself. If a proposed medicine and its labeling met the Directorate's own standards – the medicine got licenced within 60 days of the original application, barring mitigating circumstances.

Assessment in this stream seems straight-forward, and it was – or, at least as straight-forward as any comparative activity. Reasoning through comparison and taxonomy is often straight-forward ("anyone could do it") *once the world is arranged for the comparison*, and only until there is an *issue*.

For instance, the processing of Trans-DIN applications (in another assessment stream) was supposed to be so purely comparative that it would be purely administrative – because Health Canada had already issued a licence for the marketing of a health product (a DIN number), these product were to be grandparented using the old licence as the standard of safety and efficacy (claims), but also taking into consideration the new regulatory regime which had specific

requirements such as labeling of non-medicinal ingredients, for instance. When I worked on a batch of these medicines, however, there was a major hitch: several labels for these already-marketed products did not correspond to the conditions of their licence: there were different claims, ingredients, and so on, not featured in the original licence. The comparison was not possible because the world had not been sufficiently arranged for the comparison; the process had to be refigured.

I draw primarily from my own experiences for the remainder of this chapter because I worked in the Compendial Assessment Stream for a year.

Forms in compendial assessment

When I began work in the Monograph Management Unit, my initial assessments of medicines were structured by a checklist that a more experienced assessment officer had kindly prepared.[16] The Compendial Submission Checklist walked me through the steps I needed to complete in my assessment; it included everything from how I should order files from Central Registry, to how to track the file in a myriad of electronic databases, and when I should consider certain brand names misleading. This checklist was literally an algorithm. For instance, step 8a was "Is a brand name provided" on the Product Licence Application form – if yes, I needed to input the name into a database and proceed to step 8b; if no, I needed to "outline this deficiency in IRN, [then] proceed to step 9." There was also a Labeling and Packaging Checklist, that I needed to also use after using the Compendial Submission Checklist if it looked like the medicine might be licenced (e.g., without

too many deficiencies). The algorithm, at each step, provided a clear rationale for the legal (regulatory) basis for each step.

As a new employee, these checklists were invaluable. They scaffolded my learning the job. After a few weeks, I tired of using the long “Compendial Submission Checklist” document with all its regulatory justification (which I had mostly internalized), because it was difficult to glaze over the regulatory rationale without also glazing over the subsequent checklist step. So I created a 45-page “unofficial shortened version” of the Checklist for my use, so I would not get sidetracked by all the regulatory explanations I no longer needed. After a few more weeks, I decided that it would be better to have a printable version on which I could actually enter checkmarks into boxes, to make sure I did not miss a step; so I created a one-page (recto-verso) checklist consisting of the section headers of the original document; essentially, I knew what I needed to look for in each section, but I still found the use of the checklist handy for thoroughness.

As time progressed, an increasing number of activities and algorithms in the original checklist became, quite literally, habit. While my way of proceeding my have been idiosyncratic, the development of habit through some means was not.

When my assessments were first peer reviewed I was shocked when the peer reviewers did not actually read through the entire draft Information Request Notice I had prepared; they skipped over all the material in the generic template – even

generic material in the individual Standard Lines – to get to “the deficiency,” to ensure that I had noticed and correctly addressed any deficiencies in the application. When I made a remark about this, a peer reviewer stated that she doubted the experienced applicants read the top and tail of the Information Request Notice, either. I, on the other hand, had to read all this information to because otherwise I could make neither heads nor tails of what was going on. It was not until my thirteenth week that I wrote in my fieldnotes that I felt much less overwhelmed – that because I knew where to look for things and what exactly I could ignore (because they were invariable), and so it took much less time to be precise. By the thirteenth week, to some degree, I had sufficiently learned the forms of regulatory assessment.

A few months into the job, I had asked an experienced assessment officer in my unit if I could watch her do an assessment, because she seemed so thorough without using a checklist. Her method involved using the categories in the Product Licence Application (PLA) itself to scaffold for her reasoning activities. She would go through each entry in the PLA form, making sure it was appropriate and, where required, ensuring a match to both: (1) the entry on the NHPD monograph, and (2) the label statement. (This involved much flipping of pages.) She noted any deficiency on a regular letter-sized piece of foolscap: deficiencies in the PLA in a column beginning on the top left hand side of the paper, and deficiencies in the label as a column beginning on the top right hand side of the paper. She wrote the daily dose, notes, and any required calculations on the bottom half of the foolscap.

After she had gone through each entry in the PLA, comparing it to both the monograph and label, she did a final label verification: she grabbed a list of label requirements (according to the regulations) off her cubicle wall and made sure that each element required on the label's principle display panel or elsewhere on the label was present. (There were a few items required on the label that did not correspond to a section of the PLA form). She then numbered the deficiencies on her foolscap paper, and moved to her computer with her foolscap paper to write up the Information Request Notice. From that point on, I used her method. I am unsure why I had not previously thought of doing assessment using the PLA form itself as my 'checklist'; or why the spatial organization of notes on a piece of foolscap paper made such a difference, but it did.

At this point, the Product Licence Application form – the one that I was assessing – became the implicit checklist ensuring my thorough consideration of each element I was required to consider in the application; depending what I had written on the foolscap, I knew where I was in my assessment, and at the completion of the process I had the application's deficiencies to be communicated via standard lines enumerated, and that I would later type up on the computer.

This way of approaching the assessment of a proposed medication would not have been possible when I first began work. This way of approaching the file required *already* knowing what to look for, where and why; and, conversely, what text could be assumed to be invariant and therefore ignored.

Tailoring of eyes, actions, sensibilities

In any competent comparison, one needs to know what to compare. In this case, it required knowing where to look. Before I knew where to look, everything was overwhelming: from the *Regulations* with the 115 clauses in legal jargon, to the multi-page Information Request Notices templates, from the gigantic Standard Lines document, to finding the French equivalent of English-language scientific and regulatory terms.[17] But four months in, I knew where to look, and in each location, what I might be looking for. I had internalized the checklist including the regulatory rationale for each comparison. I had spoken with many peers and begun learning what I should be looking for: the "so many ways it can go wrong," to use Binta's words.

This incredibly boring account of my wielding of various checklists, and how it changed over my first months of work – from my dependence on a fifty-page checklist to my use of only a blank foolscap – is a story of the tailoring of notice. I will return to this in a moment.

The checklist imperative and impossibility

My colleagues expected a fully accurate ("perfect") assessment before the application reached the final level of the process (Decision, L4). These colleagues, however, did not expect perfection in any one individual's assessment. As one of

my peer assessors explained, it was “not that we do not trust people, but everyone is human.” The assessment process in every stream, including the Compendial Assessment Stream, required an inordinate amount of concentration and attention to detail. I was useless as a scientific regulator the morning I went to work without having eaten breakfast, and in the days following the death of a family member; I even noticed an increase in silly little errors when I was angry. The extent to which these comparative reasoning activities required a well-rested and well-fed body was readily admitted by scientific staff:

> Naavah: I can’t do [a peer review of] the tricky one [file] today because I didn’t sleep well last night and I am really out of it today.
>
> Zahra: I’m going to take my personal day tomorrow because I can’t work in this heat (it was summer, and the air conditioning broken) on these files because requires so much attention to detail.

One of my colleagues liked the work but missed the sociality of a previous lab environment:

> As opposed to in lab, where [I was] working with my hands, and didn’t need to concentrate, and could talk/ But this sort of work, there’s no time for that. Your work is just being concentrated, right, and reading, so.

New assessment officers had their assessments peer-reviewed, and then examined by the Unit Head before her signoff. Experienced assessment officers had their assessments reviewed by the Unit Head at a minimum. More experienced assessment officers would often ask a colleague to peer review more complex files, such as files with a dozen or more medicinal ingredients, even after

peer review was no longer required. Assessment officers extolled the benefits of having "another pair of eyes" examine files.

> And even though I might look through an application and actually do it three times during the review process, I might miss the same thing, three times.[18] Because I'm only human, I'm under a lot of pressure to do a lot of applications, and [so the unit head] is definitely that quality control at the end of the line.

The same assessment officer continued:

> And even though I very rarely get anything back from [the Unit Head] – I'd say 90% are fine – and if anything, it is that I forgot to sign the label because I'm in such a hurry just to get them on [the Unit Head]'s desk...
>
> But then again, [the Unit Head] is only aware of what she's been made aware of. And things like [certain Issues], it is not something that we have internal guidance for. Actually, we do have internal guidance [textual standard or record], it is just something that we've been told is no good.

Comparison was fallible not only because of the humans conducting it. Even with my tailored notice, and at least one other pair of eyes, although checklist-based comparison is all good and efficient, if one is unaware of a mitigating circumstance that makes a particular comparison non-obvious, one might make the wrong decision. And then there are also the cases in which until one cannot make a decision yes or no in checklist-style reasoning.

When insufficient expertise to make yes-no decision

Checklists were not only featured in the Compendial Assessment Stream. During my fieldwork, there was a period of time during which staff hired as biologists (safety and efficacy assessment officers) were asked to complete the Quality

Assessment Report, which had previously been completed by staff hired as chemists, and who tended to have some experience with or at least awareness of manufacturing processes. In a lunchtime debate among biologists over their ability to assess quality, one biologist scoffed, saying –"it is simple – we go down the list, just checking whether everything is there, yes or no." Another, however, explained she found it so complicated, with flow diagrams of the manufacturing processes; the scoffing biologist, it turned out, had not yet encountered a file requiring consideration of anything other than whether a test result was less than the maximum allowed (on a checklist). He no longer seemed so confident. Reasoning by comparative processes is simple, in some cases involving literally entering checkmarks on a checklist – until – and I am not being facetious here – it is not simple, because the application does not meet standard, or it is unclear whether it has any relation to the standard. When it is not simple, the comparison must be rearranged, or another level of expertise is required – whether or not it is just a checklist that is being completed.[19]

Sameness and difference in yes-no decisions

Let me return to assessment in the Compendial Assessment Stream, in which the proposed medicine's dose, directions for use, claims, and so on had to correspond to that described for the medicine in a NHPD monograph. This is, at first glance, easily checklist-able.

The applicants in the Compendial Stream did not need to have the label claims for their proposed medicine correspond *word-for-word* to the claims on the

monograph. “Statements to the effect of” the monograph entries were permitted. This required perpetual judgement regarding whether a discrepancy in wording changed the meaning of the original statement. Most judgements were routine to the assessment officers. When they were not, they often became little “issues” and, in those points of uncertainty, staff tended to informally consult their peers or supervisor. Sometimes the issues could not be resolved and required more extensive work: these became Issues.

One common type of issue was the minor discrepancy between Product Licence Application Form and monograph in such statements to the effect of that required an investigation of evidence that supported the statement in the monograph. For instance, while I was still using the checklist, I was unsure whether, for a particular medicine, the proposed directions of use “boil for 15 minutes” could be considered equivalent to the monograph’s directions of use – “pour boiling water over herb and let sit for 15 minutes.” For some plants overboiling might impact safety and efficacy; for others not. For small discrepancies such as these, which could be solved by more knowledge, the most expedient approach was often to consult the expert, in this case, the writer of the monograph. (Which I did in this case, and found out that with the particular plant the preparation did matter).

Other minor discrepancies were a matter of individual judgement, not really calling for scientific expertise or knowledge. As I was walking down a hallway of cubicles, one of my colleagues, Brandon, called me into his cubicle. He pointed to a

response to an Information Request Notice he had just received. In the Information Request Notice he had sent a month prior, he had explained to the applicant that, because the applicant wanted to make a traditional use claim, the medicine had to be taken as an infusion, not what the applicant had originally proposed, a capsule. (Traditionally, the plant material was not eaten). The company had faxed back a revised Product Licence Application form – not changing the dosage form "capsule," but instead altering the directions of use to: "put the contents of eleven capsules in hot water & infuse for ten minutes."

> Brandon: We're not going to accept that!
> Jennifer: Well, I guess if they put the contents of 11 capsules in the cup and infuse, why not? It seems stupid – and who would buy it? – but that is their right, to be stupid, no?
> Brandon: Yes, but these capsules are not even ones that you can break open. You'd end up with some sort of gooey mess. *Not* an infusion.

In many cases these discrepancies – the almost, but not quite matches – were due to constraints in the company's manufacturing or the company's inability to provide evidence for the type of finished commodity they were importing. Sometimes, in the Compendial Assessment Stream, companies would explain why the product could not meet the monographed standards; these rationales were sometimes valid and taken into consideration.

In other cases, especially with higher-grossing medicines, the discrepancies between monograph and proposed medicine were due to the applicant strategically pushing the envelope for their market segment gain. It was no unknown for applicants to ridicule the NHPD's judgement when the judgement was not in their favor, presumably in the hopes that this would result in a decision or judgement in

their favor. For instance, an applicant once was so frustrated with my judgement and science-based rationale for why I would not consider his claim “Enhances the human fatty acid profile” a statement to the effect of the Fish Oil monograph’s “Helps maintain / support cardiovascular health” and “Helps to reduce serum triglycerides / triacylglycerols,” he resorted to name calling – calling me a bureaucrat. (!) With larger sale products like fish oil, there were so many applicants trying to push the envelope on the monograph’s claims that the units’ scientists had an extensive e-mail debate over acceptable statements (to stay consistent among officers) which ended in a consultation of an internal expert, the “fish oil queen,” whose “noble (yet humble) opinion on the state of the evidence regarding your discussion,” was the following:

> SEO = "Statement to the Effect Of"
> "cardiovascular" is a SEO "heart and blood vessels"
> "cardiovascular" is a SEO "heart"
> "cardiovascular is a SEO "blood vessels"
> "cardiovascular" is NOT a SEO of "circulation" (implies blood pressure […])
> "triglyceride" is a NOT a SEO "cholesterol"
> "triglyceride" is NOT a SEO "blood lipids"(as there are a bunch of them and fish oil does not lower them all)

She also argued that following would all be acceptable verbage for cardiovascular claims for fish oil:

> "support health of"
> "maintain health of"
> "for the good health of"
> "promote health of"
> "enhance health of."

(Although a second e-mail followed the first, with “Okay, okay. Scratch out "enhance health of." Second thoughts on that one - that's pretty strong.”)

Sometimes there was no expert resident at the NHPD, or the discrepancy was not resolvable through scientific expertise. For instance, faced with non-official language text (but that we could read) that was clearly against the regulations: did we just need to verify the regulatory requirements in French or English on the proposed label? Or did we have to act as label police and call applicants on the other promotional statements they included as extraneous information on the label and that possibly contravened various laws? In these cases, the "issue" was assigned to someone in the unit to investigate. There were so many decisions on interpretations such as these, that the unit had an entire process of input e-mails, minute-keeping and, when the decision was approved by the unit head, inclusion in the unit's Record of Decisions database or Standard Operating Procedure.[20]

There were so many possible discrepancies between the monograph and the proposed medicines' labeling – for instance, could the statement "healthy heart" be on the main panel of the label if the full claim were elsewhere on the label? – that there were several mantras for simultaneously deciding and rationalizing whether a discrepancy was worthy of the scientists' attention, or could be dismissed as irrelevant. During my fieldwork, two mantras in widespread use in the unit for such decisions were: (1) "If it is an issue of science, deal. If it is an issue of marketing, it is not our business"; and (2) "If it doesn't affect the safety and efficacy of the product, we let it go." Therefore, the 'healthy heart' question was answered in the

affirmative, because, it was simultaneously reasoned and rationalized, it was a “marketing,” not a “science” issue.

Mantras such as these were in widespread use among assessment units. As sociologists Bowker and Starr point out, "[a]n anomaly may be acknowledged, but be too expensive -- politically or bureaucratically -- to introduce into a system of record keeping" (1999:12). One supervisor recalled that she had to learn to let go of “issues,” especially compared to the early days of the NHPD, when “everything was an issue.” It also helped, she said, knowing the approach of management: *is it a safety concern? No? Well then it goes through* [and got licenced]. She began realizing that she could fight a bit and go a certain distance but then had to “let it go within reason”; and, she continued, she saw their [management’s] point:

> If there is an issue with safety, there is a problem. If the issue is with efficacy, it has to be dealt with. But other than that…. One has to let go.

Sometimes there were “issues” that affected assessment in more than just one unit. These were often encountered though unexpected juxtapositions – by chatting with scientists in other units, for instance. By chatting with a quality assessment officer, a compendial assessment officer discovered that in the Non-Traditional Assessment Stream, the specifications sheet for proposed fish oil medicines included specific stability tests for oils; but these additional tests were not in the Compendial Specifications to which applicants in the Compendial Assessment Stream attested. These matters of consistency were sometimes dealt with simply

by assessment officers in one unit deferring to, and assimilating, the expertise or standards used by the other.

There were many other issues, however, of relevance to medicines described in applications that were evaluated by many units. The decision therefore had to be taken by a manager, director or management committee overseeing all those units. There was a specific chain of meetings – beginning with the regular "PLA Issues meetings" of all Unit Heads in product assessment, possibly followed by meetings up the organizational hierarchy if the issue were not resolved. In some cases, the decision on an issue was taken by even higher management. Resolving some issues was quite a challenge, because they involved legal issues, or even other Directorates within Health Canada. During my fieldwork, two ongoing issues related to BSE and Schedule A. As Emmanuel explained,

> On those issues, it was continually a matter of not knowing what to do; there were always people working on that issue whether science or policy.[21] It takes time to get the right science to do policy, and people do not always realize that. Not that anyone was dragging their feet, but policies take time.

During the time when the upper echelons were making the decision or policy, the files for which a clear comparison or determination could not be made due to the Issues under discussion, would be "halted." The assessment could not continue of the proposed medicine, because a decision could not be made one way or another. The applications were "stuck" in the flow of files through the four-level process.

At the beginning of my fieldwork, I had pinned a sticky note on my cubicle wall reminding myself that assessment was halted for Compendial stream applications with any of the following ingredients: feverview, valerian, calcium, cornflower, melatonin from bovine pineal gland, lysine from bovine blood, and anything from bovine bones. Towards the end of my fieldwork (on June 11th, 2007), I included in my fieldnotes a list of the reasons that nearly 300 files were halted until an internal decision was reached.[22]

Many scientists found this 'halting' frustrating, because as a rule scientists were committed to getting their assessments done, and files could be halted indefinitely. One assessment officer, Pink, had to get the halted files out of her cubicle: "I had 100 files on hold [halted]– I took them to CR [Central Registry]. I do not like being stuck. If I am, I often cover it [the file] up with something else." Scientists strategized about how to get management to make the decisions that were required, when the issue was not a science one; for instance one manager decided that, to elicit a decision that did not seem forthcoming from upper management, that a file should "be brought up to level 4" (recommendation), because then, the pending issue would have to be dealt with by upper management (i.e., at level 4 the file sits "halted" on the director general's desk, not the desk of scientists in assessment units).

Issues

In sum: the inability to make a comparison was often characterized as an “issue.” Little issues were often solved informally by consulting with experts, or more formally by asking the Unit Head to make a Decision. These little issues compelled the scientist or manager, as a minimum, to rationalize their decision. The inability to make a comparison, even with expertise (inherent or via internal consultation), created “Issues.” These Issues can be imagined as log jams blocking the flow of files through the assessment streams. The blockages often required time to unjam, and the successful procedure for doing so was unpredictable to some extent. Although different strategies for approaching Issues were fielded, solving Issues often required unpredictable courses of action under uncertainty, and sometimes unavailable, or unattainable (because the knowledge area did not yet exist), expertise. Sometimes instead of undoing the logjam the flow of files was simply redirected: some upstream element in the overall algorithm used by the NHPD in its pre-market assessment of medicines was reworked. In either case, the issue or Issue was resolved when reasoning by taxonomy and comparison could move the file along in the appropriately carved Assessment Streams. In either case, once a particular topic became an Issue, there was a locus for discussion which, while not always a dossier in the same sense as described in Cambrosio, Limoges and Pronovost (1990: 200-209), became a magnet channelling related queries from inside and outside the institution; the locus made somewhat stable by virtue of being a recognized Issue.

Issues and flows in scientists’ sensibilities

Six months into my work as a scientific regulator, my fieldnotes frequently featured the same observation: “nothing happened.” I made this observation even when – especially when – I was assessing a great number of files. It was not that I was not assessing files and so on; but that these particular activities had become “nothing,” simply “common sense.” By the six-month mark, I had sufficiently internalized the processes, the streams, the algorithms – for the flow of files to become the unnoticeable state of inertia in this particular “common sense.”

There was a flip side to this new sensibility. I wrote “nothing happened,” in the mindset of a regulator, when there were no decisions to be made on issues. By the six-month mark, the only activities that became “noticeable” were the Issues, Decisions, or other unexpected events such as faux pas, organizational changes, new concerns and standards– things that threw me out of the flow of reasoning-in-task.

I began this chapter with Binta’s reflections: “At first you think it is straightforward the licence, but the more you see and the more you talk to people the more ways you find out that things can go wrong.”

On the one hand, the more one sees – but on the other, the less one sees. After thirteen weeks I had become efficient at seeing the same deficiencies as my peer reviewers. I no longer “saw” the text in the template of the information request notice. It was blocked out of my vision, because I assumed I knew what would be

there, and so there was no need to notice anything there. After application, application, application I no longer even thought to compare certain things. In some cases I did not even *think* about the medicine I was assessing – I was looking and acting. In fact, after working six months as a scientific regulator, I doubt I could have provided the dosage and claims from any monograph from memory: my memory was all in the monograph. (Many other assessors did learn this information, though). This lack of "thought"' was implicitly encouraged insofar that it yielded faster accurate assessments and standard communication: "The more standard lines, the less thought required" was the statement a presenter made in the introduction to assessment standard operating procedures.

The standards I needed to use in my comparative reasoning had become clear; I no longer reasoned in any way separately from them.

Affective work

This style of reasoning, based on a certain number of established standards, required specific affective work on the part of the scientists. It required a degree of "letting go" of certain expectations or attachments to research and curiosities. This "letting go" was facilitated by the mantras, already mentioned; these mantras helped to distinguish issues that needed investigation, and those that did not. This "letting go" was also facilitated through the use of particular activities such as the completion of Monograph Issue Sheets.

Whenever an assessment officer in the Monograph Management Unit noted an error or problematic component of a published NHPD monograph, we were encouraged to write up the issue in a Monograph Issue Sheet. While these Monograph Issue Sheets ostensibly served as the impetus to revise the monographs published by the NHPD, this was not their primary purpose as I came to understand them during the time of my fieldwork. I experienced, and several other assessment officers experienced, these Issue Sheets as an affective training tool, e.g., helping us "get over" the fact that the monographs – the standards we were using as the basis of efficacy and safety in our assessments – were imperfect.[23] They provided a channel for us to articulate our concerns with the monographs. It appeared that all new assessment officers in the unit conscientiously completed Monograph Issue Sheets. Each of us, with one exception (Claude, described below), eventually concluded that the process was a waste of time, because, for whatever reasons outside of our control, the monographs were not getting edited unless there were major safety issues, and we were not permitted to edit the monographs ourselves.[24] This transformation was part and parcel of becoming a scientific regulator at the NHPD: realizing one could not single-handedly change "the system," that one had to act despite imperfections, and coming to terms with the fact that everyone had too much work to do and so only a small amount of what should get done actually would get done. The exercise in developing the appropriate affective dispositions for actions

allowed us to see the futility of certain actions, and to turn our attention to what might be more useful, to “learn to pick one’s battles.”

For some of us, our affective dispositions in this regard were evidently easier to remold; we were never instructed to stop completing Monograph Issue Sheets, but we stopped nonetheless. The exception I mentioned above, Claude, did not ever, to my knowledge, “let go” with respect to working with inexact standards. This vexed many of Claude’s colleagues, one of whom visited my cubicle to vent, and after a long description of Claude’s difficulty coming to terms with inexact standards, she concluded:

> I’ll leave you alone [to get work done]…
> [She spins around as leaving cubicle, annoyed]
> Claude *still* hasn’t gotten over it. *Get over it already!* But then I think back to how long it took for me to get over it, and I remember it took me a while. But Claude just gets *so* upset about it, and is working up into a frenzy.

Our colleague’s inability or unwillingness to enact the required dispositions, including affective ‘detachment’ from certain inaccuracies, for reasoning in the style of reasoning, led to Claude’s actions sometimes considered unreasonable by peers, and at least once peers considered Claude’s arguments unrecognizable as reason. It also led to Claude’s own visible frustration.

Regulatory sensibilities

While certain personality attributes may predispose one to entering a particular state of activity, the cultivated sensibilities, affective dispositions, and ‘notice’ that

follow are inseparable from that activity. I will first speak of cultivated sensibilities, and then notice.

There are two sensibilities that I believe were honed by the use of a checklist-style approach to a flow of files on a limited number of medicinal ingredients (the way reasoning activities were structured). One sensibility was with respect to applications; and the other was with respect to the standards used as comparator to the applications.

The first was satisfaction in "cleanliness."

This language worthy of *Purity and Pollution* (Douglas 1966), cleanliness referred to the degree to which the file aligned with the standards used in assessment. In the Compendial Assessment Stream, there was continual discussion of the "cleanliness of the files," of whether they corresponded to the monograph. Various procedural initiatives were spearheaded to address elements of the files, such as the non-medicinal ingredients and proposed labels, that tended to be "messed up" (e.g., did not correspond to the appropriate standards). Some of these initiatives did indeed result in "the new files actually coming through cleaner." This satisfaction in clean files was no less salient in other Assessment Streams.[25] Essentially, in all cases, "cleaner" files allowed regulatory scientists to begin the comparison sooner, rather than having to spend time and energy cajoling the applicant (via Information Request Notices) to arrange the file in such a way that a comparison could be made. There was general agreement among colleagues that

"messy files" were very difficult. In any event, there was an acute sensitivity to category violation, to use a term used in anthropology (Herzfeld 1992: 33; Douglas 1975). One of my less politically-correct colleagues referred to the files that seemed particularly recalcitrant to the comparative process as the "freak files." I believe this characterization of matter-out-of-place (cf Douglas 1966) to be quite accurate, anthropologically speaking, although the characterization is less apt, regulatorily speaking (no tact or discretion).[26]

cleanliness: files:: consistency: standards

This satisfaction in cleanliness also dovetailed with an acute sensitivity to consistency: consistency in the Directorate's textual standards, and across assessments. Given that cleanliness was relative to the textual standards used in assessment, inconsistencies among those textual standards were a source of frustration, and, like the imperfections in any given textual standard, needed to be addressed through affective work. I use an example of yet another colleague who popped into my cube to vent. I was quite worried about him at the time because he had some other life stressors and I believe he was extremely short on sleep. Although the extent of his emotion was unusual, the direction was not – his venting clearly outlines the way in which affect, emotion, and the structuring of work are related:

> I hate inconsistencies. I really hate inconsistencies.
>
> The *marketed products* guidance document defines "naturally-sourced," right?

> But in *our* guidance document for product licencing it says right in there that something is synthetic if there is any bit synthesized (e.g., semi-synthetic).
>
> And so I'm arguing with this applicant on the phone, but I know the applicant is right, so it is just stupid. What am I supposed to say?
>
> [I offer options…]
>
> Ya, I know. I just need to vent. It's just that I feel all this pressure to get files done quickly and I do but then I get/
>
> I hate the curve files, you know. If I can refuse them, fine; if I can recommend them, fine. But it's these other ones I can't deal with.
>
> And I'm not really getting faster.

Affective disposition to Issues

As this colleague's rant demonstrates, Issues (or the little issue "curve files") – as fundamental blocks to reasoning through taxonomy and comparison – are affectively notable given these particular sensibilities in comparative assessment. Issues did not always provoke negative affect; I noticed two main affective valences towards issues and Issues. The first, as expressed by this colleague, was negative. This negativity could involve more complex negative emotions such as annoyance, anxiety, or derision. It also could involve negative impacts on scientists' experience of their integrity. (Because decisions on Issues often changed the algorithm or standards of subsequent assessments, scientists' own assessment before and after the decision were often incommensurable.)[27]

The second affective valence to issues and Issues, was neutral to positive. Occasionally this neutral or positive valence involved curiosity, but at a minimum it seemed to involve increased levels of general awareness.[28] A typical response of

some of my colleagues to me asking one of my many questions (often leading to issues) was a sort of longish pause – followed by a thanks for "making [the respondent] *think*." Amélie attributed some of this to scientists' curiosity:

> We need to be very flexible with resources here. We do not deal with a few applications of a specific nature, but rather with products ranging from foods, isolates, combos, really big combos, and so we have to become a jack-of-all-trades. Everyone has strong scientific training, but there are not tons of people coming out with natural health product PhDs. I think AOs [assessment officers] like moving around the Directorate, because they like learning. I think scientists are very curious and like to see different things. But science is still science, and you've either proved something or you haven't, no matter the particular training. So it is good our scientists are very flexible with their areas of expertise.

Scientists sometimes evinced both positive and negative affect when encountering issues. In the botulism issue I describe in the next chapter, I was simultaneously very glad to work on the issue, and filled with dread. On the one hand, it was an interesting puzzle, I got to learn quite a bit through the research, I had a valid reason to leave my cubicle and to speak with many of my colleagues and learn from them, and I felt the issue was important; but on the other, the thought of working on the Issue sometimes filled me with dread, because I did not know where to start on the puzzle, or even whether the puzzle was solvable, and mild anxiety, because reasoning through the issue required so much time I was not completing "my work," which I had configured to be making recommendations on individual applications.[29] Likewise, Karl explained how she really "liked working with really smart people" who do not always agree on everything – she enjoyed the discussion and debate regarding issues, and having to figure out where her colleagues were coming from in some of their positions. Nevertheless, she

especially enjoyed the challenge and change of a so-called blitz on a category of Product Licence Applications. This blitz involved a team of scientists, “working at breakneck speed” for a few days, doing evaluations. They were given a very specific checklist to follow, and there was a rule that there was no debate over anything not already decided, so the evaluations could be completed for the easy files; there was also a runner who chased files, ensured flow, directed traffic, and got immediate answers from management for any questions arising. (The blitz was initiated so management could “get the numbers up” before meeting with a particular lobby group). Karl explained how she derived much satisfaction from this blitz, both in terms of the satisfaction of completing files, but also in working closely with colleagues in a team and being able to “trust them completely” to do everything. The balance of any given scientists’ affective disposition towards working on Issues was clearly undetermined, but one pervasive and important factor in addition to expertise was whether the scientist was permanently or temporarily working in the Directorate (discussed in chapters 14 and 17).

Conclusions regarding files and Issues and decisions and consistency and dread

I asked one scientist-manager, as I asked many interviewees, about the sort of files that he dreaded. He replied as a consummate professional spokesperson and public servant, but still his answer evinces with the way in which the style of reasoning in the premarket evaluation of medicines features certain sensibilities (consistency), standards (guidance documents), affective work (“getting over it,” it usually being one’s anger or frustration at one’s impotence in the face of

inaccuracies), and the inseparability of this reasoning from the organizational structure:

> Being consistent is always a big challenge…. [He describes specific instances of inconsistencies when medicines were assessed in different Assessment Streams]
>
> *Did these situations happen because there are so many units and people don't talk?*
>
> That's part of it, there are so many units, and we don't all happen to share the same understanding or interpretation of the guidance documents. That's big. And I think that's at all levels.
>
> One of the things that, for me, that is very frustrating, is [pause] having decisions made out of the spur of the moment [pause] which I clearly know are not right – and, and
>
> [long pause: at a loss for words – visibly overcome by emotion, upset]/
>
> That for me is the most frustrating.
>
> Or being tasked with projects that/ and being asked to, almost to / it's sometimes it's happened in a certain direction and knowing that if you really allowed the project to unfold, that direction would not necessarily take that course. So that tends to be a huge huge challenge.

He immediately continued to explain the NHPD's organizational problems retaining staff and other staffing concerns. In the pyramidal hierarchy typical of the Canadian Public Service, part of one's affective work as a regulatory scientist involved learning to gauge the sort of things and decisions that one could control, and the sort of things and decisions that one could not control (because they were made by one's superiors). Another scientist-manager responded to my question about personal attributes helpful when one had to implement decisions that did not seem scientifically-ideal but were nevertheless taken, by remarking:

> I guess, there's a certain amount of fatalism sometimes. The decision has been made so it's out of your hands. So, all you can do is try and make

> sure that when it's implemented, it, it's implemented in a way that still makes it a, a good decision (Jack)

Summary: the checklist imperative, and impossibility

When everything in a file was consistent with the NHPD's processes – there were clear standards, and the entries on the Product Licence Application form corresponded to those standards – the course of reasoning that regulatory scientists had to take was clear. Reasoning proceeded through taxonomy and comparison, often guided by standard operating procedures and checklists. In instances where the comparator was amply clear, some evaluators denigrated these processes as mindless work;[30] although I hope my descriptions of Alex's and Guineviere's assessment activities expresses the degree of concentration and focus required for multiple, often simultaneous, expert comparisons even when the comparator was clear.

When the comparator was unclear, the evaluation was anything but simple. The inability to make a comparison was often characterized as an "issue"; while issues could sometimes be solved by consulting experts, there were Issues that could not be solved with the expertise at hand. These Issues can be imagined as log jams blocking the flow of files through the assessment streams. The blockages often required time to unjam, and the successful procedure for doing so was unpredictable to some extent, and in some cases perilous. Sometimes instead of undoing the logjam, the flow of files was simply redirected: some upstream element

in the overall algorithm used by the NHPD in its pre-market assessment of medicines was reworked. In either case, the issue or Issue was resolved when reasoning by taxonomy and comparison could resume, and the file could be processed along in the appropriately carved Assessment Streams. Comparing, while it might seem simple, requires intellectual, affective, and physical work. (Physical: think of all that page flipping; the anatamo-politics; the glancing; all those Ctrl+F, Ctrl+C, Ctrl+V keyboard shortcuts and mouse scrolling).

Grouping and change

I have my own little rant, and no cubicle in which to go vent; so I will do it here. I have often heard upper management in the Canadian Public Service characterize public servants as resistant to change. From my experience and observation of regulatory scientists, their resistance to certain changes stemmed less from their personalities than the regulatory style of reasoning and the functional (cf. *fonctionnaire*) imperative to speak-as-one.[31] For scientists, learning the important comparisons and setting up their immediate environment to make those comparisons efficiently took time and effort; having to refurbish one's habits and one's external reasoning instrumentation and social network of experts meant that one had to start anew in the process. Take, for example, Naavah's exasperation:

> Finally you get proficient at a job and then you get changed [positions], or the procedure changes. There are all these initiatives and I do not know if they are worth it.

I found this spontaneous outpouring of exasperation coming from Naavah a surprise, as she spearheaded certain desired changes, was vocally supportive of

various managerial initiatives, and was very committed to the NHPD's mission; as such I cannot chalk such a statement to any innate resistance to change, but rather to the importance of habits and expertise for comparison in the regulatory scientists' style of reasoning.

Some scientists did of course attribute these affects to personality, although I would quibble in many cases this is not pre-existing. To end with Binta's reply to an interview question:

> *You mentioned liking assessment. What are some of the things that you think make you like assessment?*
>
> Well maybe I should start with personality. I don't like cleaning, but I like when it's clean. I always argue about that with my mother in law. I don't like the process, but I like the end result.
>
> So I think, when I think of the Directorate, you know, because I know that these products are potentially drugs existing on the market, and sometimes I go to the vitamin and mineral section at [a major box store], and when I see what there is for sale [pause]/ that hopefully won't be in the future. I know that this drug will eventually come through us, and we won't allow this thing, so it is almost like cleaning, you know: like "what's safe" and "what's not safe." So I like that I participate in this process, that I'm a part of it. So when I'm assessing a product, I'm thinking of the end result of it, you know, that there will be one more product on the market that is safe for the public. That is tracked and approved. I tell my friends to only buy product with the NPN on it, because nobody is really aware of that.

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1 The NHPD had its own flow diagrams spanning hundreds of pages: the Submission Administration Unit's "Process Diagrams."

2 For example, there is a 101-step flow chart (prepared May 2, 2007) entitled "Flow Chart of the SOP "How a Product Assessment Officer evaluates the Safety and Efficacy of a Natural Health Product."

3 While the NHPD listed seven, I do not believe homeopathic medicines that had previously received DIN-HMs (licences to be marketed in Canada) were evaluated any differently that homeopathic medicines that had not.

[4] Although most files stayed in one assessment stream until the proposed medicine was licenced, refused, or withdrawn, sometimes files were moved from one assessment stream to another. Generally, files were shifted midstream because the proposed medicine did not correspond to a standard listed higher in my diagram (and so the file moved further down in my diagram) or, because a staff member noticed the proposed medicine corresponded to an accepted singular textual standard and contacted the applicant to find out if they were willing to have their application transferred to the expedited process of the other assessment stream. (Expedited because a clearer standard for the comparison usually entailed shorter queue and assessment times). The movement of the file according to this algorithm was not at the level of any individual staff member; it was an achievement of the collective.

5 The use of foreign regulatory standards, as I describe in later chapters, is more complicated than I sketch in this paragraph. Nevertheless, in some cases, if a proposed medicine met certain specifications of, say, the *Pharmacopoeia of the People's Republic of China* and met a host of generic Canadian regulatory requirements for medicines, the medicine could be licenced.

6 Using the statistics dated August 16, 2007.

[7] I completed safety and efficacy assessments in the Non-Traditional Assessment Stream in some instances after reclassifying a Compendial file as a Non-Traditional file at the applicant's request (e.g., occasionally I continued the assessment in the other stream for efficiency purposes).

[8] The applicant wanted to make the claim that ashwagandha could be used for rejuvenation. The published monograph for ashwagandha, at the time, permitted the claim "Traditionally used in Ayurvedic Medicine as rasayana (rejuventative tonic). This permitted claim was not equivalent to the claim "Use to rejuvenate," for several reasons – but the company was aiming for this second type of claim, and so the application was transferred to the Non-Traditional Assessment stream and the company sent in "evidence."

9 Homeopathic medicines received DIN-HM numbers, whereas all other natural health products received NPN numbers upon licencing.

[10] The "Product Details" table dated August 16, 2007, circulated with the "submission status Summary" table of that same date. The final row and the bolded typeface in figure 6-2 are my additions. The column "Total Complete" would include submissions that were licenced, refused, or withdrawn. The row "Total possibly involving non-science paradigms" assumes that half of Compendial files are based on traditional evidence, which is likely an over-estimate.

[11] My supervisor instructed the unit's scientists via e-mail which files we were to deal with first:

> Given that you each have a large number of files, always process files based on how close they are to being licensed/signed-off, e.g., if you have:
> a) 4 files for which you received the 2nd IRN [Information Request Notices] responses
> b) 2 files back from peer review
> c) 3 files back from UH [unit head] approval
> you should address c) then a) and lastly b).

In my first week of work, my trainer told me that it was up to me to organize my files in a way that let me prioritize correctly – however, she continued, this was how she organized her files (an organization I adopted): she used separate filing cabinet drawers for different levels of files, and used post-it notes with "must respond by dates" on files for which Information Request Notices had been sent (because applications could be refused on administrative grounds if the applicant did not respond within 30 days of receipt of an Information Request Notice.)

12 From presentation slides for "NHPD Progress update, June 2-3, 2005 (Version 3). Presentation to MAC, senior management." From slide 28, under heading "Improvement Activities," and subheading "Reviewing of Submissions:" "Public domain evidence used in assess [sic] for respective ingredients to be grandfathered and used as corporate knowledge (will lead to monograph development). [new bullet point] Extension of proprietary evidence to other submissions will not be allowed unless a significant health risk has been identified on the basis of this information."

13 I allude to many file tracking databases in this dissertation. There was one, a tracking system in Excel sheets, that was actually popular among scientific staff because, in addition to providing the required statistics for management, the system permitted the scientists to organize their own work. This original Excel system had a master spreadsheet that pulled, on a weekly basis, information from certain fields in each assessment officer's spreadsheet. While each scientists' sheet had to have certain mandatory fields (that were linked to the overall Excel sheet), scientists could add also extra columns for themselves, to track information useful to their future assessments; scientists could also use the text formatting and style they desired, and so many used features such as "highlight text" to code rows (files) according to their own colour legend, to be able to see at a glance which files were complete (often in a dark colour); were on hold; or were priorities (often a bright colour); and so on. This sheet was phased out as the tracking sheet because it was too much work for IT to maintain. (The days of IT *support* and user-driven computer programs are perhaps in the past in government; although supposedly with over 100 scientific staff and thousands of files the spreadsheet program was pushed beyond its capacity). The irony was that because the replacement databases did not provide any of the at-a-glance functionality for scientists' tracking of files, many scientists continued using their no-longer-required Excel sheets because it was the only way they could meaningfully track their own files electronically. (In the new database, getting a list of one's own files was eventually possible – via a long and complicated series fo actions which often resulted in the program crashing – but the only way to sort these files according to level was to copy and paste the list *into an Excel sheet* and then sort.) Clearly, and much to my chagrin, the programmers had not seen or learned their lessons from *Sesame Street* as children, nor examined the filing systems in efficient medical offices, and are therefore unaware of the powerful role colour can play in classification-at-a-glance.

14 This practice was technically not allowed. We were expected to have shortcuts to the original template on our desktop, not saved copies that we then modified; this was because the original templates were invariably "living documents," meaning they were changed as required by their guardians, and these updates were not always announced to the scientists.

15 I am not saying that scientists did not consider the file in front of them; but the consideration was not unique in the sense that the way the scientist went about reasoning was no different than for other files in the same Assessment Stream and at the same level, e.g., in the same pile.

16 By the time my fieldwork ended, there was an SOP "How to Assess a Compendial Product Licence Application (PLA).

17 In Canada, English and French translations of legal documents are equal force of law. NHPD's documents were largely written in English, and then translated into French of varying quality. Occasionally backtranslation from the French to English document did not yield the same meaning and so occasionally both versions needed to be considered. The language of operation of the science-heavy Bureau was largely English and therefore French was generally only of interest as a derivative translation of the English texts. There were translation databases available, such as Termium with its government-wide vocabulary, but these tended to not be useful for technical, scientific language. The most useful was the internet, because on any Health Canada website one could change the "e" to "f" in the webpage address and immediately move from the English text to its approved French translation – translation at Health Canada tended to be sentence-by-sentence, so the two documents could be used together as glossary. Until I figured this out (and had English-language and French-language documents open simultaneously on my computer when I spoke with a French-speaking applicant), speaking with applicants in my second-language, French, about scientific and regulatory concerns was quite stressful.

18 This is not implying the Assessment Officer triple-checked her work. It could indicate she completed the initial assessment plus two reviews after the applicant responded to an Information Request Notice.

19 I believe that this is why, at the NHPD, the issue of who-is-doing-what-where in the organizational structure was inseparable from science-based reasoning. During my fieldwork, the Directorate's processes and organizational units in assessment were continually reshaped to maximize efficiency (e.g., use of checklist-style reasoning) while having the expertise where required (when the checklist is not easily completed). The Director of the Bureau of Clinical Trials and Health Sciences remarked, on the organization of the science units:

> And it will probably evolve again, because one of the things that we're looking at now, is whether it makes sense to divide products according to the substance type, or should we do as TPD does: divide things by their pharmacological class, [e.g.] have cardiovascular natural health products, musculo-skeletal-type natural health products, central nervous system, or hormonal… that's an idea that's being considered now. It's a future possible reorganization. It's a question of whether people's expertise lies really in herbal medicines versus isolates, or whether their expertise lies in cardiovascular disease versus infectious disease. Because, of course, we want to match people's skills to their tasks as closely as possible…

I will revisit this theme of the inseparability of organizational chart from science-based reasoning in Chapter 17.

[20] Issues that affected applications assessed by only one unit could generally be resolved by the Unit Head's decision.

21 The Policy Bureau was a separate bureau in the NHPD; the workings of this bureau, and its staff, are not addressed at all in this dissertation.

22 The reasons were varied and numerous. I believe I copied the numbers and reasons from an e-mail circulated to BPRA staff, but I do not believe the reasons are verbatim.

130 at food – NHP interface
108 pending decision on the definition of homeopathic medicines
20 decision on special containers for homeopathic medicines
27 boron
14 chromium picolinate
13 policosanol

under 10 for decisions needing to be taken on some facet of the following: hydrogen peroxide; bovine liver; vitamin E risk statement; "professional use" statement on label; CLA; both traditional and non-traditional label claims; benzalkonium chloride as non-medicinal ingredient; chitosan; proprietary blends; issues with monograph; there were also many more files halted without a reason stated in the tracking database.

23 In 2006-2007, many of the monographs used in the Compendial Assessment Stream were draft monographs uploaded in late 2003 or early 2004. Although there had been hundreds of researched "long form" monographs in preparation before 2004, the story went that in 2003-2004 the NHPD's scientific staff were told in no uncertain terms by upper management that short versions of the monographs had to be published on the website within a week. Clearly, there were many substantial, and sometimes silly, errors on the monographs that were published as part of this cohort. I will speak to this process more in Chapter 16, but for now it should suffice to say that the quality of some of the monographs during 2006-2007 (and from several years prior) was considered by many scientific staff as one of NHPD's notable "early blunders":

> Monographs – they could have been done a lot more rigorously. We've definitely got a lot of feedback, negative feedback in many cases, about the quality of the monographs. And a lot of time its not overall quality, it is just a single simple thing, but it is something that we have to enforce, unfortunately. So for example. Rosemary [according to the published NHPD monograph] had a frequency of one time daily. There was no frequency in the reference [citation in the monograph] regarding once a day. All the research says three times daily. So the monograph should not have been so restrictive. And there are a lot of other examples, but I think it is unfortunate.

This was widely recognized at the NHPD, but not loudly stated, because nearly everyone who had worked at the NHPD during 2004 or before had worked on a monograph – and no one remembered who had developed which ones when. There were hundreds of long form monographs from 2004 or prior "languishing" on the joint N:/ drive. In many cases, there was insufficient evidence for the development of a monograph. In other cases, it was just that work priorities had changed. During the period of my fieldwork, upper management discouraged the scientists developing the monographs from taking too long or from being "picky," and, in a memorable turn of phrase that that was repeated by many a scientist (some disgruntled), to make "Volkswagens not Cadillacs." Again, this relationship between scientists and upper management will be discussed in Chapter 16.

24 The Monograph Development Unit – the one responsible for revising the monographs – was in the midst of being cut by upper management during the period of my fieldwork, and so the unit neither had the time nor the inclination to address the Issue Sheets calling attention to non-safety issues.

[25] In the Non-Traditional Assessment Streams, there was a widely-expressed sentiment (hope) that applications were coming into the Directorate cleaner as the years progressed, as industry learned how to complete Product Licence Applications in ways that facilitated scientists' comparison activities. In the Traditional Assessment Stream, this involved the inclusion of two textual references describing traditional use including dosage information, and claims that made sense within the traditional practice of medicine. In the Non-Traditional Assessment Stream, cleaner files contained only evidence that was relevant to the proposed medicine's claim (or general safety), and from reputable sources.

26 "In a more formal sense, monsters and freaks are also ways of speaking about the constraints of the classifying and (often) dichotomizing imagination" (Bowker and Starr 1999:304).

27 Two assessment officers explained why they preferred getting files in batches grouped by medicinal ingredient:

> Madison: It is better if there are batches, if IRN are batched, and the files stay close together. Rather than leaving [assessment of the files to span] over a year, it can be a year-long process, and in a year, a lot can happen.
>
> Moira: It is really hard when I got a couple of the problematic files. It is especially hard when it is the first of a batch that is being pushed through. That can cause issues, because the policy changes, and you don't assess them [the later files] the same way[…]
>
> Madison: and when you're on your fiftieth file of the same thing, you've read a lot of studies. So you'll know there is a risk statement and then you're reading stuff that shows it's not necessary
>
> Moira: so you have to backpedal on that. So internal policy changes, and new information, which you can't control for, but you feel like it's a reflection of you.
>
> *Has anybody every said anything, where you really feel it did come across as a reflection of you?*
>
> Madison: They've never said anything. I've never had anybody address it, but I feel like I know that they don't remember [that the inconsistency is due to a change in process in the intervening time].

28 The way I often noticed in myself, which had nothing to do with annoyance or even pleasure in puzzle, was the pleasant sense of being awoken from a deep stupor when Something! – Anything! – "happened": an Issue, an interesting file, -- even particularly cantankerous applicants on the phone who has threatening to sue because he or she was in disagreement with a decision. Because I did not remark this reaction in anyone else, I will attribute it to the (unusual?) level of boredom that I personally experienced as a scientific regulator.

29 No supervisor ever framed it this way; I would say this interpretation was entirely self-imposed however given that many scientists spoke that way there must have been some element that was not determinable by any given individual, such as myself. This point will be revisited in later chapters.

30 For instance, one evaluator characterized her work as "mind-numbing", explaining that it was mostly verification or "doing the work for the applicants," and managing many texts and databases (Patti).

31 Another strategy for speaking-as-one, that I have heard is employed in other areas of the public service, is to speak-as-one by mimicking and employing whatever key words the higher powers-that-be (often the head of institution) happens to be using. That strategy was not a strategy that I noticed the regulatory scientists I studied using as a strategy of speaking-as-one. While political imperatives were noted to lesser or greater extents, they were not the primary means of speaking as one among this group that defined themselves, to some extent, as professionals.

Chapter 7
The example of an unassuming garlic file and its Issue
A study of a scientist's notice

Sometimes the best way to make an argument is to tell a story. What follows is less a story than the reconstructed plot of a saga from my time as a scientific regulator: I describe such an instance in my change in notice, notice of a potential health concern, that became an Issue.[1] To some extent, resolving the Issue required an unpredictable course of reasoning. The Issue was eventually resolved by lightly rejigging the overall algorithms and standards used in assessment.

This is an anecdote, but it covers many facets of daily life as an assessment officer, including the affective responses towards standards when reasoning in situations of uncertainty in public health protection in an era of little authority. (In other words, I was grasping for any standard, or expertise, anywhere).

Much of the path that the Issue followed was due to my lack of expertise in the area. Readers may think, "well, this account just demonstrates that she didn't know anything about the production of botulinum toxin or what she was doing." That is absolutely true -- at least in the beginning. Throughout the month following my notice of the issue I felt entirely unqualified, wondering what on earth I had gotten myself into: *really I'm just an anthropologist, I wasn't supposed to actually have to worry about standards that would stop people from dying, darn that B.Sc., what has it gotten me into, I don't want this responsibility – I cannot even fathom what a "12 D" canning process is, where are the* real *scientists who actually know about*

these things and are experts *and who can really protect the public?* I WANT AN EXPERT*!* By the end, however, I was very well prepared to present myself as an expert if I had to, to convince upper management that the risk of botulism from medicines made from storing roots in oil was not just a “theoretical” risk.

The point, however, is that no scientific staff member, even the most experienced and educated, is an expert on all things; although some staff had extensive experience in the manufacture of medicines, some had a similar level of non-experience that I did, but nevertheless: all needed to act (reason and judge). Whether I acted well or badly is a moot point for this dissertation; my notice, reasoning, and activities with the Issue are presented here towards a study of regulation, development of safety standards, and uncertainty within a complex institution in public health protection.

I hope the story also permits the reader a peak into the everyday world of science-based regulation in which questions of who-knew-what-when in the pre-market evaluation of medicines in large complex institutions (or even worse: “when did Health Canada know”) are either impossible to answer, or missing the point.

An unassuming garlic file

One morning I entered my cubicle at the start of an unremarkable work day: I picked up the pile of files that my Unit Head had left on my chair, and, after settling

in, looked through to see which files I could send on to the Director General because my Unit Head had signed off on my recommendation. My Unit Head often left little sticky notes on the file cover with directions, e.g., “take to DG [Director General],” or “sign label and then take to DG,” or directions regarding some element in the file that I had missed or some decision of which I was unaware but needed to take into account in my recommendation for licencing or refusal. Invariably these directions were clear.

On this fine morning, however, one file in the pile had a sticky note with a direction I had never before seen: it instructed me to take another look at the file, and then bring it back to my Unit Head. I assumed this meant that I was no longer being hand-held – that I needed to figure out for myself what I had missed. I was happy with this state of affairs, and threw myself into the task of figuring out what I had missed. I redid my assessment of the file from scratch.

But I could see nothing wrong with my original assessment.

I flipped through the file again – now I was on the hunt. I still didn’t see what I had missed, what element of the file did not correspond to the garlic monograph published by us, the NHPD. It was an incredibly straight-forward file in the Compendial Assessment Stream, with the entries in the Product Licence Application Form matching, nearly word-for-word, the corresponding sections of the monograph (Figure 7-1).

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Figure 7-1: Garlic Monograph in Use in Summer 2007

GARLIC----- DRAFT

Date:	May 7, 2004
Class:	Plant
Proper Name:	*Allium sativum* L. (Alliaceae) (USDA 2003)
Common Name:	Garlic (McGuffin et al. 2000)
Sources:	bulb, oil from bulb (ESCOP 1999)
Route of Administration:	Oral (WHO 1999)
Dosage Form:	Those suited to the allowable route(s) of administration
Use or Purpose:	Statement to the effect of:

Oral:

- Traditionally used to treat the symptoms of upper respiratory tract infections (Barnes et al. 2002; World Health Organization 1999; Bradley 1992; Felter and Lloyd 1983).
- Helps maintain cardiovascular health (Warshafsky et al. 1993; Bradley 1992; Auer et al. 1990; WHO 1999).

Dose:

Oral:

- Fresh: 2-5g/day (Bradley 1992).
- Oil from bulb: 2-5mg/day (Bradley 1992).
- Powdered: 400-1200mg/day (Bradley 1992).
- Other preparations: corresponding to 2-5 mg allicin (Bradley 1992).

Duration of Use:	For prolonged use, consult a health care provider.
Risk information:	Statement to the effect of:
Cautions/Warnings:	Consult a health care provider prior use if you are taking blood thinners, EPA in fish oils (Brinker 2001; Barnes et al 2002).
	Consult a health care provider prior use if you have a blood clotting disorder (Brinker 2001).

Canada

	Consult a health care provider prior use if you are taking cholesterol-lowering medication (Jellin et al. 2003).
	Consult a health care provider prior use if you have diabetes. (Sunter 1991; Ernst 1987).
	Consult a health care provider if heartburn, flatulence, gastro-intestinal irritation persist (Brinker 2001).
Contraindications:	Do not use if you are pregnant or breastfeeding.
	Do not use if you have pemphigus (Boon and Smith 1999).
	Do not use prior to surgery (Brinker 2001; Blumenthal et al. 2000).
Non-medicinal ingredients:	Must be chosen from the List of Acceptable Non-medicinal ingredients and must meet the limitations outlined in the list.
Specifications:	Must comply with the minimum specifications outlined in the Compendium.

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Please note this monograph is still in DRAFT form. Further revisions will be made in accordance with the Standards of Evidence (SOE) guidance document, pending analysis of the SOE Consultation Report.

The product seemed entirely inoffensive – the company was taking garlic, macerating it in vegetable oil, and encapsulating the macerate in a capsule. It actually was a natural health product, I thought, in line with what the public likely thought was ‘natural.’

I looked through the file again – still nothing out of the ordinary. The magical formula in the Compendial assessment stream: Product Licence Application (PLA) = label = NHPD Monograph was true.

Was I becoming demented? Blind?

The only thing slightly out of the ordinary was that my Unit Head had circled the word “macerate” in my recommendation, and put a question mark around it. This word was in my recommendation because it was how the garlic was made into the medicine. Surely, I thought, she must not have circled “macerate” because of unfamiliarity with the word; she could have looked up the definition in any dictionary. My unit head was a very intelligent woman, so I must have missed something. I just had to find the reason for her sending the file back, a reason that presumably was related to “macerate.”

I sat back in my chair, away from the file on my desk. I mentally went through recent “decisions,” thinking that maybe there was one that I should be applying in this case. Nothing came to mind.

I consulted the unit's Record of Decisions on the computer – nothing of relevance that I could see.

I looked at the file again. Still nothing out of place. But there *had* to be some element missing in my reasoning for this file, for my Unit Head not to have signed off on the recommendation. What was it?

I sat and puzzled. I puzzled. I lost hope.

I was about to physically move the file aside, hoping that something would occur to me later in the day, or that I would catch one of my colleagues to ask them, and, my mind wandering a little, I started thinking about the garlicky stir-fry I had made the previous week – I mean, what is offensive about garlic? I remembered how delicious the stir-fry was and how annoyed I was at my dinner companion nagging me in the middle of the meal – "put away the stir-fry in the refrigerator right away, it has got garlic in it." (That dinner companion had a long-standing and perhaps overzealous interest in food safety.)

Aha! Garlic in oily food: risk of botulism! Garlic macerated in oil: risk of botulism?

I was so proud to have solved the puzzle, which required such 'outside the box' thinking, that I jumped up to head towards my Unit Head's cube to see if that was what I had been supposed to figure out. I bumped into her in the hallway:

> Jennifer: Right, so this garlic file recommendation you sent back. Is it because, you know, like when you're cooking, you have to worry about botulism if garlic is left around in oil on the counter?
>
> Unit Head: Oh! [Taken aback] Now that's interesting.
>
> Jennifer [deflated]: But that wasn't the problem you saw in the file? OK, I'll go back and figure out what the problem is.
>
> Unit head: No, I didn't have any problem in mind. I just like to send the file back sometimes to see what happens. So why don't you look into the botulism thing?

Is there a botulism issue?

(Week 1): I knew nothing about botulism other than the fact that it featured in occasional nags. So for a few hours, I read about botulism, and *Clostridium botulinum*, the bacterial spores that can produce botulinum toxin if they are in an anaerobic environment (one without oxygen) at room temperature. I examined cases of botulism from garlic in food. I learned that it was possible for *Clostridium botulinum* to produce toxin in the intestines of infants, because infants have less acid in parts of their digestive tract, and this is why infants should not be fed honey. I tried to find cases of botulism attributable to medicines (or "dietary supplements") by searching pubmed; I could not find any cases. I decided that even if there had been such cases, the chance of anyone attributing a case of "food poisoning" to a garlic capsule was close to nil. One pubmed search for the combination of "drug"

and “botulism” did turn up cases of wound botulism. I learned that in wounds, it was possible for an anaerobic environment to be created, and if the wound were contaminated with bacterial spores it was possible for the person to get botulism; in North America, there were less than a dozen recorded cases, all among intravenous drug users. (Natural health products, by regulatory definition, could not be injected; but I kept ‘wound botulism’ in mind in case should I come across a garlic-in-oil skin rub with the claim “Traditionally used to ward off vampires” – I was always hoping for such claims, but they were never submitted by industry.) I searched the web for other countries’ standards for garlic medicines… Nothing. I searched the entire web for any attention anywhere to the risk of botulism from medicines or food supplements; I got nowhere.

Getting nowhere fast through my general searches on the computer, I decided I needed an expert to direct me where I should look. I asked around the directorate; everyone pointed me to one particular scientist, who was away that week. I looked on the Health Canada site for food standards related to botulism and came up with a consumer information piece; it was interesting, but it was not the information I was seeking. I could not figure out from internal Health Canada directories who might be in charge of such standards. (Lest the reader assume that a government worker, immediately upon entry into the public service, develops an innate knowledge of the positions and expertise of the other thousand workers in her department: nope, sorry.) I sent two e-mails through Health Canada’s public

internet site to the organizational units that I thought might be in charge of such things. I also sent an e-mail to the general Health Canada inquiry e-mail. I waited.

(Week 2) And I waited. I continued asking around, but no luck.

I began wondering: what if there is no one around who actually knows about these things? I began to feel some dread at the thought of working on the issue, because I was at a loss of where to look. One could not refuse a medicine with *garlic* for *safety* issues: how to become a regulatory laughingstock.[2] I had no standards, no models, not even any recorded cases. But I was worried. So I just let the file sit there. It was only on NHPD day 30 or so. The limit was 60 days.

The internal expert returned to the office, and, in response to my e-mail, came by my cubicle:

> Expert 1: How did the issue come up?
>
> Jennifer: [explained….] But it is probably not a huge issue because none of my searches turned up anything.
>
> [I was feeling so at a loss of where to look and what to do I was actually hoping a most ignoble hope: that Expert 1 might say there was no need to look into it further.]
>
> Expert 1: That may be, but now that we know about it, we have to do something about it, and we can't licence the file.
>
> [My ignoble hope shattered.]
>
> Expert 1: Have you checked the monographs by USP [United States Pharamcopoeia] and the European Union too see what they do? To make a decision, I'd also need to know about botulism tests, how reliable they are

etc. If the company is following GMPs it should not be a problem anyways, because the spores should not be introduced.

What I took from this exchange was that there was no way of getting out of having to address the issue. It had become an Issue.

Botulism as Issue

I tried to find manufacturing or testing standards in the USP and European Pharmacopoeia for garlic products but none seemed to apply. My dread increased. As much as I am committed to public health protection the thought that was going through my mind was “why did I open my big mouth.” I simply had no idea how to find relevant manufacturing and testing standards.

Expert 1 dropped by my cubicle again to say that the issue would be brought up at a meeting of the quality assessment officers later in the week. My dread lessened with the possibility that someone there may actually know what to do.

Later in the week, I asked Expert 1 with whom I should speak in the Food Directorate, because I could not tell from the website, and I had not heard back from my e-mails sent through the public site, even though I can clearly indicated in the e-mail that it was an internal request. (Flagging e-mails as coming from an internal source sometimes resulted in quicker replies). The expert did not know anyone. I decided to wait another week before starting to call around.

[Week 3: I continued to sit on the file in question, waiting for something useful to come to me]

Week 4: An assessment officer transferred me another garlic-in-oil file because he did not want to have to deal with it. I left a phone message with someone in a seemingly appropriate section of the Food Directorate. Both the original file and the transferred file were starting to get close to the limit of 60 NHPD days in the Compendial Assessment Stream and so I was going to have to do something about them pronto.

My heart leapt up one morning when I listened to my voicemail, because I had a message from a “botulism expert” – A BOTULISM EXPERT! Redemption! “I got your message from at three different places.” [Good to know the e-mails and phone messages get forwarded to the correct person, eventually]. After three days of phone tag we spoke. I learned about an outbreak of botulism in Canada due to garlic-in-oil in the 1980s. The issue, however, was not restricted to garlic; while root crops were the biggest concern, the risk of botulism would theoretically be present from any plant matter with soil on it and that is stored in an anaerobic environment. I understood that manufacturers of foods that could be conducive to the production of toxin had four options:

- using a heat killing step in the manufacturing process
- keeping the pH of the product under 4.6
- ensuring water activity was under 0.95
- completely drying the herb or plant before putting it in the oil.

If the food manufacturer did not wish to use one of those four methods, I was told, the onus was on the manufacturer to demonstrate the safety of the product. Because the quantities of toxin that could make people sick was quite small, there was no less concern because the dose was small, or encapsulated.

I was so happy! An answer! Standards!

My Unit Head advised me to write up the conversation in an issue sheet. I was going to send the issue sheet back to the botulism expert to ensure I understood the safety concerns and methods of mitigating them correctly, but I found out that I would not be able to circulate a draft issue sheet to another part of Health Canada without internal consensus within the NHPD. (Faux pas number one). So I wrote up a summary of the conversation only and asked the botulism expert to verify; it turned out I misunderstood several crucial details, given his corrections and additions to my summary. The four options for the manufacturers were more correctly characterized as:

> - subject the product to a 12D process to inactivate spores of *C. botulinum* [my 'heat killing']*,* **or**
> - adjust the pH of the plant material to 4.6 or less before adding the oil
> - reduce the water activity of the plant material to 0.94 or less before adding the oil, **or**
> - dry the plant material before adding the oil.

Once I knew there was an expert on whose knowledge I felt I could rely, I was happy as a lark working on the Issue Sheet, deriving satisfaction from finding out

the answer and putting together a thorough response. I tidied up the issue sheet and sent it to my unit head for her comments.

Also, armed with the knowledge that there were minimum standards in the food industry, I could contact the applicants of the two files that were sitting on my desk. I sent an Information Request Notice to each, asking them to send information about how they mitigated the risk of the medicine being conducive to the production of botulinum toxin. (The Notice was sent partially to pause the NHPD days, and also partially as a fishing expedition, as recommended by an internal expert, to find out whether there were already standards in place in the natural health product industry, perhaps modified processes from the food manufacturing sector).

In the meantime, Expert 1 came by my cubicle:

> Expert 1: Are the files “garlic oil”?
>
> Jennifer: No, garlic macerated in vegetable oil
>
> Expert 1: Because I was just speaking with [another NHPD expert] who showed me this – [Expert 1 shows me an entry in a textbook]. It says here that garlic oil is not found in fresh or dried garlic, but is a product of a certain procedure, steam distillation.
>
> Jennifer: So it gets even more complicated.
>
> Expert 1: I just wish we could find out about these things **before** they become an issue.

My Unit Head returned with two recommendations for the Issue Sheet. First, she told me that I had used the wrong issue sheet template. It was not that it was

“wrong,” but that there was no way of tracking that type of issue sheet. So I rewrote the issue sheet in another template that could be tracked. Second, it would be important to find out how many files would be affected by the Issue; this required using an obscure search engine, that few staff members (if any) were trained to use. I had to locate a unit with students on staff, get the necessary blessings for a student’s time to be used for this endeavor, and then advise the student what to search for (e.g., what would be other names for oil? she asked), and then, after the student kindly completed the search, include the search results in an appendix to the Issue Sheet.

I also had to propose options in the Issue Sheet. Having worked previously in non-hierarchical, consensus-based environments my approach was to speak with the scientists responsible for each of the four main areas that would be affected; to explain what I had learned about the issue and to find out what they thought were the main concerns and options; and then cycle through the group of four until there was effectively consensus. This approach worked very well, with interesting discussions, until I hit a snag: I had completely forgotten to take into account the government hierarchy. (I was in the lowest rung). When one scientist suggested that all the monographs with plant matter would have to be revised, I asked if it would be more expedient to revise the *Compendium of Monographs* (with the quality specifications) rather than the fifty plus individual monographs as had suggested another scientist; this suggestion was taken in stride, but when I said I had better consult my supervisor as well, the higher-ranked scientist looked

completely taken aback, and then joked: “Yes. Of course I value her opinion. If she disagrees we’ll deck it out.”(Faux pas number two: It might seem like a collegial environment, but it is not, fundamentally, collegial, in the sense of consisting of equals). One surprising outcome from the discussion for me, was that another scientist brought the issue of wound botulism back on the table: if a topical product gets used on broken skin, could it pose the risk of wound botulism? Another scientist clearly thought it was ridiculous initially because many manufacturers of topical products were large pharmaceutical-style operations, but, over the course of the conversation, ended by rationalizing: “Well they [applicants] should be thinking about this, at least, and telling us what they are doing.”

I worried that the entire issue process was making a mountain out of a molehill. What started with one errant garlic capsule file, was now ending up involving any plant-matter-in-oil with an oral or topical route of administration. But without clear standards or relevant studies, where to draw the line? (cf. Salter 1988)

Week 5: I sent the revised Issue Analysis Summary to three other scientists. One scientist found a description of the “12D process” on the FAO website. (I had assumed the chemists would know what the process was, but I guess I was not the only one who did not know what the 12D process was). It turned out that the process had to do with packaged meat, fish, and other foods. So the scientist justly asked: is a heat process suitable for canning going to be usable for natural health products? I doubted it, but given my level of knowledge regarding manufacturing

processes (zero) I did not comment and forwarded the website to all the scientists I was consulting on the issue.

One of the scientists came by to say “I haven’t read your issue sheet yet;” I responded I thought I had done what I could given my (lack of) knowledge of manufacturing processes, and that now it was at the point of decision for management. The scientist assured me: “It will be brought forward [in meetings] to see if – no, not if, because we have to deal with it, it is just a matter of how.” I was asked to track in the issue sheet in yet another system; so I had to cut and paste everything into another issue sheet template.

I heard through the grapevine that the Issue was moving forward in meetings; the content was not really changing, just the wording; the *Compendium of Monographs* would be edited, a new standard line would be made for applications in process, and letters sent out to applicants with licenced products.

Week 6: I was no longer really involved as the Issue bounced around management meetings. At one point I heard that upper management decided that nothing needed to be done, because, they stated, the risk was theoretical. That made me quite angry. I realized one had to be rather politically astute for these science things. I decided that if I was asked to revise the sheet I would argue there was a difference between an extant oral risk (e.g., people have been made sick orally as

demonstrated in the food sector), even if the overall extent of the risk (e.g., risk from topical administration of plant-in-oil products on broken skin) was unclear.

Week 8: I was asked, orally, to make the issue sheet shorter for upper management. I ignored the request.[3]

I got a response to the Information Request Notice I had sent weeks prior for the original garlic file. The applicant called to tell me she had been thrown for a loop by the request. (So much for the fishing expedition, hoping that industry already had standards.) The applicant had gone to a university-based food information service. She sent in the professor's preliminary report. I examined the response. The professor concluded that "This product is not conducive to the production of *Clostridium botulinum* toxin." Excellent.

The problem was, there were several inconsistencies within the report and between the product as described in the report and that in the Product Licence Application form. The author stated the garlic was extracted into "garlic oil," but canola oil was listed as the non-medicinal ingredient. When I called the applicant to clarify the non-medicinal ingredients, the contact said they used olive oil, or maybe vegetable oil; and this extraction was "similar to a garlic oil[4] process." (While there was no difference from my perspective whether olive, canola, or another vegetable oil was used, it was not a good sign that no one seemed to know what the oil was, or whether in fact the 'oil' was actually a product of steam distillation ('garlic oil')

and that technically speaking, might mean the proposed medicine did not meet the definition of a natural health product). There was also an inconsistency regarding whether there were, or were not, garlic pieces in the final product. The author of the report stated that the finely macerated fresh garlic was extracted in oil, and then the oil was filtered through a multi-layer filter; but the Health Canada botulism expert, who I asked to comment on the applicant's response, explained that there would still be pieces, even if these were very small, and it was possible that the water and oil phases would separate and create microenvironments that would be conducive for the production of toxin.

A chemist in the directorate suggested that I get around having to directly point out these inconsistencies by asking the applicant for: (1) a flow diagram of manufacturing process, (2) a batch record (when someone signs off on the completion of each step in the manufacturing process), and (3) specifications, in hopes that the company would clarify (to us and to itself) what exactly was going on. I explained to the applicant that the proposed medicine would have to be assessed in the Non-Traditional Assessment Stream, because it was going to require a full quality assessment (and therefore was not subject to the 60-day disposition of the Compendial Assessment Stream); I sent another Information Request Notice to that effect. Interestingly, I could find no standard line for a general safety concern. So I had to make my own, citing the clause in the laws about safety.

Week 9: No news on botulism. One lower manager said she worried that my work would be lost. (I worried that people might get sick!)

Week 12: I was tasked with hunting down methods for determining “moisture content” because a number was needed: “drying,” one of the options to be given to manufacturers, was insufficient to ensure safety. I asked quality assessment officers about standards and appropriate numbers for “dryness”, but clearly methods for determining moisture content were not frequently of concern: one chemist had to think for a while, before speculating, “maybe USP?” [United States Pharmacopoeia] But when we looked, the method was designed for calculating moisture in synthetic chemicals. We asked more senior quality personnel; they said that moisture content is submitted sometimes by the applicant in the specifications – if the applicant is attesting to USP quality then technically moisture content is important, but they never actually check. (It would be checked on “a case by case basis.”) I was flummoxed that such a basic thing, a method for figuring out how much water was in something, could be difficult to find. I did several general computer searches for methods. One of the few articles that I could find describing methods was from the FAO – essentially, it was a guide for food producers in countries with very low GDP. (Excellent! I thought. Industry will be unable to use their usual complaint, that the test is too expensive and will put them out of business).

The problem was, I still could not find a number. Where to get it? There were some moisture content limits in the *Food and Drug Regulations* for certain spices, but these numbers ranged from 8-12% -- and I was unsure whether 8% would be feasible for a spice with a maximum moisture content listed at 12%.

Week 13: And then, my year was up at the NHPD. While that remark seems facetious, staff leaving 'in the middle of' projects was a recurring theme in the organization. A colleague graciously took over "the lead" on "the Issue;" I noticed a *Communiqué* on the issue was published in the months that followed, so presumably upper management finally decided the risk was not merely theoretical.

Conclusions

This anecdote, the "botulism Issue," is an example of regulatory scientists' decision-making under uncertainty. A decision required either familiarity (expertise) or time (to get the expertise, workable standards). The decision was also not really about "knowing" – it was about reasoning in social and institutional context, and was not reducible to any one scientist. But more importantly, the anecdote illustrates how not every safety concern leaps out from the file, batting one's nose and commanding immediate attention. Had I not been thrown out of my reasoning-in-activity – by my supervisor's wise but distinctly non-backlog-reducing activity of sending a file back "just to see what happens" – I would never have noticed the safety concern. While notice of this safety issue was unpredictable in the sense

that neither I nor my supervisor noticed it initially; the notice was predictable in the sense that it was apparently impossible in one type of reasoning activity.

A reflection on causality and performance standards

When I felt I was expected to, I saw an application that was consistent with the regulations, and recommended it for licencing. When I felt I was expected to, I saw a health risk posed by that same application, and could no longer recommend it for licencing.

These feelings of expectation were, to a large extent, self-imposed. That particular unit head *never,* explicitly or implicitly, told me she expected a certain number of recommendations weekly. That particular unit head also never told me, directly, that there was a problem with file (although the file return was sufficiently unusual to perhaps merit such an assumption). Even though “self-imposed”, the change in expectations changed my ability to notice safety issues. Had I spent the five minutes reconsidering the file before I had originally sent it to my Unit Head, rather than after it was returned with her cryptic sticky note, I am quite sure that the risk of botulism would never have emerged.

I cannot go further with a causal analysis. I cannot specify *why* this change in my ability to notice happened with the change in implied expectation. My commitment to the public interest did not waver, although the way in which it was manifest in thought and action was very different.

I do have a few suspicions, however. One, is habit: the tendency of operating procedures is to facilitate, and with time hone, efficient thinking habits. There are many safety issues, such as ensuring a correct dose, and ensuring the absence of contamination by bacteria, solvents, pesticides fungicides and so on, that are probably best caught by a systematic, thorough, habit-based and efficient style of reasoning epitomized by the checklist, and honed with standard operating procedures. (Even better caught, of course, by random and published laboratory testing, but that was beyond the NHPD's abilities). But there are also many safety issues that are non-standard, and their notice through non-directed reasoning was not factored into, or honed, by standard operating procedures and the like. (This is not to say that non-directed reasoning could not become part of a standard operating procedure or checklist; for instance, one step in these procedural lists could be to spend five minutes imagining that there is a major problem with this product and you have to find out what it is).

My other suspicion is that it comes down to expectations due to humans being innately social beings and aware of others; this sensitivity to implicit expectations amplified by being humans kept in relatively close quarters and relatively immobile and devoting great swaths of time dedicated to what is, essentially, drudgery; amplified by these humans being pre-selected for their interest in working on a communal project with no hope of individual, public recognition (unless something goes very wrong). In such situations, I believe, little things matter.

Beyond my suspicions regarding the roles of habit and innate sociality of human beings, I cannot go further in analysis. While the “mechanism of action,” as it were, for, say, my notice of a health risk when momentarily freed from the backlog and its trimmings (performance standards) – when the purpose of my reasoning activities shifted from “let’s complete the checklist and be productive” to “what’s wrong with this picture, I need to solve the puzzle” – would be immensely interesting, not only for myself as anthropologist but I am sure for the hypothetical and nefarious creature who wishes regulatory reasoning to go against the public interest – is it even there?

Let me turn from bureaucrats to headhunters. A generation ago, anthropologist Needham considered various ethnographic accounts of headhunting around the globe; it was relatively non-controversial that globally, in communities that practiced it, headhunting was associated with good harvests, good health, fertility, and so on in the community. What Needham took issue with was the ethnographic interpretation of this association. The explanation in many ethnographic accounts of headhunting involved the transfer of some life-force or soul-force from the severed head, to the warrior, crops, or community. In these explanations, Needham explains, the relation between “head-hunting and welfare is the causal relation *Skull* → *(soul-substance)* → *fertility*, etc.” (1976: 72, emphasis added in lieu of original line breaks.) Needham does not doubt that members of communities in which headhunting was practiced believed there was causal relation between

head-hunting and various benefits for the head-hunter. Rather, he doubts whether any quasi-physical soul-substance is involved in local explanations. Explanations involving soul-substances as part of a mechanism of action, Needham argued, were those of the anthropologists attempting to make sense of the connection, and did not represent understandings of participants in headhunting. These participants simply said they severed heads because if they did not, their ancestors would be angry and cause misfortune to befall their crops, their health, and so on. And when, in the colonial era, formal law, Christian missionaries, and other factors prevented the practice of headhunting, elders blamed reduced birthrates and fertility on the lack of headhunting. There was no mechanism or intermediary ever reported in the causal relationships claimed by those in headhunting communities. Needham argues this lack of intermediary would not make the non-anthropologists' accounts incomplete; rather, it makes the previous anthropologists' accounts of headhunting revealing for *their own* assumptions of appropriate causal attributions.

Social facts, according to Durkheim's approach to sociological method, can only be explained by social facts.[5] I would argue that the change of institutional notice in the botulism Issue is such a social fact, and as such, can only be explained by other social facts. I speak of habit and innate sociality as social facts, not psychological ones. To posit a psychological mechanism of action, for instance, may satisfy a curiosity for "how things work" but is rather irrelevant in the sociological (anthropological) project of this dissertation.

For the purposes of this dissertation, it is enough to say that expectations arising from reasoning-in-activity have an effect.

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1 The order and timing of the events and my reactions are reconstructed from my fieldnotes more than two years after their occurrence. When writing my fieldnotes, especially at the beginning of the events, I did not know the events would become an Issue whose resolution might serve as exemplar. Furthermore, these events happened in Ottawa's non-snowy season and so I was often biking to and from my fieldsite and thus not confined for two hours daily in a seat on public transit which, incidentally, is very conducive to the regular and thorough writing of fieldnotes when colleagues are not on the same bus. As such, the exact timing of certain conversations or revisions occurred, or exact content of various revisions may not be entirely accurate in my reconstructed account. This is irrelevant, however, to the gist of the saga.

2 Garlic capsules are often used as the no-brainer safe reference medicine in discussions of drug safety. For instance, in the Vancouver Sun, in an article entitled "Doctor flags serious flaws in our system for regulating drugs," Michele Brill-Edwards, who had then recently resigned from her evaluator position at Health Canada because of concerns she had regarding drug safety, is quoted as saying: "I have personally seen the uneven application of the law that sees thousands of lives lost through lax regulation of high-risk products like blood and prescription drugs while low-risk products are suddenly regulated off the shelves [….] There is a huge difference between receiving a blood transfusion, taking aspirin and taking garlic capsules" (DeMarco 1997: B7).

3 Orders from up the hierarchy received orally could, to some extent, be "forgotten." Orders given in writing had to be followed or subordination was evident. Orders could at any point be contested; however the final written order was an order. Some scientific staff considered that not kowtowing to every implied desire, or off-the-cuff statement of management as "pushing back" against activities or changes with which they were in disagreement (usually on matters that they felt were not conducive to public health protection or a healthy work environment, not silly matters of document length.) Therefore, among scientists permanently appointed to their position one would hear the statement "When I get it in writing, by e-mail I will worry about it."

4 "Garlic oil" is, from what we could tell from one reference text in the Directorate, different than "garlic-in-oil." "Garlic oil" is a product of the steam distillation of garlic; and it contains compounds not naturally found in garlic.

5 Mary Douglas was concerned that following Durkheim's practice, his attention to emotions, rather than his teachings against such psychological attributions would lead to a faulty "functional argument [because it] depends on the unconvincing loop connecting social and psychological effects" (1986:35). If, however, one does not approach emotions as psychological any more than one approaches reasoning as psychological, the problem is obviated.

Chapter 8
The evaluation of traditional medicines
The challenge becomes change

> « Through the Natural Health Products Directorate, Health Canada ensures that all Canadians have ready access to natural health products that are safe, effective and of high quality, **while respecting** freedom of choice and philosophical and **cultural diversity**.»[1]

While setting up its assessment programme, the Natural Health Products Directorate's staff went about respecting "cultural diversity" by developing procedures that would not exclude the medicines of any ethnic medical tradition, provided the medicines were deemed suitable as over-the-counter medicines. Staff designed policies for numerous contingencies that might otherwise have precluded the pre-market licencing of traditional medicines. Preparing for the possibility that the traditional use of a medicine might be part of an undocumented oral tradition, the NHPD established a procedure for accepting oral histories as evidence supporting the safety and efficacy of a medicine. Preparing for the possibility that the written record of a traditional medicine might omit crucial (for the NHPD) details like daily dose, the NHPD developed criteria for acceptable Expert Advisory Reports supplying this missing data. Preparing for the possibility that researchers or companies would argue that the randomized, controlled trial was ill-suited for evaluating efficacy in a particular medical tradition, the NHPD advertised that it would happily consider many non-standard clinical trial methods in the evaluation of the efficacy of medicines from non-biomedical traditions. In any event, NHPD officials repeatedly broadcast that clinical trials would not always be required as

evidence of safety and efficacy. In the words of the Director of the Bureau of Clinical Trials and Health Sciences, Robin Marles:

> What we did not want to do, was to force homeopathics, or traditional medicines, based on different healing paradigms, with different concepts of causation of disease and treatment of disease, to all be *forced* into the pharmacological paradigm of demonstrating efficacy through randomized, placebo-controlled clinical trials. That would *not* be respectful of cultural and philosophical diversity.

I had high hopes for a fieldwork experience filled with many kinds of traditional medicines and novel measures of efficacy.

Despite the Directorate's efforts towards being inclusive of all possible traditional medicines, through the summer of 2007, successful Product Licence Applications in the Traditional Assessment Stream were generally associated with only three *paradigms* of traditional medicine: traditional Chinese medicine, Western Herbalism, and, rarely, Ayurvedic medicine. There are at least three reasons for this *de facto* restriction of traditional medicines to those of three medical traditions. One is the definition of "traditional medicine" used by the NHPD, which I will describe in the first part of this chapter. Second, while the NHPD can extol the virtues of a multicultural Canada, the NHPD cannot create pre-market applications and must assess whatever pre-market applications industry submits, and if these applications only pertain to the medicines of a few healing paradigms, or to medicines from countries who export more non-chemical medicines than they import, so be it. (By the end of my fieldwork, most of the 3619 applications ever received by the Directorate in the Traditional Assessment Stream had been

submitted by six companies).[2] Both these reasons are tied to a third: the importance of textual standards in the assessment process. Traditional Chinese medicine and Ayurvedic medicine are scholarly medical traditions, and, like traditions of herbal medicine falling under the rubric of Western Herbalism, have extensive textual histories and standards in the form of pharmacopoeia, formularies, dispensatories, textbooks, and handbooks. Other scholarly medical traditions such as Japanese, Tibetan, and Unani medicine were not cited in Product Licence Applications at the time of research, nor had they drawn the attention of Health Canada during the previous two decades.[3] The focus on these three traditions of medicines is not Canadian-specific; I note that the Australian Therapeutic Products Administration, the analog of the Canadian Health Products and Food Branch of Health Canada, divides traditional medicines into three as well: Ayurvedic medicines, traditional Chinese medicines, and other traditional medicines (Australian Government 2006).[4] My initial hopes were not realized; nevertheless the evaluators' reasoning proved to be more interesting in other ways.

The Traditional Medicines Unit

The Traditional Medicines Unit (TMU) was responsible for assessing the safety and efficacy of all Product Licence Applications in the "Traditional Assessment Stream." The Unit was composed of approximately four assessment officers (BI-03s) serving under a Unit Head (BI-04). All assessment officers who had ever worked in the Unit had qualifications in the biological sciences, with most holding at least a master's degree; several of the scientists associated with the Unit had relevant post-doctoral

laboratory experience. At least four of the Unit's past or current assessment officers had previously worked in at least one country as a licensed health care practitioner, including as: medical doctor, traditional Chinese medicine doctor, naturopath, Ayurvedic doctor, and aromatherapist. I observed or interviewed nearly every assessment officer who had, to my knowledge, ever worked in the unit; for reasons of confidentiality, I do not distinguish between present and past members of the unit.[5] In addition to individual interviews and observation, two group meetings inform this chapter, as well as some document analysis.[6]

This chapter discusses the assessment of traditional medicines at the Natural Health Products Directorate, in four parts. The first and foremost activity in TMU's assessment activities was to determine whether a Product Licence Application really proposed a traditional medicine, as defined by the Directorate. Therefore, I begin this chapter by presenting the way in which the Unit's scientists operationalized "traditional medicine." One feature of this operationalization is especially notable: scientists reasoned medical paradigms as untranslatable. This feature causes me to reiterate my caution against exclusive reliance on policy or regulatory *documents* in social science research and also to undergird my assertion, to be expounded in the next chapter on homeopathy, that personal conviction and belief regarding medical practice had relatively little bearing on scientists' reasoning in the Directorate.

In the second part of this chapter, I describe the process of evaluation in the Traditional Assessment Stream using examples from my observations of evaluators working in their cubicles. I argue that evaluators in the Traditional Medicines Unit were adept at assessments of the safety and efficacy of traditional medicines that were clearly documented in textual standards like pharmacopoeiae. The corollary of this proficiency was scientists' acute awareness of the challenges posed by heterogeneous and evolving medical traditions, when they were perceived to diverge from the documented norm. Discrepancies between the composition, preparation, or dosage form of traditional medicines in Product Licence Applications, compared to those of pharmacopoeia and other textual standards, were described by evaluators in the Traditional Medicines Unit as "issues" and "challenges." The third part of this chapter will present three such "challenges" involved in the evaluation of traditional Chinese medicines by the Traditional Medicines Unit. The way in *science* and *tradition* were enmeshed in the use of the *Pharmacopoeia of the People's Republic of China* as evidence of safety and efficacy is the subject of the chapter's final discussion.

Traditional medicines as defined in regulatory texts

The *Natural Health Products Regulations* (2003) mention "traditional medicine" only in the section defining "natural health product," namely that a traditional medicine is by definition a natural health product under many circumstances.[7] There is no definition of traditional medicine in the regulations, nor do the

regulations mention whether traditional medicines must be assessed for safety and efficacy differently from, or identically to, any other type of natural health product.

The NHPD's definition of "traditional medicine" is established in a series of Guidance Documents.[8] In these guidance documents, the Directorate uses the World Health Organization's definition of traditional medicine, word-for-word:[9]

> Traditional medicine represents the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (Health Canada – NHPD 2006c)[10]

The indigeneity, or cultural requirement, was an integral part of this definition in practice (see Figure 8-1).

Figure 8-1: Slide "Traditional Medicines" from an NHPD internal training session titled "An Overview: Evidence for Safety and Efficacy of Traditional Medicines" held April 10, 2007. Used with permission. [Slide 6 in original presentation].

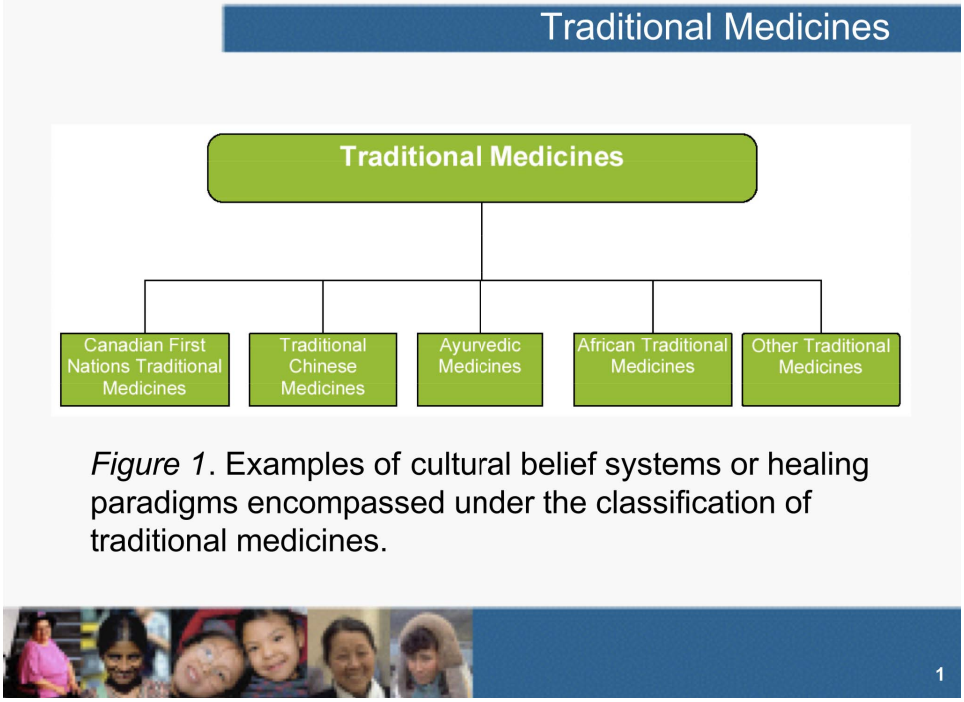

Figure 1. Examples of cultural belief systems or healing paradigms encompassed under the classification of traditional medicines.

This requirement allowed the Directorate to clearly exclude several health traditions from the ambit of the Traditional Assessment Stream.

One such excluded tradition was aromatherapy. The Traditional Medicines Unit had received several Product Licence Applications for aromatherapies. At the time of my research, the Traditional Medicines Unit had decided that aromatherapy did not meet the definition of a traditional medicine, and thus could not be evaluated in the Traditional Assessment Stream. One of the unit's members argued that *if* the applications in question had involved essential oils used in, for instance, compresses used in a traditional paradigm of medicine (e.g., Western Herbalism), the medicines could have perhaps been assessed as traditional medicines, because then there would be a clear, cultural origin. But when, for instance, applications were for bath salts "for indications that are definitely not recognizable within any traditional system of medicine,"

> That's where you, kind of have this other challenge, where, it doesn't necessarily fit within the definition of what a traditional medicine is... (Ampan)

The Unit left open the question of whether aromatherapy constituted a "health paradigm" and could have an assessment stream developed according to appropriate standards, perhaps like had been done for homeopathy.[11] That question was not for the Unit to answer.

While the NHPD used the WHO definition to exclude whole classes of medicines from the category “traditional medicine,” the WHO definition was otherwise relatively insignificant in the daily work of the Traditional Medicines Unit.

The criteria used to determine whether a Product Licence Application would be considered in the Traditional Assessment Stream constituted the practical, everyday definition of *traditional* for the purposes of the Unit.

The everyday, working definition: non-essentialist

NHPD’s approach to traditional medicine, in its everyday practices, was decidedly non-essentialist. In the context of the Traditional Medicines Unit, a statement like “Ginger is a traditional medicine,” was absolutely non-sensical. Medicines with ginger in them could be assessed in either the Non-Traditional or the Traditional Assessment Streams. For a medicine to be licensable in the Traditional Assessment Stream, at least three conditions had to be met:

First, as already mentioned, the medicine had to have been used within a traditional system of medicine, as defined by the WHO, for at least 50 years.

Second, the medicine had to be prepared using traditional methods. Traditional methods of preparation accepted by the NHPD were: infusions in oil or water, balms using beeswax, extracts using pressure, water, ethanol, glycerine, or vinegar, and the use of whole or tangible parts of organisms.

These first two conditions were necessary for the NHPD to take traditional use as an indicator of the safety of the medicine. Failing to meet either of the first two conditions would result in an easy rejection of the Product Licence Application in the Traditional Assessment Stream.

The third condition pertained to the health claim on the proposed medicine's label. In the concise wording of the *Evidence for Safety and Efficacy of Finished Natural Health Products* Guidance Document, "Products are divided into two categories *according to the claim*: traditional use claims, and non-traditional use claims" (Health Canada – NHPD 2006c, emphasis added).[12] In the Traditional Assessment Stream, the recommended use or purpose for the medicine, or the health claim, must:

(1) begin with the phrase "Traditionally used in,"

(2) State the "system of medicine or healing paradigm" in which there is traditional use,[13] and

(3) Make a claim regarding a health condition that is logical and diagnosable within that system of medicine or healing paradigm.

In other words, "efficacy has to be within the context of the paradigm" (Ommy).

Health claim is key

The health claim – rather than the medicinal material itself – was paramount in determining whether the application was admissible in the Traditional Assessment

Stream. Many health claims in the Product Licence Applications received by the Traditional Medicines Unit were unacceptable because they were deemed “not really traditional.” Most often, applicants would confuse a traditional use with a “plausible scientific justification for traditional use” (Ampan), for example proposing claims such as “Traditionally used in Western Herbalism to increase serotonin levels.” Applicants frequently made claims regarding conditions diagnosable only through laboratory-based procedures, such as high cholesterol, or low potassium levels in the blood. For this reason, Megha, an assessment officer in the Unit explained how she could often tell, upon glancing at the sixth page of a Product Licence Application, whether a file would have to be refused in the Traditional Assessment Stream:

> Sometimes by looking at the claim I know that it is not traditional use. For example, there is one Ayurvedic herb, it is called guggul. The terminology in Ayurveda is different than in Western medicine. So it can be translated as “for aggravated kappha,” which is an Ayurvedic diagnosis, [but it] has been translated, non-properly... [as] “for hyperlipidemia.”

After explaining that there is actually a connection between aggravated kappha and hyperlipidemia, she continued:

> There is a connection, but it is not to be found in Ayurvedic texts. Obviously [guggul] should be used in hyperlipidemia; in clinical practice, the Ayurvedic properties of herbs are used for hyperlipidemia. So if I read “traditionally used for high cholesterol,” I know what they [the applicants] are thinking, I know the link between traditional use, which is aggravated kappha, and hyperlipidemia. But I can’t recommend it for traditional use: because there is no strong tradition.

Typically, in such a situation, the Traditional Medicines Unit would request that the applicant either revise the claim to a truly “traditional” claim, or transfer the

application to the non-Traditional Assessment Stream by dropping the word *traditional* in the claim and supplying non-traditional evidence of efficacy.[14]

No essentialism, but no translation of paradigmal terms either

This distinction between traditional and nontraditional was not essentialist, but rather a pragmatic organizational decision on the appropriateness of assessing a health claim in the Traditional Assessment Stream. When I asked Megha whether it bothered her that she could not recommend claims based on current usage in the Traditional Assessment Stream, she replied:

> Sometimes, but, like, you have to follow some rules. Because when you translate something from traditional to Western, right, there are so many points that you have to consider.

Another evaluator-practitioner, Tommy, explained that sometimes,

> You should not translate [the diagnosis] to the modern scientific term. [You should] keep like it was 100 years ago. If you translate, maybe there is some overlap, but the old & new terms are not completely interchangeable and you make some mistakes. That's the thing.

By the time I did my fieldwork, the Traditional Medicines Unit, in some ways, had begun advocating a radical position of untranslatability. The original (2003) version of the guidance document titled *Evidence for the Safety and Efficacy of Finished Natural Health Products* stated that the health claim had to include, as a qualifier, the healing paradigm or system of medicine *only if* a paradigm-specific term like *qi* or *agni* was used. By April 2007, this had changed. At a meeting on April 19, 2007, Unit scientists explained to me that not only did the healing paradigm *always* have to be specified in traditional use claims, but furthermore, inexact English or French

translations of “the ‘native’ term, as we call it” were generally not acceptable. This meant that paradigm-specific terms had to appear as-is, and could not appear only in French or English translation. The biggest offender in this category was probably the substitution or translation of *qi* with *energy*, *power*, or *vital energy*. The Traditional Medicines Unit would not allow claims like “Traditionally used in TCM [Traditional Chinese Medicine] to enhance energy,” because, as scientists from that unit argued, “energy, in white Canadian culture means a very different thing” from *qi*.[15] *Qi* had to appear in the claim, with “energy” permissible only as additional information, for example in parentheses. Likewise, for a particular medicine the NHPD did not permit the claim “Traditionally used in Ayurveda as rejuvenative tonic,” but allowed “Traditionally used in Ayurveda as *Rasayana* (rejuvenative tonic).”

No translation, and no mixing either

Just as so-called translation between traditional and scientific claims was not permissible, the combination of different traditional medicinal paradigms was not appropriate in the Traditional Assessment Stream.[16] Evidence supporting a health claim had to be from a single “medical paradigm.” It was not possible to support the efficacy of a medicine by taking the dose of, say, ginger used in traditional Chinese medicine, and combining it with health claims made for ginger using Ayurvedic terminology.

There were a few instances in which NHPD-authorized label claims referenced multiple health paradigms. It was possible that a medicine containing ginger, for example, could acceptably have four different types of claims: (1) Used for the relief of motion sickness, (2) Traditionally used in Western herbalism for the relief of nausea, (3) Traditionally used in TCM to disperse cold phlegm in the lung, and (4) Traditionally used in Ayurveda for digestive disorders. In this instance, however, each separate claim would require evidence from a separate paradigm and be assessed independently, and on the label each claim would have to be stated in a separate sentence.[17] The label was thus interpreted to be consistent with NHPD's approach to traditions of medicines as separate, self-contained and internally logically consistent, "paradigms."

Science, "Western medicine" other paradigm(s)

This non-translatability between paradigms also meant, that to some extent, science did not trump traditional knowledge, in the sense that science was conceptualized as its own paradigm. For instance, the labels of traditional medicines regularly contained warnings from multiple health paradigms, because the label had to include cautions and warnings found in the scientific literature *and* those found in the relevant traditional literature.

> So, there's actually two levels of safety [for traditional medicines. For instance] your ginseng must not be taken when you have symptoms of excess yang, because it, it is a *hot* medicine. So there's a traditional caution, in addition to any concerns about, um, blood sugar levels being under good control, because ginseng will affect blood sugar levels.

These two types of risk information – traditional and scientific – were not to be confused or merged, however, by scientists in the Traditional Medicines Unit.

An instructive error in reasoning

Scientific staff in one of the NHPD's other science-based units, at one point prior to my fieldwork, had argued that traditional risk information should be "translated" into scientific terminology.[18] Specifically, the unit took issue with a risk statement to appear on a label: "Consult TCM Practitioner if the external pathogenic influence still remains."

> The main concerns that we have (and have heard from consumers) is that risk statements should be clear and understandable to consumers. Not only those that [sic] have consulted a TCM practitioner. I can guarantee you that there are some consumers out there (my grandmother is a prime example) who may have heard something about a particular product and will take it, not understanding what chi or ying mean. If there are any concerns wrt [with respect to] risk, they should be very clearly outlined on the label so that my grandmother understands that if she has liver problems, she should consult a practitioner prior to use of this product. [….]
>
> All [we are] requesting [is] that if risk information can be translated, it should be, as we want to ensure that consumers have as much information as possible on the product, and risk information is paramount in the use of OTC [over-the-counter] products.

Scientists in this unit argued that, for example, a grandmother might take a traditional medicine having heard about its virtues, but not understand the traditional risk statement. Scientists in this unit felt that such traditional risk statements might not be consumer friendly, and should be "translated."

The unit's concerns were overruled by reasoning from higher up in the NHPD hierarchy. A manager reiterated that for traditional medicines, the label must

contain two types of risk information: that from the scientific literature, and that from the traditional literature. Because of this two-fold approach, so the manager argued, there was no reason why the grandmother would not get "consumer-friendly" risk information from the scientific literature. Furthermore:

> traditional healing paradigm cautions, warnings, contraindications, and adverse effects may refer to paradigm-specific symptoms or conditions. These paradigm-specific statements are often NOT TRANSLATABLE. Part of our mandate is to respect freedom of choice and cultural and philosophical diversity. It would be disrespectful and even deceptive to try to translate such concepts since they do not necessarily relate to pharmacological concepts or common English understandings.
>
> Of course there are many consumers out there who will not understand either the indications/claims or the contraindications/risk statements for traditional medicines from particular paradigms. We allow paradigm-specific labeling out of respect for those consumers who do understand the paradigm. It was never part of our mandate to try to homogenize traditional medicines so that they all fit the western pharmacological paradigm. That would be neither possible nor desirable.
>
> Since the inclusion of any risk information from the scientific literature (i.e. pharmacological paradigm) is mandatory, this provides the same level of consumer protection as for any other NHP.
>
> We go even further with traditional medicines out of respect for those traditions. Please note that we are talking about further information, not a substitution or deficit of information.

Summary

So far, I have advanced two arguments. (1) Although the NHPD used the WHO's definition of traditional medicine to exclude non-ethnic healing paradigms from the framework of traditional medicines assessment, this definition did not usually come into play in the daily assessment work of the regulatory scientists. In day-to-day assessment, the assessment officers used a pragmatic and non-essentialist definition of traditional medicine that centered on the health claim made for a

medicine. (2) The Traditional Medicine Unit generally treated systems of traditional medicine as separate, self-contained and internally logically consistent, “paradigms.” The Unit discouraged slippage between paradigms – between traditional paradigms and scientific paradigms, and between two different traditional paradigms. To a certain extent, the Unit’s everyday requests to applicants evinced a politics of radical untranslatability.

I hope this section has underscored the importance of an anthropological approach to the study of government activities. While the Directorate’s official definition of traditional medicine literally exists in black and white print on a page, the way in which the traditional medicines unit approached traditional medicines (e.g., the *de facto* policy) was not entirely predictable from the official document. For instance, the rather radical position of untranslatability eventually espoused by the Traditional Medicines Unit did not in any way necessarily follow from the general or the working definition of ‘traditional medicine’ set out in guidance documents.

Now that the reader presumably understands the definition of “traditional medicine” in the Directorate’s regulatory texts and in other regulatory practice, as well as the evaluators’ non-essentialist approach to “medical paradigms,” I continue my description of the processes of evaluating medicines in the Traditional Assessment Stream. After I explain the extent to which the process favors scholarly, standard reference documents, it will likely come as no surprise that the scientific staff in the Traditional Medicines unit felt the biggest “challenge” in the Traditional Assessment

Stream was “change.” Throughout these next sections, I present a few excerpts from my observations of assessment officers in the Traditional Medicines Unit at work, to complement the description of Alex’s assessment of a Traditional Chinese medicine file with 25 medicinal ingredients in Chapter 5.

The traditional assessment stream:[19] tradition as documentation

As with any Product Licence Application received at the NHPD, applications in the Traditional Assessment Stream were first processed by clerical staff, who bundled the paper application received into a file. These clerical staff also verified the administrative information in the application. The files were then given to scientific staff for screening. If the applications were deemed complete after the screening process, copies of the file were simultaneously sent to two assessment officers: to a chemist for the evaluation of quality, and to a biologist employed in Traditional Medicines Unit for the evaluation of safety and efficacy.[20]

In general, the evaluation of quality at the NHPD was standard across all assessment streams with no special considerations given to traditional medicines, except to ensure that the medicine was prepared according to a “traditional method of preparation,” as defined by the NHPD. (Rarely, the safety assessment officer would also examine the details of the methods of preparation.[21]) One quality assessment officer remarked that the only thing he felt was noteworthy in terms of difference for applications in the Traditional Assessment Stream, was that

manufacturing was more frequently located overseas and this implied increased communication challenges between the NHPD and overseas quality control personnel due to language barriers.[22]

Safety, in the Traditional Assessment Stream, was basically assumed if two criteria were met. First, the product had to meet the definition of a traditional medicine – e.g., had to have a history of at least 50 years of safe use in a particular culture.[23] The NHPD explicitly stated that 50 years of use in a particular culture was sufficient evidence of safety in the first and second generations, provided there was no evidence to the contrary. The second criterion was a search for evidence to the contrary: a pubmed (MEDLINE)[24] search for each medicinal ingredient that yielded no reports of adverse events. The pubmed search was rationalized as a verification regarding the product's safety when used concomitantly with pharmaceuticals like blood thinners and beta-blockers. There were a few medicinal ingredients that the assessment officers had learned, with experience, had safety concerns, but these were few and far between.[25] Generally, safety assessment went hand-in-hand with efficacy assessment, because both safety and efficacy were largely established through adequate documentation of traditional medicinal use.

In the Traditional Assessment Stream, applicants could take either of two approaches to providing evidence of a medicine's efficacy. Both approaches involved documenting the medicine's use within a traditional medical paradigm.

Efficacy as two independent, authoritative references from reputable sources

The first and most general way in which applicants could provide evidence supporting the efficacy of a traditional medicine, was to provide two independent and authoritative references from reputable sources to document traditional recommended conditions of use.[26] A few applicants were able to successfully support claims using this approach. Most were not. Many applicants attached the following types of documents as evidence supporting the traditional use of a medicine: printouts of opinion blogs and commercial websites, photocopies of current self-help books, and comments like "the professor at this University said …" This could perhaps generously be chalked up to genuine ignorance regarding what should be considered "authoritative and from a reputable source," as stipulated in the NHPD's guidance documents.[27] Applicants with basic research skills included photocopies of secondary sources and review articles,[28] but the Traditional Medicines Unit found many of these sources unacceptable. Often, these secondary references provided scientific or 'holistic'[29] justifications for (possible) traditional use, rather than documenting traditional use itself. Certain secondary sources also contained a citation trail that stopped cold, e.g., "if you dig deeper for what is there, for the ground [of the traditional use], it is not there" (Tommy). Even when applicants had sufficient research skills to locate appropriate primary sources, these primary sources often lacked information the NHPD considered crucial, such as the part(s) of the plant used traditionally, the quantity of plant consumed traditionally, how frequently and for how long. Even the NHPD's standard reference texts for Western Herbalism – *A Modern Herbal* (Grieve 1976 [1931]) and *King's*

American Dispensatory (Felter and Lloyd 1983 [1989])[30] – lacked crucial pieces of information regarding the medicine's recommended conditions of use. For the NHPD, a reference text's straight-forward statement like "Use mint for the relief of bellyache, by making it into a tea" provided insufficient information on the recommended dose, frequency of use, and plant part used. This problem was not restricted to the texts of Western Herbalism; handbooks of medicinal herbs from other continents, and even the *WHO Monographs on Selected Medicinal Plants* (1999, 2002, 2007), were similarly problematic for the purposes of the NHPD's Assessment.[31] Although the NHPD had a system of accepting expert opinion reports supplying missing information like "plant part used", by mid-2007, no applicants had produced any expert opinion reports that met the NHPD's criteria, at least according to one long-standing employee of the unit.[32]

To give the reader a sense of a typical assessment in the Traditional Assessment Stream, I describe Kieran's assessment of a medicine containing pau d'arco. Unlike the other examples of assessments I give in this chapter – where there is some hope of the medicine being licenced in the Traditional Assessment Stream – this example is perhaps more representative of most applications received by the Traditional Medicines Unit. One of the Unit's employees estimated that 80% of the applications received by the Unit were inappropriate for the Traditional Assessment Stream because of the Unit's working definition, and, like the pau d'arco example below, would probably have to be reclassified into another assessment stream or (eventually) refused a product licence. Common reasons for the inappropriateness

of applications included: making scientific rather than traditional health claims, lacking evidence of traditional medicinal use,[33] and making claims for serious diseases. The pau d'arco application evaluation by Kieran had the last two problems.

Example observation. When "everything is wrong."

The moment I sat down in the cubicle, Kieran began expounding on the problems with the company whose application she was currently assessing. For instance, the company would invariably send unsolicited changes to its Product Licence Applications, including changes to the medicinal ingredient's dose – which meant that the assessment officer might have to repeatedly redo the safety and efficacy assessment in its entirety. In addition, the company did not seem to understand NHPD's requirement that evidence of traditional use be established in "authoritative, reputable sources." The company submitted as "evidence" an unpublished statement, by an Australian naturopath, that a South American herb had been used for thousands of years. Kieran was assessing a response provided by this company to her original request that the company provide proper evidence of the traditional use of the medicine.

The sole medicinal ingredient in the particular Product Licence Application was pau d'arco, a plant native to South America. This was where the problem began. Kieran told me that she knew of no authoritative sources adequately documenting traditional South American medicines generally, and pau d'arco in particular. Extant authoritative sources were too vague regarding how pau d'arco was traditionally used, by whom, and at what dose. The plant species in question was also unclear in many references; it was possible that mentions of pau d'arco referred to a range of plant species, not one specific plant. Furthermore, many references Kieran had previously seen submitted in support of pau d'arco discussed the medicine's *in*

vitro properties rather than its traditional medicinal uses. Kieran stated that she knew of no pau d'arco product that had been licenced in the Traditional Assessment Stream based on evidence of its traditional use in South America. This particular file did not promise to break the trend. In addition to sending in a printout of an opinion website, the company had cited, as evidence of the medicine's efficacy in a traditional context, a monograph in a book that I will rename *The Mystery and Science of South American Cures*.

Kieran's instinct was that the reference book was inappropriate. She began searching for precedents by other assessment officers in the Traditional Medicines Unit regarding pau d'arco medicines. While searching through previous Safety and Efficacy Assessment Reports on the shared computer drive, Kieran became increasingly frustrated, muttering "BAH," because the same issues of insufficient evidence recurred in multiple files. But in one of these precedents, another assessment officer had objected to another company's use of *The Mystery and Science of South American Cures* because the health claims in the book were based on an extrapolation from traditional uses, rather than the traditional uses themselves. "At least I know I'm not crazy," remarked Kieran.

In our ongoing discussion in the cubicle, Kieran hypothesized that the traditional use of pau d'arco could perhaps be established in Western Herbalism, because if the plant had truly been used for centuries in South America, she explained, presumably the eclectic Western tradition of herbalism would have assimilated, and documented, this use. Unfortunately, Kieran reported, pau d'arco was not included in the most frequently used reference materials used by the NHPD for Western Herbalism. Kieran opined that the company representative in charge of the application was unlikely to search for documentation of pau d'arco's use in more obscure texts associated with Western Herbalism, because "We've all got quotas, and so there's only so much work [the company representative is] going to do."

This fundamental problem – the lack of adequate documentation of the traditional use of pau d'arco – was only the beginning of the problems with the Product Licence Application, from the evaluator's perspective. To be licensable in the Traditional Assessment Stream, Kieran decided, each of the four health claims included in the application would have to be revised, even if the company were to submit authoritative, reputable evidence of traditional use. None of the health claims listed on the Product Licence Application specified a paradigm of traditional medicine, and each claim had an additional, major flaw. One claim stated pau d'arco "clears blood poisoning and is useful as a general tonic." Neither indication stated in that claim was permitted by the NHPD. 'Blood poisoning' is synonymous with 'septicemia', a "serious disorder" included in Schedule A of the Foods and Drugs Act, and thus not suitable for an over-the-counter label claim. The NHPD does not permit general tonic claims, requiring that tonic claims specify an organ or bodily system (e.g., liver tonic). A second claim was for pau d'arco's direct use in wounds, a use inconsistent with the company's declaration that the application was for a pill to be administered orally. A third claim was for sore throats; but again, to reasonably make this claim in the Traditional Assessment Stream, explained Kieran, the company would likely need to change the dosage form from pill to gargle. The fourth claim was "traditionally used for carcinoma." Kieran began shaking her head: "They should know better than that one," as cancer is listed on Schedule A of the Food and Drugs Act, and thus ineligible for the label of an over the counter medicine in the Traditional Assessment Stream. Kieran explained that normally, with this particular company, she would suggest alternative claims, but in this case, because there were so many issues, she would not.

Kieran cycled through many documents in the physical file with the Product Licence Application, and NHPD's computer drive, before deciding how exactly she would explain to the company why the evidence and claims it provided were unacceptable: there were just so many reasons.[34] Kieran decided to request that the applicant remove the Schedule A claims, as that was a black and white issue. But after some thought, Kieran deleted that Information Request from her

Assessment Report; she explained to me that because the company had not provided any appropriate evidence for the traditional use of pau d'arco, the lack of evidence should be the overriding concern in the current assessment report. Throughout her composition of the Information Request section of the assessment report, Kieran repeatedly wrote statements, stalled, then backtracked, because she was giving multiple reasons why a particular claim was unacceptable, which she said was not desirable. Kieran had to find the singular, most important deficiency in the file (which, given that scientists were not encouraged to write "your evidence is bullshit and you know it," required ample creativity). Kieran predicted that the company was "not going to be happy with this [lengthy Information Request Notice], but I've got to do my job, you know. I can't just let anything, any crazy claim go through." Kieran predicted that as soon as the company received the Information Request Notice, a company representative would immediately call Kieran's supervisor, and ask "what do you mean the evidence is no good?"

This example of Kieran's assessment of the pau d'arco file in the Traditional Assessment Stream, is likely representative of much of the work of the Unit. When I asked the Unit's staff, in interviews, whether they knew of any medicines licenced in the Traditional Assessment Stream that explicitly drew from indigenous traditions of medicine in the Americas,[35] the interviewees could not recall any. A few interviewees also stated that they could not think of any traditional medicines from Africa licenced through the Traditional Assessment Stream, either. As I explained in the introduction, despite the many practices of medicine throughout the world, the reality is that at the NHPD there were only three systems of traditional medicine from which pre-market applications in the Traditional Assessment Stream successfully drew: (1) Western herbalism, (2) Traditional Chinese medicine, and to a much lesser extent,[36] (3) Ayurvedic medicine. This restriction to three traditional

medicines occurred despite the fact that staff in the Traditional Medicines Unit were (I believe quite genuinely) “very careful not to exclude” any medical traditions out of considerations for fairness. But these three systems of traditional medicine have established textual standards: ample written, sometimes scholarly, evidence, in the form of historical treatises, 19th and 20th century textbooks, and – the subject of the next section – pharmacopoeia. Pharmacopoeia were especially important as they often contained details on the plant or animal part to be included, dose and so on.

Efficacy according to standard documents: the pharmacopoeial substream

The second, and often more successful, approach that applicants could take to providing evidence in the Traditional Assessment Stream was pharmacopoeial. If the medicinal ingredients, dosing regimen, and claims for the proposed medicine exactly matched an entry in the *Pharmacopoeia of the People’s Republic of China* (e.g., 2000),[37] the Chinese *State Drug Standard*, or the *Ayurvedic Pharmacopoeia of India* (2004, 2001, 1999), the applicants needed only to include a copy of the relevant pages from the pharmacopoeia.

Generally, if a medicine and its claims as described in a pharmacopoeia were suitable for the regulations applying to natural health products in Canada, the medicine could be licenced in Canada on the basis of the foreign pharmacopoiea. The general exclusion lists applied: a medicinal ingredient was unsuitable if it was included in one of the following Canadian legal lists: Schedule F of the *Food and Drug Regulations* (e.g. prescription-only), any list of the *Controlled Substances Act*

(e.g. psychoactive) or the *Convention on International Trade in Endangered Species of Wild Flora and Fauna* (CITES) or the *Species at Risk Act (SARA).*

The pharmacopoeial approach had been suggested to the NHPD by a traditional Chinese medicine lobby group, and the NHPD had readily taken up the suggestion – and extended it to Ayurvedic Medicine – as an approach consistent with the NHPD's goal of "leveraging all information used by other regulatory agencies" to be *flexible* in its assessment processes, and of reducing the backlog of Product Licence Applications (goals that will be addressed in later chapters). (Although the unit stated that the pharmacopoeial approach would also be applicable to other traditional medicines documented in pharmacopoeia, such as Unani medicine and Kampo, there had simply been no applicants asking to use the approach for these other systems of traditional medicine.)

Assessing a Product Licence Application using pharmacopoeial evidence was simpler than assessing an application in the more general Traditional Assessment Stream, in the sense that the standard itself did not need to be judged for appropriateness to the same extent as texts like *The Mystery and Science of South American Cures*. Assessment largely involved ensuring an exact match between the information in the Product Licence Application form and that in the pharmacopoeia. In the pharmacopoeial substream, the match of medicinal ingredients, method of preparation, dose, and claim had to be identical, except in a few cases when "*similar* can be identical" [38] to allow for substitutions when a

medicinal ingredient was on the list of endangered species, or when a claim was covered by Schedule A.

Using this form of reasoning, reasoning through a very strict comparison, helped to reduce assessment time, because attention was acutely directed. Even an assessment officer without any background in Traditional Chinese medicine could assess an unfamiliar medicinal ingredient in as few as three minutes if the *Pharmacopoeia of the People's Republic of China* were the sole reference. [39] Although the entries in the *Pharmacopoeia* extend over a full page of dense text, most of the information included in each entry pertains to methods of processing and identification, which, at the NHPD, were considered part of the assessment of quality, not safety and efficacy. Assessment officers learned which sections of the *Pharmacopoeia* required attention. When I observed one safety and efficacy assessment officer, Terry, consulting the "Tokay Gecko" entry in the *Pharmacopoeia*, Terry did not even glance at the introductory text of the entry.[40] Terry physically highlighted, on the photocopied page of the pharmacopoea, the information required for her assessment report, including the common name, action ("To reinforce the function of the *lung* and the *kidney* to relieve asthma, and to promote virility and replenish *vital essence*"), usage and dosage ("9-30g; in exceptional cases, 30-60g"), and precautions.[41] Terry then extracted this information from the photocopied entry of the *Pharmacopoiea,* typing this information into her electronic assessment report word-for-word.

The challenge, with tradition-as-standard, became change

The assessment work of the Traditional Medicines Unit relied on standards, preferably unchanging standards. These standards consisted of pharmacopoeia and a variety of other texts. Changes of and from these standards, posed "challenges" for the Traditional Medicines Unit. This phenomenon was also found in other Assessment Units relying on clear standards, such as the Homeopathic Medicines Unit and the Compendial Assessment Unit, however given the intention of the fieldwork project it is best to explore the phenomenon in terms of traditional medicines. I explore three challenges the Unit perceived, challenges associated with applications referring to the *Pharmacopoeia of the People's Republic of China* as evidence:

1. When a Product Licence Application combined medicinal ingredients with separate entries in the *Pharmacopoeia*;
2. When a Product Licence Application listed a medicine's dosage form as pill, and the dosage form listed in the *Pharmacopoeia* was decoction; and
3. When new editions of the *Pharmacopoeia* resulted in the incorporation of new medicines.

All three challenges described were summarized in separate, internal NHPD documents (using the template for "Condensed Issue Analysis Summary for PLA"), and were collectively discussed at an internal meeting that I observed in July of 2007.

Issue 1: Combination medicines

The first volume of the *Pharmacopoeia of the People's Republic of China* documents many multi-ingredient traditional medicines. In the Traditional Assessment Stream, Product Licence Applications often featured multiple medicinal ingredients, sometimes as many as 50 medicinal ingredients in one medicine. When these combinations were documented in the *Pharmacopoeia,* multi-ingredient medicines did not pose any challenge for assessment because the assessment was still predicated on correspondence between the medicine documented in the Product Licence Application with the medicine documented in the traditional standard. The assessment of documented multi-ingredient medicines took longer than the assessment of documented single-ingredient medicines, but the assessment was not otherwise qualitatively different. Ampan explained:

> When there is no deviation in terms of the claim or the doses, those [combination medicines] can be reviewed by – I don't want to say anyone – but those can be reviewed by those who are not as knowledgeable in TCM.

For Ampan, the challenge came with combinations that were not strictly documented as combinations in the *Pharmacopoiea*:

> Where you run into problems is when they've done a formulation that is not necessarily a classical formulation, or a formulation that is not a fixed combination, in that it hasn't been documented as such in a given reference.

The issue of non-fixed combinations was not specific to traditional Chinese medicine. For multi-ingredient ("combination") traditional medicines, the Unit specified that the combination had to be "guided by the principles" of the traditional

medical paradigm in question, and that the company had to provide a rationale for the particular combination.[42] The Traditional Medicines Unit generally recognized three ways that medicinal ingredients, that are each individually supported by the traditional literature, could be logically combined in the Traditional Assessment Stream.[43] Combinations could be "logical" by virtue of being:

A) Additive. With additive combinations, evaluators had to calculate the additive effects of the medicinal ingredients to ensure an adequate quantity for efficacy, but not so high a dose that safety became a concern. This calculation, which involved filling out an additive table, was called applying the " 80% - 120% rule";[44]

B) Complementary. When medicinal ingredients were said to be complementary, the evaluator expected that full doses of each medicinal ingredient would present in the medicines, because presumably each ingredient treated a different symptom of the same condition;

C) Mitigating. Medicinal ingredients could be included to counteract expected adverse reactions to other medicinal ingredients. This last rationale was most commonly seen with applications for traditional Chinese medicines.

According to one assessment officer, combinations were usually fine as long as the ingredients were consistent with one of the above rules, the combination rationale was not "totally ridiculous," and the individual herbs were safe.

A complication arose with non-fixed combinations in Traditional Chinese medicine, however. The question arose of how to appropriately use the additive table (the 80-120 rule) for traditional Chinese medicines, medicines which regularly included dozens of medicinal ingredients. I was told by evaluators that in traditional Chinese medicines, medicinal ingredients may play one of four roles: King, Minister, Assistant, or Messenger. These roles are not additive, nor are they necessarily complementary, complicating the three rationales (A-C) that the Unit generally recognized for non-fixed combinations.

At the internal meeting in July 2007, a scientist proposed that separate additive tables be used for ingredients of the same type, e.g., one table for all the Assistant herbs, one for all the Messenger herbs, etc. A practitioner demurred, suggesting that *only* the chief herbs contributing to the health claim (i.e. King herbs) should have an additive table; another practitioner explained that ingredients with other roles (e.g., Assistant herbs) are included in the medicine to come at the health problem from different angles, and so the ingredients that are assistant herbs do not have an additive effect. The conclusion of the internal meeting, was that the Directorate's policy as established in the guidance document (the additive table) was correct, but that the Unit had to come to a better internal understanding of how to apply the policy in the case of combination traditional Chinese medicines, and to tailor a new standard line for this purpose.

In interview, one scientist-practitioner emphatically explained how s/he did not necessarily agree with this decision to tailor a new standard line specific to traditional Chinese medicine combinations. This practitioner was keen to explain to me how fairness, in terms of fairness across medical traditions, was very important at the NHPD. This practitioner argued that since free combination was allowed for Indian or African medicine, then free combination should be allowed for traditional Chinese medicines, although

> the practitioner and the Chinese people do not like or allow the combination….
>
> Some Assessment Officers, their mind is still in China. One should not regulate this way, saying it should be like it is regulated in China. This is not the way. If you regulated TCM completely the way the Chinese did, and Indian medicine the way the Indian government did, then you'd have consistency problems with the Traditional Medicines Unit as a whole.
>
> The Canadian government is a separate standard, and should have separate standards, to be consistent for all traditional products.

I will return to this issue of fairness when discussing the second issue discussed at the internal meeting, and in more detail again in Chapter 18.

This issue of non-documented combinations, speaks to the relation of textual standard to medical practice. As noted by social scientists, textual standards are rarely followed to the letter in the practice of medicine, nor are texts generally designed to be so followed (Young 1995b).[45] Overall, scientific staff at the NHPD were of the same opinion as these social scientists, and furthermore, in one way or another, *all* practitioners I interviewed distinguished between (traditional) medical *practice* and *documentation* of traditional medicines. (This held whether the

practitioners worked in the Traditional Medicines Unit or elsewhere in the NHPD). Nevertheless, certain textual standards – most notably pharmacopoeias – are designed to be followed to the letter in the practice *of regulation*. Thus, although discrepancies between textual standards and (traditional) medical practice were widely recognized by the scientists in the Traditional Medicines Unit and the NHPD at large, this recognition did nothing to alleviate the quandaries posed by these discrepancies to the regulatory assessment process.

In practice, the way that assessment officers dealt with nonstandard combinations in traditional Chinese medicine (TCM) depended largely on whether or not they were TCM experts. (At the NHPD, expertise in TCM was generally attributed to assessment officers who had medical training in China, irrespective of the tradition of medicine they practiced). According to non-experts, the resident TCM experts could glance at a file and, as long as they knew the medicinal ingredients in the file, they could tell whether the combination made sense within TCM. But for non-experts, the steps required to ascertain the appropriateness of a free combination TCM were involved and numerous. One non-expert stated that although she probably could figure out all the little rules involved in deviations and substitutions in free combination traditional Chinese medicines, it would take her all day – possibly all week – to determine the appropriateness of the overall combination. It was much easier to simply consult a colleague who was a TCM expert: “the good thing about working here is that we have experts,” explained Kieran.

Example observation. A non-practitioner assessing a TCM combination medicine

Terry, who did not have any background in traditional Chinese medicine prior to her work at the NHPD, approached a combination traditional Chinese medicine as "a bit of a puzzle" to be solved through assessment. In preparation for the assessment, or perhaps my observation, Terry had brought several of the NHPD library's reference books on traditional Chinese medicine to her desk.[46] The Application in question, consisting of a file about two centimeters thick, was well put together in the sense that the company provided exactly two reputable references for each medicinal ingredient, and had arranged the photocopied excerpts from the references by order of medicinal ingredient as listed in the Product Licence Application form. When I sat down, Terry explained to me that evidence for single medicinal ingredients was sometimes insufficient to support the efficacy of a combination medicine; but that, in any event, the evidence of the traditional use for each individual medicinal ingredient was "good for safety [assessment]."

It took Terry two hours to sequentially and methodically examine the evidence for each of the 16 medicinal ingredients, making sure that each individual ingredient's dose and uses were supported by the evidence of traditional use included in the file. The only remark Terry made regarding the ingredients (which to me were quite exotic, including many animal parts) was a brief

> interesting! I checked the species because the indication [use or purpose] for this ingredient is totally different than what I've seen before for the same ingredient. It turns out it is basically the same animal, but just with the heart added in.

Through the two hours, Terry documented deficiencies in the Safety and Efficacy Assessment Report. For instance, although the company had not indicated any duration of use for the medicine, which implied that the medicine was safe for long-term use, there was no evidence for the safety of long-term use of one herb in the combination.

As Terry was entering the information for each medicinal ingredient in her electronic Safety and Efficacy Assessment Report, she also noted information in a table on a scrap piece of graph paper. In the table, Terry inscribed the medicinal ingredient name, along with its primary actions and precautions, as listed in the *Pharmacopoeia*:

Figure 8-2: Terry's initial table

	Uses (Actions)	Cautions
Ingredient 1	xx	[none]
Ingredient 2	yy	zz
Ingredient 3	aa	yy
…	…	zz

Terry had clearly assessed numerous TCM files, as the table was filled with her own paradigm-specific abbreviations: "hs" for heat signs, "df" for deficiency. Furthermore, Terry explained to me how, based on her experience assessing other traditional Chinese medicines, she was able to discern which actions listed in the *Pharmacopoeia* were likely to be salient: for instance, she had noticed that dampness and yin deficiency tended to be more frequent in health claims, and so she was sure to record those actions in the table. Terry explained that she felt the table was necessary when a combination traditional Chinese medicine had more than 5-10 ingredients, because she could not keep that amount of information in her head.

Terry explained that the table was useful because "sometimes the uses and cautions cancel each other out – but it takes a while." For example, one medicinal ingredient in the file had the contraindication: "not for use with spleen deficiency with dampness." Terry explained that if another medicinal ingredient had, as an indication, "use for spleen deficiency with dampness," then the contraindication and the indication would cancel each other out. Terry was not concerned with the exact

amounts of each medicinal ingredient in this particular cross-elimination endeavor, because in combinations in TCM, she explained, presence was what mattered; and in any event, the amounts were all small.[47] After Terry had finished assessing each individual ingredient for the purposes for safety, she then turned to the completed table. Terry eliminated the duplicate cautions (e.g., the extra zz) and also the entry that appeared in *both* the uses and cautions column (e.g., yy and aa):

Figure 8-3: Terry's revised table

	Uses	Cautions
Ingredient 1	xx	[none]
Ingredient 2	yy	zz
Ingredient 3	aa	yy
Ingredient 4 …	bb	zz, aa

Terry stated that the uses and cautions that were not eliminated, according to this rough estimate, should be the uses and cautions of the overall medicine. She then compared the resulting uses and cautions with what the company had entered on their application form, and noted the deficiencies in her Assessment Report.

Terry toyed with ideas for how to address efficacy in her Assessment Report. The Product Licence Application listed three separate tonifying claims as the medicine's health claims. Terry noted that usually there are not so many claims in combination TCM medicines: she suspected the company had thrown three traditional formulations together for a broader overall action. This observation had prompted Terry, when she was first looking through the file, to comment she "had a feeling of how it's going to go." Terry did not seem to have the expertise or resources, however, to make a decision solely on this feeling. She decided it was necessary to consult a TCM expert. So, Terry stood up and, with me trailing along, walked through the maze of cubicles to go visit a TCM expert.

The TCM expert took one look at the proposed medicine's label, and observed, impassively, "Well this is a big tonic." She took several minutes to flip through the file. S/he advised that the company would have to provide a combination rationale to justify the particular combination of ingredients. Also, she advised that the company would need to provide evidence that compounding the ingredients into a pill form, rather than making a decoction, would not require any changes to the quantity of each medicinal ingredient in the formulation. Terry asked: "do you have a standard line for that?" and so the TCM expert sent the standard line to Terry by e-mail.

Back in her cubicle and computer, Terry wrote several "AO Comments" into the Safety and Efficacy Assessment Report: "The evidence provided is for individual herbs, based on dosage for decoctions. The dosage form for the product is a pill. In addition, the combination rationale was not provided," and she remarked:

> It's too bad because they've actually done a decent job of evaluating the ingredients – but in the wrong dosage form.

Terry continued working through the rest of her Assessment Report, including what was mentioned by the TCM expert. Terry also documented the Application's easily-fixable deficiencies, such as incorrect proper names of the medicinal ingredients (the company had used pharmaceutical names instead of proper names) and the lack of traditional qualifier and paradigm in the health claim. Terry emphasized to me that these deficiencies were not because the company was doing something wrong; the applicant was just doing something *different* than what was required according to NHP regulations and policy. Terry made a note-to-self in the Assessment Report that she had not done any assessment of the risk and label, explaining to me:

> If they [the company] ever come back with something, I'll have it in the file. But they won't come back.

Terry then composed the information requests by consulting her previous, related Assessment Reports, along with the standard line the TCM expert had sent by e-mail. But after Terry had finished the Information Requests, Terry decided not to

use the standard line about the combination rationale, because the issue was secondary to the issue of having no evidence for the pill dosage form. But Terry was unsure of that decision, and so decided to double check with her unit head, and included a note on the file to that effect.

The issue of the commensurability of decoction and pill dosage forms in this example brings me to the second "challenge" posed by changes in traditional Chinese medicines.

Issue 2: incommensurability of decoctions and pills

Another Issue discussed at the internal July meeting was the issue of changing dosage forms in the practice of traditional Chinese medicine. As Emmanuel, an assessment officer, had explained to me in an interview, "young people don't want to make messy, time-consuming decoctions anymore. They want to take pills.'' But many, if not most, of the standards in the first volume of the *Pharmacopoeia of the People's Republic of China* referred to decoctions. (A decoction involves boiling the crude medicine(s) in water for a certain amount of time, often 20 minutes or more, then straining the preparation; the resulting liquid, the decoction, is consumed when cool.) Sometimes, for the same combination of medicinal ingredients, the *Pharmacopoeia* includes separate dosing information for decoction, tincture and pill forms. Often the quantities of medicinal ingredients in the three dosage forms are quite different; in some cases, the decoctions and pills are indicated for separate conditions. According to the pharmacopoiea, the quantity of a 'non-medicinal ingredient' (so designated by the NHPD), for instance the strength of the

alcohol in a tincture, may also affect the medicine's efficacy. When both decoctions and pills were included as dosage forms for a medicine in the *Pharmacopoeia,* the NHPD assessment officers thought that the approach they should take in assessment was clear: the information in the Product Licence Application must match the dose and claim appropriate for the dosage form.

The issue at stake for assessment officers was whether to licence traditional Chinese medicines in *pill* form when the application relied on the *Pharmacopoeia*'s dose for a *decoction*. In the Non-Traditional Assessment Stream, assessment officers calculated equivalencies based on the crude weight of the herbal starting material (crude dried equivalent). This approach using crude dried equivalent was also used within the Traditional Assessment Stream for Product Licence Applications using the texts of Western Herbalism as evidence. But one of the Traditional Medicines Unit's evaluators had safety concerns regarding using crude dried equivalent to equate decoction and pill dosage forms in traditional Chinese medicine. She summarized the background to the Issue:[48]

> Typically, Traditional Chinese Medicine (TCM) herbal formulations have been prepared and administered as decoctions. …Consequently, many of the available references suitable for supporting Traditional Chinese Medicines (e.g. the Pharmacopoeia of the People's Republic of China, the Chinese Materia Medica, etc.) commonly provide dosage information for decoctions only.
>
> The modernization of TCM formulations from that commonly used (i.e. decoctions) to solid dosage forms (e.g. pills and tablets) has been carried out for a number of TCM formulas. In cases where this conversion has been carried out, the resulting dosage range for the solid dosage form can be considerabl[y] lower than utilized for decoctions…. Under the Chinese regulatory framework, the dose for a decoction is inappropriate for supporting a solid dosage form and the modernization of TCM formulations

as seen with the conversion of a decocted dose to a solid dosage form progresses via lengthy and costly bioequivalency studies.[49]

The discussion of the Issue at an internal meeting involved five scientists, three of whom, as far as I could understand, were completely talking past each other. These three differed, fundamentally, on what was most at stake with the Issue. Because it captures the group dynamics around the issue, I provide a loose transcription of the discussion (loose because it was taken simultaneously by hand), using 'P' to indicate "practitioner-scientist" and 'M' to indicate a scientist in a 'management' position. What was most at stake for the participants was: safety, given incommensurable dosage forms (for P1); commensurable manufacturing processes, to ensure safely commensurable doses (for M1); regulatory pragmatism, in situations without proven safety concerns (for M2).

P 1: Manufacturers should not be allowed to use the decoction dose to support a pill dose because the amount of medicinal ingredient absorbed by the body is different – there are safety concerns.

M 1: It would be acceptable if the manufacturers were following the manufacturing procedure for the decoction, and then drying the decoction and packing the dried decoction into pills. BUT then the product would not meet the standards of the Chinese Pharmacopoeia.

M 2: Well, our [NHPD] default is to go back to the crude dried equivalent. If there is direct evidence saying that another amount should be bioequivalent, then we should not allow the decoction dose to be used for the pill dose. But otherwise our fallback, although I know it is not totally scientifically valid, but it is pragmatic, is: crude dried equivalent. Otherwise not enough applicants would use the monographs.

P 1: But as you can see from this table comparing the quantities of medicinal ingredients in bioequivalent decoctions and pills for four products, using the crude dried equivalent could allow 10 times more constituent to be absorbed into the body in pill form as compared to the original decoction.

M 1: With pills, they'd need to go through the same manufacturing process as they would for a decoction, and therefore this would not be the case.

M 2: We really need to focus on the crude dried equivalent. Never mind the process. If we have solid evidence that the pill and decoction dose are not equivalent, then we would not allow the equivalence for licencing purposes.

P 2: But there are two elements of the Issue here. First there is the issue that, in the decoction, you do not eat everything. The second issue is that the solubility of various compounds, and how the compounds are affected by powderizing the herb and making it into a pill, whether or not the flow chart for the process of making a decoction is followed. It is quite complicated, and very hard to judge.

M 2: If there is no overriding evidence, then the safest way to proceed is to use the crude dried equivalent…..

M 2 and M 3: We went over this when the Guidance Document [*Evidence for the Safety and Efficacy of Finished Natural Health Products*] was written; we've already gone over it.

M 2: But the important thing is that you [P1, possibly P2] feel comfortable.

M 3: We want to give you an opportunity to air your concerns.

And so the discussion ended. For two managers, crude dried equivalent was the most important indicator of a safe dose, unless other evidence proved contrary for a particular preparation, because, as Robin Marles, Director of the Bureau of Clinical Trials and Health Sciences, also explained to me in interview:

> that's what was agreed upon [in 2004 and prior] as a reasonable approach, that we would handle it consistent with all other herbal medicines, in the absence of specific information. But if a pharmacopoeia provides a specific dosage for a pill form, that trumps our rule of thumb.

The meetings' discussion ended by two scientists, M 2 and M 3, if I may put it crudely, pulling rank over the other scientists to maintain a previous decision. Although M 2 and M 3 encouraged P 1 to further develop the issue sheet if s/he still had concerns, when I asked P 1 a few weeks later whether there had been any

further discussion on the issue, P 1 explained with a slight tone of defeat that s/he had let the issue drop: “If I’m the only one at the NHPD who thinks it is an issue, then I guess it is not an issue.” Neither did I hear of the issue being further pursued by M1 (for whom the manufacturing process was the key).

In this second Issue (decoction versus pill dose), unlike in the first Issue (combination medicines), consistency across medical paradigms superseded considerations deemed important within traditional Chinese medicine. Even M1’s technological fix – asking that the manufacturers follow the manufacturing process for decoction, and then compressing the dried decoction into a pill – was not adopted. This may possibly have been because this technical solution, unlike the technical solution of assessing the medicinal ingredients in their role as King, Minister, Assistant, or Messenger, could then have been applicable to other traditions of herbalism and effectively changed the rituals of assessment more broadly. Or it may just have been, for no particular reason.

Issue 3: changing medical traditions

A third Issue discussed at the internal July meeting pertained to the “challenge” of change and development in traditional medicine. Given that NHPD regulators depended on a relatively stable “tradition” of medicine for the documentation of traditional use to logically act as a barometer of safety and efficacy, it is no surprise that change was perceived as a challenge to assessment in the Traditional Assessment Stream.

One day in the early summer of 2007, a discussion wafted over the walls of my cubicle.[50] The discussion pertaining to propolis, a type of gum produced by bees. Propolis, as a medicinal ingredient, was proving to be difficult to licence in the Traditional Assessment Stream because suitable evidence for safety and efficacy could not be found. Propolis was an especially "tricky" issue because it is "not really traditional," so I overheard:

> Hallway scientist 1: The problem we have with the evidence that companies have submitted is that we find it is mostly based on marketing experience, not actual traditional use. Or if they do refer to traditional use it is a scientific rationalization for scientific use.

A group of files with propolis as a medicinal ingredient was essentially "stuck" at the (L3) assessment level because traditional use could not be documented. The files were in regulatory limbo because the Traditional Medicines Unit could not really recommend the files for licencing in the Traditional Assessment Stream, but the scientists did not think it was necessarily appropriate to outright refuse all files with propolis.

> Hallway scientist 2 : It comes back to the issue of refusal: are we going to refuse these files? Or assess these claims in a non-pharmacopoeial stream?

As I found out later at the July meeting, the issue regarding propolis was more complex. Assessment officers had discovered that propolis was included in the 2005 edition of the *Pharmacopoeia of the People's Republic of China*. So one facet of the Issue was whether propolis should be considered "traditional" within traditional Chinese medicine for the purposes of assessment. The Traditional Medicines Unit had tentatively decided that it should not be possible to make a

claim “Traditionally used in Traditional Chinese Medicine…” for propolis, because the medicinal use of propolis did not originate with traditional Chinese medical practice, as it had just been added to the *Pharmacopoeia* in its latest edition and so did not have 50 years of documented use in that tradition. Another problem with the entry in the *Pharmacopoeia* was that the indication for propolis, “Used as an adjuvant for hyperlipidemia and diabetes,” contravened Canada’s *Food and Drugs Act*’s Schedule A and thus was inappropriate on the label of an over-the-counter medicine in Canada. Also, several actions listed in the *Pharmacopoeia* – “To resist bacteria end relieve inflammation, regulate immunity, resist oxygenation, and accelerate tissue healing” (2005: 182) – were not considered “traditional” claims because evidence of effect would require laboratory instrumentation, and thus not noticeable in a “traditional” paradigm of medicine.

The usefulness of the new entry in the *Pharmacopoeia* for assessment purposes was not rejected outright, however. Multiple companies had tried to get pre-market approval for propolis with claims regarding its traditional use in Europe and North Africa. Although the Traditional Medicines Unit felt the traditional use of propolis in those geographical areas was well-documented,[51] none of the documentation included the appropriate *dose* of propolis when used orally. So the issue was whether the dosing information in the *Pharmacopoeia of the People’s Republic of China* for oral doses of propolis, could be used to fill in the missing dosage piece of information for applications with claims such as “Traditional African Medicine for mouth and throat infections” that were not based on the *Pharmacopoeia*.

At the internal meeting on traditional Chinese medicine, members of the Traditional Medicines Unit argued that this use of the *Pharmacopoeia* would *not* require mixing paradigms: the use of propolis did not originate in traditional Chinese medicine, they argued, it just so happened that the appropriate oral dose was first *recorded* in the Chinese *Pharmacopoeia*. This atypical use of the *Pharmacopoeia* was rationalized because "the traditional medicinal use of propolis is likely an adaptation into as opposed to an origination from TCM."[52]

The issue speaks to the relationship between coeval "traditional" paradigms. Recall that the definition of traditional medicines includes at least 50 years of use in a circumscribed culture. One, but only one, scientist stated an opinion in an interview that rendered traditional medicines rather ethnological and static;[53] even that scientist, though, stated without any prompting that "communities are no longer isolated." Most scientists with whom I spoke did not assume homogeneity in medical paradigms either through time or in current practice. This, however, seemed irrelevant to their regulatory activities.

As I explained in my discussion of the NHPD's policy definitions of traditional medicine, paradigms are established as self-contained systems, making ideas of coevalness, either on large historical terms or in any individual instantiation, irrelevant for the purposes of scientific regulation. What do I mean by irrelevant for the purposes of scientific regulation? At a meeting of several scientists who had

been or were currently with the Unit, I asked how the assessment officers would approach, say, a medicine traditionally used in Trinidad, and which entailed a fusion of Indian and Chinese medical traditions that had existed on the island for more than 50 years. In response, a scientist explained that, at a public Information Session held by the NHPD, a public participant had asked the NHPD just that question: “I take both traditional Indian and Chinese medicines together, because I am Indian and Chinese – is that traditional medicine?” The scientist did not provide a yes or no reply to my question. But after his intervention, each person around the table sequentially brought up an example of medical syncretism, such as the incorporation of the mid-20th century Soviet science’s concept *adaptogen* into Chinese medicine, and NHPD-induced anachronism like the current market use of the term *dyspepsia*. There is no question the scientists found these issues interesting. *Interesting, but,* as far as I could tell, *the scientists found these issues unrelated to the work of the Unit*. I suspect that until a Product Licence Application were made that turned these interesting issues into An Issue, the scientists had no need to do anything but treat the *hypothetical* issues as intellectual playthings or curios in discussion.[54] Even if such a Product Licence Application appeared, there is a good chance that it might be redirected to the Non-Traditional Assessment Stream. When discussing substitutions in combination traditional Chinese medicines (Issue 1) – and the limits thereof – scientists commented that things could get interesting in the future, with health claims regarding “modern Traditional Chinese Medicine” or “modern Chinese medicine.” These scientists noted that these health claims would be evaluated in the Non-Traditional Assessment

Streams, and so, this interesting scenario, to the scientists in the Traditional Medicines Unit was not only hypothetical but also not the (particular) scientists' "problem."

For the purposes of daily activities in regulatory assessment in the Traditional Medicines Unit, medical traditions were most easily treated *as if* bounded, static entities. Tradition, here, was simply a regulatory heuristic for a certain amount of trust in the medicine; encapsulating many factors that the regulators interpreted as sufficient indicators of safety and efficacy; nothing more, nothing less.

Summary of the chapter's ethnographic material

At the time of my fieldwork, assessment officers in the Traditional Medicines Unit were especially adept at evaluating the safety and efficacy of traditional medicines that clearly corresponded to textual standards, most notably the pharmacopoeia of the scholarly medical traditions. "Challenges," according to the Traditional Medicines Unit, appeared when the information in Product Licence Applications was inconsistent with pharmacopoeial or other textual standards, and also appeared when the standards themselves changed. I have given the following examples of the Unit's self-identified "challenges" in evaluating traditional Chinese medicines: (1) when applicants combined several traditional medicines into one preparation; (2) when applicants changed the dosage form from tincture or decoction to pill; and, on a different note, (3) when a botanical medicinal ingredient

associated with another medical tradition was syncretically incorportated into the first volume of the *Pharmacopoeia of the People's Republic of China*.

The working definition of "traditional" in the Traditional Assessment Stream made any type of change away from or in documentation, challenges. Scientists, with one possible exception in the Unit, readily recognized change in the actual practices of traditional medicines and did not find this problematic in general; the Issue with change, as expressed in the meetings, was that "change" posed challenges to assessment in the Traditional Assessment Stream both practically (e.g., it took longer to assess free combinations and it often required expertise) and theoretically (e.g., documentation of traditional use is persuasive as evidence of the safety and efficacy of a medicine only if the use is unchanging over a period of time). I presented individual assessment officer's related opinions that were shared in meetings and in interviews, to dispel any idea that may be formed among the readers that the "challenges" stem from the personal worldview of the scientists, and have argued that these "challenges" were experienced as pragmatic, rather than conceptual challenges. Based on the challenged and resolutions I witnessed in 2007, the way in which these challenges were resolved showed no clear trend. Many considerations were balanced off each other – including concern for each paradigm's logic, for fairness across all medical traditions and across all medicine types – not to mention the role of micropolitics and personalities, which is beyond the ambit of this dissertation.

A discussion of the tradition *in TCM*

During the group discussion of "modern traditional Chinese medicine," as well as through my observation of meetings and then interviews with experts, I could not shake the feeling that I was missing something quite important with respect to the "tradition" aspect of traditional Chinese medicine – this kept nagging me during the years after I left the field. It did not have to do with heterogeneity in practice, medical practice; neither was it related to the dissociation of customs (including material culture) from social organization (society, or culture in this sense), as Evans-Pritchard might have distinguished (1951:1620), and as one TCM expert did distinguish:

> The [NHPD's] definition of traditional is really connected with culture, belief or philosophy or something. A lot of theory which would be easy to understand in China, here doesn't make sense, because you don't have the culture background. The background could be the person and the universe, person and nature, and nothing to do with TCM. But you can use TCM to adjust the relationship of the person to season…
>
> You just don't get it if you don't get the culture.
>
> We have to face this fact, that people here [in Canada? in NHPD science divisions?] are not in the culture. So we have to figure this out.

These issues had nothing to do with the feeling that I was missing something crucial, that several experts were either unwilling, or unable, to explain.

The feeling was resolved when, reading recent anthropological literature, I understood how "traditional Chinese medicine," in English, is framed as "science-based Chinese medicine" in the Chinese pharmacopoeias. Here, I am not referring

to a completely different interpretation of science than is common in biomedicine (such as the one I will present in the next chapter on homeopathic medicines) but to laboratory-based, pharmacological sciences. Furthermore, the "tradition" in "traditional Chinese medicine" in China can be dated quite precisely: to 1955 or 1956 (Taylor 2004:101), and for many years it only appeared in English language texts produced by the People's Republic. I suspect part of what I had not been "getting," had to do with the *particular*[55] way in which *tradition* and *science* with respect to Chinese medicines included in the main textual standard used at the NHPD – The *Pharmacopoeia of the People's Republic of China* –might have been interchangeable, even fused, to bilingual and bicultural evaluators.

A summary of EuroAmerican social science approaches to tradition is a necessary prelude to these recent anthropological and historical accounts of traditional Chinese medicine, accounts that are useful to present here.

Tradition as an entity in EuroAmerican scholarship

"Tradition," as Raymond Williams noted in his *Keywords: A Vocabulary of Culture and Society* (1976:268), "in its most general modern sense is a particularly difficult word." That said, "tradition" in the social sciences through the long 20th century in EuroAmerica was enmeshed in a relatively stable core network (or dichotomy) of associations. Volker Scheid (2007:5-11) argues that the current meaning of "tradition" in social science discourse can be traced to European Enlightenment philosophy, when tradition – as dogma, habit, or custom – was viewed as a threat

to objectivity and reason. Later, influential social philosophers like Max Weber, spun narratives of progress, of modernity overcoming tradition, writing:

> modernity as governed by rational calculations of means/ends, constant innovation, and formal and transparent rules. Traditional behavior, on the other hand, is based on implicit rules legitimized by nonrational forms of authority…. [For these philosophers] It was not the disappearance of tradition, therefore, that aroused curiosity, but its stubborn resistance to modernization and its endurance or even revival within the contemporary world. (Scheid 2007: 6).

As characterized by Bruno Latour (1993), these narratives were often spatialized, creating The Great Divide: on one side, modernity with the West, and on the other side, tradition with the rest. The implication also became that the West had history, development, progress; while the rest, with static, 'traditional' culture, had none – as pithily captured in Eric Wolf's famous title, *Europe and [versus] the People without History* (1982).

As my allusion to *We have never been modern* and Wolf's *Europe and the People without History* suggests, in the 1980s and 1990s, these narratives of progress-versus-tradition were actively contested in many academic disciplines. (This was true also in medical anthropology; during this period anthropologists made biomedicine an object of anthropological inquiry, in so doing sometimes claiming to overcome the opposition of the West and tradition.) But perhaps most salient to the study of "tradition" in particular was the 1983 publication of *The Invention of Tradition* (Hobsbawm and Ranger), which was notable at the time on two counts: first, the work discussed tradition in the West, rather than elsewhere; second, the book investigated the invention of traditions as "political instruments" (Scheid's

term 2007:10) used to legitimate the (rational, Western) state and its power. *The Invention of Tradition*, in conjunction with a second, influential book published the same year -- *Imagined Communities* (Anderson 1991 [1983])[56]— served as foundation for the project of historicizing nationalist traditions and sentiment, and of demonstrating the importance of "tradition" in naturalizing nation states. In the body of literature ensuing from these two publications, 'traditional' needed not entail "a long-established custom or belief," nor exclude historical investigations of the development of traditions. Examples from within medical anthropology are many (e.g., to take only a few examples pertaining to herbal medicines: Lock 1990; Miles 1998a,b; Hayden 2003; Brotherton 2003; see also the broader summary provided in Roseman 2002: 132 n6).

As pointed out by Volker Scheid, there are two drawbacks for the anthropologist today in relying on the frameworks established by these two books for any investigation of tradition. The first difficulty in using Hobsbawm and Ranger's work, argues Scheid, is that Hobsbawm and Ranger distinguish between "invented" and "genuine" traditions. This distinction is inextricable from the fruitless (for today's anthropologist) question of authenticity, and, furthermore, dehistorizes so-called genuine traditions. The second difficulty in using Hobsbawm and Ranger's work, according to Scheid, is that examining the invention of traditions does not lead to scholarly accounts of the plurality of traditions (2007:8). To use the language of NHPD scientists, these are "issues" for the early twenty-first century anthropologist because by the end of the twentieth century it is standard disciplinary practice to

research and discuss various traditions of medicine (including biomedicine) as coeval.

I summarize here a growing body of medical anthropological literature on the coeval production of science and traditional Chinese medicine through the 20th century, with an eye to explaining the particular fusion of science and tradition.

Science, tradition, and the Chinese pharmacopoeiae

The first Chinese pharmacopoiea, Paul Unschuld (1986) states, was published in 1930. Although there had been many previous treatises on medicines, and drug compendia produced by imperial order or by the public service, “none of these works could justly be called a pharmacopoeia in the modern sense of the term, simply because they were not designed to provide physicians or pharmacists with fixed standards of drug quality and drug usage, adherence to which was enforced by government authorities” (1986:262). The first pharmacopoeia, the *Chung-hua yao-tien, ti-i-pan* (“Chinese Drug Code, First Edition”) containted over six hundred monographs. These monographs, ordered by Latin name, represented materia medical distilled and translated from Europe. Unschuld remarks, that if, “in some rare instances, one finds a drug described that was known in China traditionally, it was incorporated only because it was part of European pharmacy” (1986:264-6).

Up to and including the “Chinese Drug Code, Third Edition” of the Republic of China (Taiwan) published in 1980, this series of pharmacopoeia was entirely

commensurble with “modern Western-type pharamcy” (1986:274). Unschuld frames this in terms of the uptake of science at the time –

> It is difficult to imagine the excitement with which China met the introduction of Western science and medicine in the late nineteenth and early twentieth century. The powerful military, technological, and ideological impact of Western culture on China occurred toward the end of an epoch in Chinese history that had left the “Middle Empire” so exhausted that neither its political structure nor its economic resources – and least of all its traditional sciences – provided any realistic chance for coping successfully with this new force from outside…. Into this multifaceted internal struggle for the appropriate way out of confusion [especially regarding the heterogeneity of Chinese medicine] …. A magic word entered China which in the eyes of many influential thinkers soon became linked with the promise of a better future – the word was “science.” (1986:261).

Influential Chinese Marxists were, in the early twentieth century, very explicit in their embrace of science in pharmacy, and their overthrow of Chinese medicine. In 1941, an “eminent Marxist” (T’an Chuang) called traditional Chinese medicine “millenia-old garbage” – enmeshed in feudal society and needing to be overthrown by science (i.e., Marxist revolution; Unschuld 1986:276). One might think from the 1953 preface of the first pharmacopoeia of the People’s Republic of China, that traditional Chinese medicine would be included; the pharmacopoeia’s authors declared the text was required to fulfill two conditions:

> First, it must be popular, that is to say, it must conform with the needs of the broad masses. Second, it must conform with our national conditions, that is to say, it must fully utilize pharmaceutical substances produced in this country. (as translated by Unschuld 1986: 277).

But Unschuld’s count of “raw drugs described in the traditional Chinese pharmaceutical literature already” among the pharmacopoiea’s 581 monographs,

rested at 20: most of which were also part of Western pharmacy (1986:279). Even those that were not also part of Western pharmacy "were fully integrated with all ther other drugs [in the organization of the pharmacopoeia]…. except for the Chinese names, no aspect of the monographs reminds one of the fact that a traditional Chinese drug is described" (1986:279-80) as the monographs were organized into sections analyzing the microscopic powder and or employing other criteria of laboratory-infused pharmacy.

The second edition of the pharmacopoiea (1977), was organized similarly to the third edition used by NHPD staff; in these editions, there is a separate volume for traditional Chinese medicines. That said, only a few subsections in each monograph for a Chinese medicine (taste and nature, indications, functions) refer to anything other than information that is also included in the volume for other pharmaceutical preparations and derived from laboratory-based pharmaceutical sciences. The preface of the second edition, as translated by Unschuld, explains the edition was prepared "in accordance with the need to develop the public health cause of our country, in conformance with the policies of our great leader and teacher chairman Mao to be independent and to be self-reliant and to combine Chinese and Western medicine and pharmacy…." (1986:280). What transpired between the first two editions?

In 1958, Mao Tse-tung stated “Chinese medicine and pharmacy may constitute a great treasure house. Efforts should be undertaken to uncover it and to raise its standard!” (Unschuld 1986:276). This was not, Unschuld argues, a statement giving a carte blanche to Chinese medicine. Rather, it was part of a project in which science would be used to mine from two inappropriate medicines: Chinese medicine with its feudal, imperial heritage on the one hand, and, on the other, Western medical practice in its “capitalistic, imperialistic, and colonialistic” context in China (Unschuld quoting T’an Chuang 1986:276).

This explains the integration of Chinese medicine into the country’s science-based approach to pharmacy. It does not explain the making “traditional” of Chinese medicine.

Kim Taylor (2004) points out that the current Chinese-language word for Chinese medicine, *zhongyi,* dates to when Western medicine became a viable alternative to Chinese medicine. Before that date, the word for medicine in China had simply been ‘medicine’ (*yi* or *yixue*). And even then, *zhongyi* became the standardized term for Chinese medicine only in 1949; before that date, other terms used to refer to this medicine included ‘old medicine’ (*jiuyi)* and ‘national medicine’ (*guoyi*). But what is relevant to this dissertation is that while the Chinese term, *zhongyi,* has remained unchanged since the proclamation of *The People’s Republic of China*, the Party-sponsored *English translation* of *zhongyi* has changed:

> The term “Traditional Chinese Medicine’ only began to appear in the foreign-language press from 1956; previously the medicine has been referred to simply as ‘Chinese medicine’…. [T]he term applies only to post-1956 medicine in mainland China, and only that medicine practised within state-run institutions (Taylor 2004:98).

The term was introduced as part of a new policy, which included a programme to train physicians of Western medicine in Chinese medicine (Taylor 2004:101).[57] This programme also fit with the party’s broader policy of integrating Chinese and Western medicines on an equal footing, expounded in the 1960s (Taylor 2004:103).

It was not until 1974 that there was a national textbook on TCM basic theory, although there had been local textbooks. As Kim Taylor (2004) and medical anthropologists Judith Farquhar (1995) and Volker Scheid (2002, 2007) have pointed out, it is at this point that a unitary and coherent “TCM theory” was invented, to use the language of Hobsbawm and Ranger (1983). Throughout the early communist period, and previously,

> it had never been necessary in China to teach Chinese medicine based on a coherent “foundation” or “basic theory” of Chinese medicine. Rather, education in Chinese medicine at the Academies of TCM remained, until 1984, firmly based on the study of four core classical, and often contradicting texts ….It was not until after the Cultural Revolution [1966-1969] that a Basic Theory of TCM emerged as part of a general education emphasis on ‘basics’ (Taylor 2004:107).

Kim Taylor argues two high-profile, English-language accounts of Chinese Medicine drew from textbooks used in the education of (bio)medical doctors in Chinese medicine, using this unified approach to TCM (Porkert 1974 and Sivin

1987; in Taylor 2004:106-108). She does so to make her main argument that, in the late 20th century, traditional Chinese medicine "has been tailored to some degree by a Western concept of what Chinese medicine 'really' should be" (2004:93).[58]

The relevance of this homogenization of theory[59] in textbook form to this dissertation, is that it is only on the basis of a certain degree of homogenization that TCM becomes amenable as a *paradigm*, with its own rules within which efficacy can be assessed, for scientific staff at the NHPD. With the invention of this particular tradition, there developed enough internal consistency and homogeneity for it to be glossed as a paradigm.

I am not explaining this as a criticism. Schied, drawing on the work of Farqhar, "describes the development, flourishing, and decline of this lineage and its many branches, as well as that of the other medical lineages and families with which it merged to form the "current of Menghe learning," (2007:1) a current which he argues was extremely influential in the late imperial and modern China. His focus on this current or genealogy (2002a,b), rather than texts and ideas, is, he argues a departure from much western scholarship on Chinese Medicine and does not approach tradition as static rule-or text-bound. Scheid turns to the transmission of traditional Chinese medicine as experienced and recounted by physicians; when tradition is seen as inseparable from these physicians, a scholarly account need have no difficulty simultaneously discussing continuity and change, as the tradition

can be approached as a “continual coming into being of practice – a coming into being that simultaneously stretches forward and backward in time” (2007:12).

It is difficult to imagine how the conceptualization of tradition as current would work in a regulatory institution where the evaluators, whether or not they are physicians themselves, must make decisions on a wide range of medicines while meeting productivity quotas. This option is not available for the Directorate’s regulatory scientists, whether or not they are physicians themselves, because decisions must be made on a wide range of substances, whether or not the substances correspond to any given current.

Because the Chinese-language term *zhongyi* did not change, Kim Taylor (2004) asks why the English-language term changed. She argues that the change was likely due to what might now be termed brand management of the nation, to increase China’s international capital: (1) to increase interest and esteem in China by capitalizing on Western interest in traditions of medicine, or (2) a “desire to remind Westerners of the fact that this ancient therapeutic art was capable of functioning in a modern world” (2004:102). Schied based on his research among Chinese physicians, has a slightly different take:

> Chinese physicians made a conscious decision to refer to their medicine as “traditional” when they were writing for a Western audience, while simultaneously creating for it a new basic theory that made it appear more similar to Western medicine (Taylor [2004]). In China itself, on the other hand, the epithet “traditional” (*chuantong*) is hardly ever used. Attuned to the cultural sensibilities of their fellow citizens, for whom asserting their

> modernity remains an issue of face, physicians prefer to define what they do as a science (2007:5).

The Party's general emphasis on science, and disregard for both "backward superstition" and "elite scholarship" meant that its investment in Chinese medicine tended to emphasize using scientific methods to investigate Chinese medicine (Taylor 2004:103);

> Cybernetics, systems theory, black and white boxes, inferential statistics, dialectical materialism, and the Enlightenment teleology of scientific progress have become integral to how Chinese medicine physicians define what they do (Scheid 2002b:137).[60]

While the phrase Traditional Chinese Medicine may have conjured an image of a "continuous strand of 2000 years of history running from the past up until the present day" to a broad Western audience, the term in the foreign-language press referred to contemporary Chinese medicine. But still, this flattening of time with the insertion of the "traditional" into "traditional Chinese medicine" is not what previously bothered me.

I think, what I did not 'get,' and that nagged at me for months, was the extent to which some evaluators at the NHPD had experienced *both* science and tradition as explicit state projects. For bilingual, bicultural evaluators, traditional Chinese medicine *is* science-based Chinese medicine, replete with bureaucratically determined standards informed by scientific research (Scheid 2002:151, esp. n. 22). (More correctly, let me say "could be" rather than "is," seeing as this is based on my conjecture, not from an interview or other fieldwork intervention). While I had previously understood the potential, the particular juxtaposition of two culturally-

specific ways was what I was earlier unable to see, how science and tradition twisted upside down and all-around in the NHPD's use of the *Pharmacopoeia of the People's Republic of China*. NHPD scientists evaluate traditional Chinese medicines on the basis of it being a "traditional paradigm"; but Traditional Chinese Medicine, as included in the *Pharmacopoeia of the People's Republic of China*, is already part of state project to use science as the primary, and originally only, valid basis of knowledge.

Conclusions

This chapter provides a detailed description of the working, policy definition of *traditional* in a multicultural bureaucracy. I can only conclude the obvious: that the *tradition* created by scientists in the course of their traditional medicine evaluation duties was pragmatic. It was inseparable from extant, formalized definitions (e.g., WHO), internal formal and informal definitions, varied vernacular conceptions of ethnic groupings and their unchanging existence through time, nationalistic projects in documentary form (i.e., pharmacopoeia), and industry interests (i.e., Product Licence Applications). There seemed to be little attention paid to hypothetical or theoretical definitions. The regulators realized that the NHPD's definition of tradition was one of many, and did not seem to treat the definition as a fundamental one in any way other than procedurally in their assessments. The only way in which the unit's scientists were involved in the "invention of tradition" was through the "scavenging of documentary and textual traces." On work hours, there

was no need for philosophical discussions regarding what might be; in regulatory science, whether one agrees with regulatory and policy definitions or even abides by them in one's private life is largely irrelevant.

In the regulatory context, certain words are invested with technical meaning, and makes those certain words unfungible with the same words used non-technically. This technical meaning is not the same as everyday meaning, nor does it necessarily involve existential speculation. As Herzfeld argues, language used bureaucratically "opposes any recognition of semantic fluidity" (1992:115); in the Canadian case, while "tradition" was given a specific denotation, it was not a fundamental one. Take a multi-commentator conversation among NHPD officials (noted in a word processing software's track changes feature in a draft internal document) on the use of the qualifier "traditionally":

> Traditionally [Comment: I suggest using another word other than traditionally because in the context of NHPs, this has a meaning. Perhaps using something like "In general"???] *I agree* **OK. Done.**[61]

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1 From the NHPD's homepage, at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php , accessed March 16th, 2009. Emphasis added.

2 Of the 22,229 Product Licence Applications received by August 16, 2007, only 3619 (16%) were for the Traditional Assessment Stream. If we consider that Compendial applications (3231 applications, 15% of all Product Licence Applications received at the NHPD) were often using monographs with claims beginning "traditionally used in herbal medicine for…" then we could perhaps bring the percentage of "traditional" applications up to a fifth or a quarter of the total Product Licence Applications. (More than half the Product Licence Applications were for the non-Traditional Assessment Stream.)

3 20 years prior, the Expert Advisory Committee on Herbs and Botanical Preparations prepared a list of roughly one hundred and fifty “General References on Herbs and Botanicals.” The list contained specific and many references for Chinese medicine and Ayurvedic medicine, but not to any other medical systems outside of EuroAmerica (see Liston 1986).

The later *Drugs Directorate Policy on Herbals used as Non-medicinal Ingredients in Nonprescription Drugs in Human Use* (Health Canada – HPB 1995b), listed “some reference texts available to the Drugs Directorate,” grouped into three categories: (1) Western pharmacopoeia (8), (2) texts that could be considered eclectic compilations of herbs and phytomedicines (thirty or so), and (3) “Chinese Herbals” (11, which, in a rather bizarre conflation, included three texts on medicinal plants in India.)

4 I suspect there are more similarities between the Ayurvedic medicines in Australia and Canada, than that between the United States and Canada. I say this because Sita Reddy makes the argument that in the US, Ayurvedic medicine is less salient as a medicine among Americans with Indian heritage than as an element in wider US American “millennial, heterodox elements of American religious culture” (2002:97); she therefore speaks of New Age Ayurvedic practices in the US.

5 I interviewed or observed most (8) of the roughly ten assessment officers, who, to my knowledge, had ever worked in the Traditional Medicines Unit. To increase the confidentiality of research participants, I also sometimes include scientists who , as managers regularly spoke for the Traditional Medicines Unit, as members of the Unit, although this is not strictly true.

6 One meeting was called on the topic of my research, and attended by a few key current and past members of the Unit. I also observed a meeting on the topic of Issues in the assessment of traditional Chinese medicines held April 19th, 2007. Finally, I consulted key public documents like the *Evidence for the Safety and Efficacy of Natural Health Products* (Health Canada – NHPD 2006c), and all the internal documents I could find on the subject of the efficacy of traditional medicines. (I should note, though, that I was unable to locate many earlier or policy documents on the evaluation of traditional medicines on the NHPD’s internal N:/ drive).

7 The first section (1)(1)of the regulations defines “natural health product” as:

> a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in
>
> > (*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
> >
> > (*b*) restoring or correcting organic functions in humans; or
> >
> > (*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.
>
> However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. (*produit de santé naturel*)

The second section (2)(2) of the Regulations mentions traditional medicine only to specify that the Regulations do not apply to any substance included in the list of prescription-only medicines:

> For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the *Food and Drug Regulations*, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations.

There is no other mention of “traditional medicine” in the *Natural Health Products Regulations*.

8 As policy, guidance documents are merely NHPD’s suggestion as to how industry can meet the regulations; technically, guidance documents are not legally binding, and industry could take the NHPD to court and argue that a premarket application meets the regulations in a different way. In daily work at the NHPD, however, guidance documents are treated as binding.

9 In regulatory science, there is a very different attitude to cutting and pasting other people’s words than there is in academia. In regulation, at least in the Directorate I was in, this cutting and pasting is not plagiarism, in the sense that it would be in academia, because there is no singular authorship as there is in academia. Signing off on a document indicates one’s agreement with the content, rather than one’s authorship of the document. It is expected that the most useful wording will be incorporated, wherever and to whomever that wording originates.

10 In this most recent version of the guidance document, the link to the WHO is explicit. In its Fact Sheet Number 134 (revised December 2008), the WHO defines traditional medicine: “Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses.” The definitions in the WHO fact sheet, however, continue: “Traditional medicine that has been adopted by other populations (outside its indigenous culture) is often termed alternative or complementary medicine. Herbal medicines include herbs, herbal materials, herbal preparations, and finished herbal products that contain parts of plants or other plant materials as active ingredients” (WHO 2008).

In other publications, the WHO includes the phrase “whether explicable or not” referring to the theories, beliefs, and experiences that are the basis of traditional medical practices (e.g., WHO 2009); this additional clause was used by at least one NHPD science manager in discussions with me about traditional medicine, as this manager believed it was part of NHPD’s definition. (The phrase had indeed be included in a previous (2004) version of the guidance document Evidence for the Safety and Efficacy of Natural Health Products.) One of the Traditional Medicines Unit’s members felt that, according to the WHO definition, traditional medicine was necessarily an “ancient practice of medicine prior to the advent of medical science.”

11 The NHPD had still not decided how to assess the aromatherapy files, however; during my fieldwork, there were supposedly over one hundred and twenty Product Licence Application files for aromatherapy waiting for a decision regarding how to process them. The issue was a little more complex than I have presented here. From one of my interviews: “The problem [in assessement] with some aspects of aromatherapy, it is always done in conjunction with massage, or the proven properties, or the properties of the oil, based on inhalation, are as much as an effect as the massage techniques that are employed. So, it is kind of hard to put that into a product.” Some dosage forms were also potentially inappropriate for licencing as a medicine, for instance dishwashing detergent and fabric softener with claims like “Lavender for peace of mind.”

12 The guidance documents are available online at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index-eng.php.

13 Item “B” had not been required for all medicines in the Traditional Assessment Stream prior to 2007; the change was rationalized on the basis of the 23rd recommendation of the Standing Committee on Health in its final report on Natural Health Products (Volpe 1998): “The label indicates clearly the type of evidence used to support the claim.”

14 The reverse problem was also found in the Non-Traditional Assessment Stream. One assessment officer also remarked: “I’ve seen many herbs commonly used in Ayurveda [in the Non-Traditional Assessment Stream]… Maybe the companies want to use buzzwords, and not things like aggravated pitta [as label claims]. And I think sometimes they’re trying to translate traditional claims into more Western paradigm claims, without having evidence.”

15 A second reason for the refusal of the use of the English-language *energy* as primary health claim, was that a claim such as “increases energy,” the Unit’s officers wrote, “does not have a health context.” Thus applicants were asked to provide a health context involving fatigue, debility, declining concentration, etc.

16 These combination medicines could be assessed in the non-Traditional Assessment Stream, but in that case there would have to be scientific evidence for the safety and efficacy of the combination medicine. As stated in section 8.4.2. in the *Evidence for the Safety and Efficacy of Finished Natural Health Products* Guidance Document:

> "cross-paradigm formulations may combine individual components with traditional claims within their original cultural context. For example, an ingredient with a Traditional Chinese Medicine claim may be combined with another ingredient having an Ayurvedic claim. Since the new proposed formulation is neither from Traditional Chinese nor Ayurvedic medicine, the claim for the multiple ingredient product must clearly indicate that the medicinal ingredients have been used individually in traditional medicine but must not indicate that the formulation itself is "traditional" (Health Canada – NHPD 2006c)

17 An application that had a traditional claim *in addition* to a non-traditional claim would be assessed in the non-Traditional Assessment Stream. The traditional claims would ostensibly have to be assessed according to the standards used in the Traditional Medicines Unit; in practice, the traditional claims were often disregarded in non-traditional assessment, deemed 'optional additional information' and therefore not subject to assessment.

18 Debate taken from a chain of e-mail correspondence with subject "Traditional Risk Information" among scientific personnel at the NHPD; e-mails dated 12/20/2005, 12/28/2005, 1/03/2006, and 1/07/2006. The widely carbon-copied chain of e-mail correspondence was forwarded to me in 2007 for the purposes of my research.

19 As explained in previous chapters: Since 2004, companies wishing to market a commoditized, packaged traditional medicine must get a licence from the NHPD before putting the medicine on the market. Note that this does not apply to medicines compounded by a health care practitioner like a naturopath and given directly to a patient. Also note that during the time of my fieldwork, because there was little enforcement of the law, many companies are not currently complying with the law. In any event, to get pre-market clearance to market a medicine in Canada, a company must make a Product Licence Application to the NHPD. The entire application is paper-based. An application includes sections for administrative details, a description of the medicine's the medicinal and non-medicinal ingredients, the dosages and the claims. Additionally, the applicant must provide evidence for the quality, safety, and efficacy of the medicine.

20 This gloss of the process is essentially the NHPD's idealized process map. In reality, the files would at various points have sat in a queue for as little as a few days to upwards of three years.

21 There were of course exceptions; one request sent to industry read:

> According the traditional reference provided, *Citrus aurantum* (zhi shi) is powder-fried and *Glycyrrhiza uralenisis* (Gan cao) is prepared. The traditional methods employed are in order to alleviate the strong property of *C. aurantium*, which can damage the qi, as well as to enhance the property to smooth qi, tonify stomach and help digestion, whereas in the case of *G. uralenisis* it is to enhance its property to tonify the stomach, as raw *G. uralenisis* is used to clear the excess heat. As per chapter 2 of the Evidence for Safety and Efficacy of Finished Natural Health Products guidance document, please provide evidence to support that current method of preparation for *Citrus aurantium* and *Glycyrrhiza uralenisis* as consistent with that used in the practice of Traditional Chinese Medicine (bearing in mind the properties of the formulation) or a rationale as to why the methods in the literature to the traditional use of these ingredients has not been followed.

The extent to which the particular preparation was understood to be crucial to a medicine's safety varied, and depended on the expertise of the evaluator.

22 Specifically, there were several companies whose products were made in China, and whose quality control personnel did not speak English or French well enough to clearly communicate with the NHPD. In these cases, NHPD chemists were communicating either with an intermediary in the company who spoke English well but who had no clue about quality or industrial processes, or with an appropriately qualified employee whose English skills were insufficient.

This issue was apparently less important in safety and efficacy assessment. In the latter type of assessment, the only language-related issue that I noticed was the enhanced assessment ability of assessment officers who spoke a language relevant to the application. Officially, applicants were required to submit a certified translation of any documents not in English or French (although it was decided the onus was on the applicant to ensure a correct translation; see decision taken June 8th, 2005 documented in Product Submission Coordination Unit's Issues Submission Form PSCU I028, Ref: QAP: 100 on the question of "Does NHPD require proof of credentials for a "certified translation?") Most applicants submitted copies from the English version of the Pharmacopoeia. Some assessment officers occasionally consulted the Chinese version of the *Pharmacopoeia of the People's Republic of China* if the English translation of a medicine's action or indication seemed imprecise. The Ayurvedic Pharmacopoiea is transliterated, not translated, into English. There was at least one assessment officer who could read Sanskrit in original Ayurvedic texts. Furthermore, although officers are only required to assess the label text in the language of the application (French or English), in one instance, an assessment officer was able to contest the appropriateness of the transliterated brand name "Jian Zhi" ("nourish brain and enhance intelligence") a claim for which no evidence had been submitted in the file.

23 NHPD's approach with respect to the evaluation of medicines was not racist in a biological sense (e.g., enacting racialized human bodies; cf Epstein 2007.) This is an important note because other jurisdictions do require pre-market testing of proposed medicines in the human bodies located in that particular jurisdiction (e.g., Europe, Japan.) At the NHPD I never heard the suggestion that the traditional use of a medicine by people in China might not be sufficient evidence for the safety and efficacy of that medicine's use by people in Canada. In the Non-Traditional Assessment Stream, the safety of a medicine (but not its efficacy) could be established through long-term dietary intake anywhere in the world (i.e. the standard human of biomedicine described by Epstein 2007:135-154). Biological difference for any reason was largely neglected; the exceptions were restricted to certain developmental differences (e.g., children versus adults; pregnancy) and major pathology (e.g., diabetes, metabolic syndrome).

In an e-mail thread whose purpose was to respond to a query from an industry group asking, essentially, why the NHPD did not follow the European Commission's Directive (2004/24/EC) regarding traditional herbal medicines, an NHPD scientist charged the Directive with ethnocentrism:

> As for the cultural context, it is important to read the EU Directive and introductory text carefully enough to catch their rather ethnocentric perspectives which would not be acceptable to the majority of Canadians.
>
> Introductory paragraph (7) [of the Directive]: The simplified registration should be acceptable only where the herbal medicinal product may rely on a sufficiently long medicinal use in the Community [which, in regulation 16c(1)(c), is taken to be 30 years]. Medicinal use outside the Community should be taken into account only if the medicinal product has been used within the Community for a certain time [16c (1)(c): 15 years]. Where there is limited evidence of use within the Community, it is necessary to assess carefully the validity and relevance of use outside the Community….
> (Taken from a chain of e-mail correspondence with subject "Traditional Herbal Medicines in Europe" among NHPD personnel; e-mail dated 15/03/2007. As of March 24, 2009, the directive that is the subject of this e-mail correspondence can be found at:
> http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0024:EN:NOT)

When a group of assessment officers from the Traditional Medicines Unit were explaining this position to me, they dismissed the applicability of the European requirements because "we have to go with our principles here." When, in the course of the conversation, I mentioned that I had heard that such requirements were not restricted to traditional medicines – that the Europeans required new pharmaceutical drugs to be tested on European bodies at some point as well, their reaction expressed disbelief, including jokes like Tommy's: "What, do they require toxicology testing on European rats, too?"

24 Pubmed and MEDLINE are variants of a widely-used, online searchable bibliographic database of biomedical journal abstracts provided by the United States' National Library of Medicine at the National Institutes of Health; available at http://www.ncbi.nlm.nih.gov/pubmed/

25 A natural health product, by regulatory definition, does not contain most medicinal substances the government considers higher risk, such as requiring a prescription (and on Schedule F of the *Food and Drugs Regulations*), or being psychoactive (and covered by the *Controlled Substances Act*). If a Product Licence Application contains such higher risk substances the file would have been refused by the NHPD before it reached the Traditional Medicines Unit for assessment.

26 The recommended conditions of use include: the subpopulation (the default was "adults"), the dose, the frequency of use, the duration of use, the route of administration (e.g. oral), and use or purpose of the medicine.

27 This generous interpretation was the one generally expressed by the Unit's assessment officers. I could only generously chalk up the submission of a photocopied opinion blog as "evidence of traditional use" to the resistance of a staunch libertarian against any government interference; otherwise I took a much less generous, interpretation. Keep in mind that the NHPD published lists of suggested references, so it is not really possible that the applicants were truly at a loss of where to start. I hypothesized that applicants submitting printouts of commercial websites were: (i) beholden by an incredible sense of entitlement or faith, believing that they should be able to market a medicine for any claim without any form of proof other than their own word or belief, (ii) culturally incompetent or plain stupid, to the extent that they considered commercial websites and opinion blogs "authoritative", (iii) actively trying to bring the NHPD to a standstill by swamping it with seriously deficient applications, like what happened with Canada's federal gun registry, or (iv) effectively scamming the system to avoid meeting the regulatory requirements without any consequences. Option (iv) was possible because while the NHPD began its operations and had a backlog, compliance action was generally not taken against medicines with *submission numbers* (e.g., there was a Product Licence Application for the medicine at the NHPD); by continuing to make minor modifications in a deficient application, an unscrupulous applicant could keep the submission number, but without getting refused or licenced, for quite a while and continue to import or sell the medicine. Before working at Health Canada, I did meet a business man at a conference, who at a break, happily explained to me all the "loopholes" his business exploited (combination of libertarianism or option i, and option iv). I did not express any of these four interpretations in my capacity as Health Canada employee, because these are truly ungenerous interpretations of industry's actions, and furthermore they are interpretations which were untenable with the NHPD's stance, of "being flexible" (see Chapters 12 and 18).

There was, however, a fifth hypothesis that was discussed with some of my colleagues (not in the Traditional Medicines Unit). This fifth hypothesis applied only when the application was completed by a consultant, not a salaried employee of the company seeking the licence to market the medicine. Some consultants appeared to be working a racket: these consultants billed the companies according to the number of communications required with the NHPD, so by knowingly submitting inadequate information to the NHPD, presumably these consultants could increase the fees they billed the company.

28 One very common reference compilation, which was also used by many naturopaths in their practice, was the Natural Medicines Comprehensive Database (NMCD). Its entries were essentially review articles listing all possible indications for medicines, from any source. The NHPD did not generally accept the NMCD as a sole reference. For traditional medicines, it was seen as a useful tool for background information – especially safety – but otherwise its use was limited (from a presentation "An Overview: Evidence for Safety and Efficacy of Traditional Medicines" delivered April 10, 2007 at an internal training session; slide 38). As of August 28, 2010, the database can be found at http://naturaldatabase.therapeuticresearch.com/home.aspx?cs=&s=ND

29 Thus references such as *The Energetics of Western Herbs*, a book oft-cited by applicants, were considered non-suitable by the NHPD as evidence for traditional use because of the authors' attempts to synthesize energetic concepts from traditional Chinese medicine, Greek medicine, First Nations medicine, etc. (From an internal presentation "An Overview: Evidence for Safety and Efficacy of Traditional Medicines" delivered April 10, 2007 at an internal training session; slide 52.)

30 Examples taken from an internal presentation entitled "An Overview: Evidence for Safety and Efficacy of Traditional Medicines" delivered April 10, 2007 at an internal training session; slide 54.

31 From an internal presentation entitled "An Overview: Evidence for Safety and Efficacy of Traditional Medicines" delivered April 10, 2007 at an internal training session; slides 53-54.

32 The requirements for an Expert Opinion report are outlined in section 3.5 of the NHPD's guidance document *Evidence for Safety and Efficacy of Finished Natural Health Products* (Health Canada – NHPD 2006c). The committee writing the report has to have at least three members, including one with expertise in the relevant healing paradigm, another with scientific qualifications, and the members must disclose any conflicts of interest. I was told, anecdotally, that industry's attempts to produce Expert Opinion Reports consisted of gathering opinion statements from long-standing business owners.

33 Substituting evidence of traditional *nutritional* use for evidence of traditional *medicinal* use, was a common deficiency in applications for chlorella and spirulina in the Traditional Assessment Stream.

34 Part of this cycling was because Kieran took considerable care to ensure that the standard lines that she sent out to the company were consistent with both 1. what the company had previously received, and 2. other standard lines regarding pau d'arco that had been used by officers in the Traditional Medicines Unit.

35 Many of the claims beginning with "traditionally used in western herbalism for…" are based on practices that were originally taken from First Nations medical practices, as many of the references used by the NHPD and applicants are from the tradition of eclectic medicine in North America. As one Unit member (Ampan) pointed out, "it is not required that they [the applicants] identify down to the origination of the medicine."

36 Hypotheses for the small number of Product Licence Applications for Ayurvedic medicines, relative to traditional Chinese medicines, in the Traditional Assessment Stream included: the increased provincial organization and regulation of herbalists and traditional Chinese medicine doctors; the relative size of identifiable Chinese and Indian communities in Canada; the numerousness and heterogeneity of Ayurvedic medicines across India; and the speculation that Indian manufacturers do not know about the regulations. One assessment officer estimated that she had received only two or three applications for traditional Ayurvedic medicines in the last 100 applications she had received in the Traditional Medicines Unit.

37 The most recent version of the *Pharmacopoeia of the People's Republic of China* (2005) has three volumes; only the first was considered relevant for the work of the NHPD. The first volume was the only one consulted at the NHPD – it consisted of monographs for crude drug preparations, patent medicines, and materia medica that generally corresponded to what the NHPD interpreted as Traditional Chinese Medicine. The second and third volumes pertained to chemical, biomedical, and biological medicines, which would not fall under the ambit of the *Natural Health Products Regulations.* There were also some monographs in the first volume that were not considered "natural health products" by the NHPD, and thus disregarded for evaluation purposes.

38 Statement made at an internal NHPD training session, April 10, 2007.

39 One assessment officer, Terry, volunteered that she had prior knowledge about a third of the medicinal ingredients she assessed, and at least recognized the names another third, but that left a substantial number of medicinal ingredients she had never before seen; another officer estimated there was only a 10-25% chance she would have prior knowledge of all the medicinal ingredients in any given Product Licence Application. Considering the incredible diversity of medicinal ingredients in the Traditional Assessment Stream, it is no surprise that pharmacopoeia and other compendia of medicinal ingredients were so useful in assessment.

40 "Tokay Gecko is the dried body of *Gekko gecko Linncieus*... The drug is captured all year round, removed from the viscera, wiped, opened with a bamboo piece to make the whole body flattened straight, and dried and a low temperature." From the English-language edition of the *Pharmacopoeia* (2000).

41 The *Pharmacopoeia* lists the purposes of using the herb under two headings: actions and indications. In some cases the assessment officers also consulted the section "indications," but according to one assessment officer this was usually only done if required for a particular file. The "actions" were more salient to the assessment officers of the Traditional Medicines Unit, as the indications tended to be more numerous and were often based on biomedical science.

42 Slide 14, Presentation April 10, 2007.

43 The description of the four ways in which combinations could be logical for TMU is taken from a presentation entitled *An Overview: Evidence for Safety and Efficacy of Traditional Medicines*…slide 15 delivered as an internal training session.

44 Applicants and assessment officers would have to complete an "additive table" in the case of an additive combination; for an example additive table see the Guidance Document (Health Canada- NHPD 2006c).

45 Furthermore, the way in which texts are used in various scholarly medical traditions may be important in different ways. Don Bates, in *Knowledge and the Scholarly Medical Traditions*, argued that in the Chinese and the Ayurvedic traditions, "knowledge gets as much of its status from the person who knows it, while, in ancient Greece, the known gets much more of its status from the knower's capacity to justify it in terms of other knowns," justification inline with "the very Western phenomenon of active epistemololgy" (1995:3).

46 Examples of books that were frequently used by applicants, and I supposed therefore by the NHPD, were: *The Chinese Materia Medica (*Beijing University of Traditional Chinese Medicine 1998), *Chinese Herbal Medicine: Formulas and Strategies (Bensky and Barolet 1990), Chinese Herbal Medicine: Materia Medica 2nd Ed.* (Bensky and Gamble 1993).

47 The same officer explained how in traditional Chinese medicine, there is much at stake in the exact amount or ratios of ingredients; but for the purposes of the NHPD, if a practitioner or company increases some quantity slightly, that is their prerogative. From other events at the NHPD, I gathered that the exact proportions or ratios of medicinal ingredients is considered a trade secret for many Chinese manufacturers, who want to avoid revealing their trade secret worldwide by complying with the Canadian regulations (the NHP regulations require that the quantity of each medicinal ingredient be listed on the medicine's label).

48 From a Condensed Issue Analysis Summary for PLA dated July 3, 2007.

49 N.B. The Traditional Medicines Unit would consider these bioequivalency studies done for Chinese regulatory officials. For instance, a request to industry for a Product Licence Application read:

> Please provide the license from SFDA, China to indicate the quantities of medicinal ingredients in support of the recommended quantity dried equivalent dose that was higher than that included in the pharmacopoeia of the People's Republic of China.

50 Although I otherwise try to avoid reporting discussions that wafted into my cubicle, I do so in this case because the discussion itself is unremarkable, and there is a reasonable chance that the discussion was held near my cubicle for my benefit.

51 "In Europe and North Africa, the special wound healing properties of propolis were already known to the Egyptians, Greeks and Romans in ancient times. In records of the 12th century, medicinal preparations with propolis are described for treating mouth and throat infections, as well as caries." From a draft Condensed Issue Analysis Summary for PLA, dated July 3, 2007, on the issue of "How best can the propolis monograph in the *Pharmacopoiea of the People's Republic of China* be used to support a traditional claim application?"

52 From a draft Condensed Issue Analysis Summary for PLA, dated July 3, 2007, on the issue of "How best can the propolis monograph in the *Pharmacopoiea of the People's Republic of China* be used to support a traditional claim application?"

53 Interview statement: "For me, traditional medicines can evolve, but there's a limit as to how far they can go. It is also if you look at traditional medicines on the whole, I do not believe traditional medicines should be increasing. They should be really a standard thing, unless you're discovering new cultures that you weren't aware of before."

54 Not to say the play was without effect, in line with NHPD's regulatory responsibilities. I have no doubt that should the issue become an Issue at a later date, these playful discussions would be influential in the shaping of the official Issue because they expanded scientists' range of examples and an approach to the issue. Several assessment officers told me they found the impromptu discussions around the NHPD to be the most interesting, to be the most memorable. As an anthropologist, I would probably have to hang around the NHPD for years before witnessing the development of that particular Issue.

55 This is not the application of science to investigate traditional medicines of Canada popular over the past two or more decades; nor making "traditional medicines" "more effective by subjecting [them] completely to the principles of 'science'" – most significantly by concentrated extracts or isolates – popular in Japan in the 1970s and 1980s (Lock 1984 [1980]:ix); nor the phytomedicines of Germany, and so on.

56 In *Imagined communities,* Benedict Anderson (1991) uses *imagined* to described the community of the nation states because its community members cannot know each other face to face, but rather imagine a community, something facilitated by, among other things, nationally-standardized language emerging with commercial publishing and "traditions."

57 A summary of the various and sequential policies until the 1990s is provided by Young *et al.* (1995:499-502).

58 For a somewhat analagous summary of the recent history of Ayurveda in India and the US, see Reddy's article (2002:100-105).

59 As Farquhar has suggested (1994, 1995), the idea of a "theory" separate outside experience is a culturally-specific way of approaching medicine.

60 For an ethnographic account of the science in Chinese policy development in another discipline, demography, see Susan Greenhalgh's discussion of the one child policy (2008).

61 Multi-commentator entries in 2003 draft document on clinical trials, document on internal shared N:/ drive.

Chapter 9
Homeopathic medicines and *acting as if* one believes

« Through the Natural Health Products Directorate, Health Canada ensures that all Canadians have ready access to natural health products that are safe, effective and of high quality, **while respecting** freedom of choice and **philosophical** and cultural **diversity**.»[1]

The NHPD's Homeopathic Medicines Unit

The Homeopathic Medicines Unit was an assessment unit like any other in the Bureau of Product Review and Assessment (BPRA). The Unit was responsible for assessing all Product Licence Applications for homeopathic medicines. At the time of my fieldwork, Product Licence Applications for homeopathic medicines only represented five percent of all Product Licence Applications received by the NHPD,[2] and the bulk of these applications for homeopathic medicines were made by five or six companies.[3] The Unit's officers, however, were expecting a substantial number (~4500) of applications in 2010, when homeopathic medicines previously licenced by another government agency (the Therapeutic Products Directorate) would be required to receive a licence issued by the NHPD.[4] The officers were therefore hoping to have addressed all "issues" in the evaluation of homeopathic medicines before the wave of applications in 2010.[5]

As in every other pre-market assessment unit, the officers in the Homeopathic Medicine Unit were all scientific staff, qualified in the biological or chemical sciences. At the time of my fieldwork, the Unit was composed of a Unit Head, two

dedicated assessment officers, and occasional affiliates. (Because of the small numbers, I refer to all of the following staff as part of the unit: Unit members during my fieldwork, Unit affiliates for the purposes of assessment, and scientists who were previously affiliated with the Unit).

The unit was exceptional, however, in that each current evaluator (affiliate or not) was a young[6] woman homeopath. This uniformity in age and practitioner background was unusual for the NHPD. The assessment officers in the unit expressed a feeling of unity, and noted that they tended to agree on most everything to do with product licencing. Although the unit's evaluators told me that strong differences in opinion had emerged in the unit's discussions of appropriate dosing schedules, potency levels, and claims, these differences, the evaluators believed, were due to their different approaches to *the practice* of homeopathy, and represented an opportunity to learn from their colleagues. The members emphasized the importance of staffing the Homeopathic Medicines Unit exclusively with homeopaths, because they felt that in their discussions of files, they could count on their colleagues already understanding "stuff right away because of the paradigm and practice, already speaking a language up here [gestures high] instead of having to explain the basics of homeopathy" (Olive).

Assessment officers, both inside and outside the Homeopathic Medicines Unit, perceived the Unit as isolated. This did not seem to be actively desired on anyone's part. Nevertheless, there were some simple basic facts about

homeopathy – for instance the fact that, the higher the potency of a homeopathic medicine, the less “material” the dose of medicinal ingredient – that, for whatever reason, proved to be an insurmountable conceptual barrier for some scientific staff outside the Unit. The homeopaths inside the unit found it frustrating to reexplain homeopathy to colleagues in other units because their colleagues often refused to engage in constructive commentary or joint projects even after these explanations, rationalizing “oh I do not know about homeopathy.” The unit’s scientists, in interviews, communicated a feeling that no one else at the NHPD understood homeopathy, or, more to the point, really cared to understand.

> The perception is that HMU is an isolated unit. Not that we work in isolation, it is just that we are not well understood. So if we have an issue to bring to [various meetings of lower management in the Bureau such as] BPRA or Policy or PLA issues, because others don’t understand, we get no feedback.
>
> Essentially, we have to do more work. In policy, for example. Other people lack understanding and so we have to do more information sharing. Here, upper management basically says yes or no to what we propose, whereas, in other paradigms, upper management gets more involved in the issues. (Candy)
>
> Basically, [the Homeopathic Medicines Unit] did not fit elsewhere [in Health Canada], so it was fit in the NHPD. Management does not understand [homeopathic medicine], so they rely on the homeopathic unit. (Saffron).

Indeed, policies regarding homeopathic medicines were often segregated from policies for other natural health products into separate documents, and the Unit was used by upper management as a testing ground for new assessment processes (blitzes, comparative approach) presumably because of its isolation. Another reason for the isolation was many scientists’ theoretical views on the incommensurability of homeopathy and science. When I asked Candy what she thought of the perception of homeopathy within the NHPD, she replied:

> It is thought of as a paradigm unto itself. I do not think that many people believe in homeopathy. [pause]
>
> It is easy to understand the concept of dilutions, and so they [scientists] assume there is nothing left [in homeopathic medicines]. I think the people who truly understand homeopathy are the ones who have had some training in it: naturopaths, homeopaths. When dealing with others – well…. Some scientists have said to the HMU [Homeopathic Medicines Unit]: "that is a placebo."
>
> See, these scientists are trained to understand, but it is difficult to understand. Even when scientific studies come out, [the scientists] don't believe, because it is difficult to fit in their model.

Homeopathy and Science

While homeopathy does not use certain measures of biomedicine –an institution in which measures and mechanisms of action elucidated in a laboratory play an incontournable role (see Chapter 10) – this does not say anything regarding homeopathy's compatibility with science in general. There are at least two ways to examine science, anthropologically-speaking, as it intersected with homeopathy at the NHPD. The first is to examine the NHPD scientists' declarations; I summarize the range of these statements in this section. The second is to define "science" very pragmatically: as that which scientists do. This second approach is addressed throughout the chapter, in which I report what the scientists *do* in the evaluation of homeopathic medicines. In both instances, however, I wish to point out that the scientists' understandings of "science" and its intersection with homeopathy, were very uneven. Furthermore, in terms of the disciplinary background of scientific staff at the NHPD, pluralism within and between sciences was the norm.

Science among assessment officers in the homeopathic medicines unit

The evaluators in the NHPD's Homeopathic Medicines Unit – who were all homeopaths with a university degree in a biological science – articulated different opinions regarding the relationship of "science" and homeopathy. For instance, Saffron chose to emphasize that homeopathy was *real* science:

> In fact I believe homeopathy is one of the *true* sciences. Science does not dictate the nature of our reality. Science is set up to try and understand what is happening in our reality. So in homeopathy – we don't really understand the mechanism of action, we aren't at the point where there is machine sensitive enough to detect it; you have to have a … living organism, and to put the substance into it and watch the result.

For Saffron, homeopathic provings were excellent science. (Homeopathic provings consist of a large number of detailed observations of a medicine's physical, emotional and spiritual effects on healthy persons. In homeopathy, a medicine's effects on healthy people are precisely the effects that the medicine will cure in a sick person). Saffron contrasted this type of science with the "inferior, correlative" science in randomized clinical trials.

A few other evaluators in the Directorate, including another homeopath, contextualized attitudes to homeopathy and science in terms of geography, for instance noting that homeopathy was generally seen in North America as "a backwards science," but that this was not true worldwide. These evaluators tended to find the idea of working as scientists on homeopathic medicines in a government department "fascinating" or "intriguing."

Of course, still other scientists who expressed fascination also expressed doubt that there was “science” in homeopathy. Scientists’ implicit or explicit definitions of science most often invoked laboratory science or randomized clinical trials; and often they explicitly opposed science to homeopathy. Candy, for instance, implicitly defined science as clinical trials in interview. Ommy, a non-homeopath scientist, explained that part of what he liked about working at the NHPD was looking at medicines from many different types of “paradigms,” including homeopathy – but he implicitly distanced homeopathy from science, by calling homeopathy “a philosophical thing.”

The problem of ridicule

Indeed, in confidential interviews, a few scientists at the NHPD openly ridiculed homeopathy. But this ridicule was neither public nor the norm at the NHPD. Indeed, expressing disbelief in the entire paradigm by declaring “homeopathy does not work” – even when backed up by “science” in the form of a systematic review – was treated as a serious *faux pas* in the Directorate. Given these diverse definitions of science and their relationship to homeopathy: how, then, did scientists – homeopaths or not – assess the efficacy of homeopathic medicines in the Directorate?

The chapter’s arguments regarding paradigms and belief

This chapter describes how NHPD scientists inside and outside the Homeopathic Medicines Unit engaged with the government regulation of homeopathic medicines. While it addresses the assessment of quality, safety, and efficacy of homeopathic medicines, the chapter pays particular attention to the ways in which the efficacy of homeopathic medicines was manifest in scientists' regulatory reasoning, and reported personal beliefs. I first examine homeopath-scientists' assessment work inside the "mystery unit," as the Homeopathic Medicines Unit was called by some scientists. For contrast, I then discuss the Clinical Trial Unit's assessment of clinical trials for homeopathic medicines, because none of the assessment officers in that unit were homeopaths. In addition to the descriptions, I make two arguments in this chapter.

First, I argue that the evaluation of homeopathic medicines at the NHPD was commensurable with the evaluation of other medicine types, when one takes the literal meaning of "commensurability," having a common metric or measure. In other words, when I examined the details of the measures and standards used in the evaluation of quality, safety, and efficacy at the NHPD, there was only one measure that was consistently absent in the homeopathic evaluations, but present in most other evaluations: the quantification of medicinal ingredient in the finished dosage form. But even here, this absence was not unique to the evaluation of homeopathic medicines, because some other medicine types also required the "input method" be used to quantify the medicinal ingredient present in the finished dosage form. In all other cases, the types of measures and standards used were

ones used for the evaluation of traditional medicines or that of other natural health products. Despite homeopathy's general, shall we say philosophical ("paradigmatic" in local terms) incommensurability with biomedicine, the evaluation *process* of homeopathic medicines was almost entirely commensurable, in the literal sense, with that of other natural health products.

My second argument in this chapter addresses the question of personal convictions in regulatory assessment: how scientists with varying professed convictions regarding the efficacy of homeopathy can work together in the regulatory evaluation of homeopathic medicines. It is important to note that an entire science-based bureaucracy can, and quite clearly did, operate smoothly while individual scientists expressed a range of convictions regarding whether a particular homeopathic medicine works. I argue this was possible because the directorate's scientists and managers – whether they were homeopaths or not – were required to evince a particular disposition towards homeopathic medicines. To be a competent assessment officer in the directorate, scientists (and their managers) had to act *as if* they believed in the "paradigm" of homeopathy – they had to reason with rules of the paradigm in the evaluation of any homeopathic medicines they encountered in their regulatory work activities. Here, I argue that conceiving homeopathy as "a separate paradigm" with its own rules, considerations, and sources of expertise within the directorate facilitated this regulatory disposition divorced from personal belief. While I make this argument for the evaluation of homeopathic medicines, because the question of (dis)belief was

most explicit regarding homeopathy, my discussion of the dispositions required of scientists is equally applicable to the evaluation of many other medicine types.

The assessment of quality, safety, and efficacy

How did the evaluators in the "isolated" Homeopathics Medicine Unit assess medicines for quality, safety and efficacy? The next section provides an overview of the Unit's approach to evaluating medicines with "immaterial doses" of medicinal ingredients, as a prelude to an analysis of the issue of efficacy in more detail.

The definition

The Unit's assessment of Product Licence Applications for homeopathic medicines hinged on the NHPD's definition of homeopathic medicine. To be considered homeopathic, a product had to be:

> (1) Composed of substances referenced in one of five recognized homeopathic pharmacopoeias: that of the US, of Germany, of France, of Europe, or in the "Encyclopedia of Homeopathic Pharmacopoeia",[7] and
>
> (2) Prepared according to methods[8] outlined in one of the above pharmacopoeias (Health Canada – NHPD 2007a).

The assessment of homeopathic medicines was therefore centred on pharmacopoeial standards. "We do not have the balls or the resources to evaluate" medicinal ingredients without pharmacopoeial standards, for safety and efficacy, explained Wendy.

This did not stop applicants from sending Product Licence Applications for medicinal ingredients not mentioned in the five recognized homeopathic pharmacopoeia, and that therefore did not meet the NHPD's definition of homeopathy, to the Homeopathic Evaluation Stream. Sometimes these applications were refused; at the time of my fieldwork, however, the Unit was trying to figure out what to do with many such applications. For instance, the Homeopathic Medicines Unit was faced with deciding whether isopathy fell into the paradigm of homeopathy, because the Unit had received "hundreds" of applications for medicines used in isopathy. Whereas homeopathy's overarching principle is similarity – "like cures like" – isopathy's guiding principle, or so I was told, is identity. In isopathy one might make a cure by taking the disease itself (e.g., the allergen, microbial cause, etc.) and diluting it homeopathically. The Unit's evaluators argued that because the cure is not selected according to homeopathic principles, the cure is not homeopathic. While distinctions between isopathy and homeopathy may seem minor to a non-specialist, these distinctions became Issues for scientists reasoning through taxonomy and comparison, especially when faced with a slew of applications for isopathic medicines made in the homeopathic assessment stream.[9] Like with the Traditional Medicines Unit's verdict on aromatherapy,[10] the Homeopathic Medicine Unit's verdict allowed for the possibility that isopathy could become a separate "healing paradigm" with its own standards for regulatory purposes – although I did not encounter any hope that this would actually come about.

In any event, the NHPD's assessment of homeopathic medicines was clearly centred on pharmacopoeial standards, and as such, was characterized by significant matching activity and addressing "issues" arising from incomplete matching.

Quality

Homeopathic medicines come in a range of dosage forms, includig granules (small pellets), tablets, liquids, syrups, ointments and creams, and suppositories. Despite this range, the quality assessment for homeopathic medicines may have been the most straight-forward of all medicine types at the NHPD. Malik declared that "for homeopathics, there are not many challenges for quality – it is not an issue. Identity of raw materials, that's it." There were very clear pharmacopoeial standards for preparing homeopathic medicines. In the Product Licence Application form, applicants had to list the method of preparation for each ingredient, and these methods had to be from one of the five approved pharmacopoeiae (Health Canada - NHPD 2006b:14). Because the quality assessment largely relied on ensuring applicants were using methods and tests recognized in appropriate pharmacopoeiae, much of the quality assessment – when the application was well done – was "essentially just matching." This is not to say that applicants did not try and find creative ways of avoiding meeting these standards, and so, as one evaluator explained as I observed her at work: "There are so many issues and no standard lines for any quality issues [for homeopathic medicines], so I hardly use the standard line document." A typical quality concern in the unit was for

manufacturing methods used for succussion (vigorous shaking) during the serial dilution process; if a medicinal ingredient like mercury were not properly dispersed in a serial dilution process, “material doses” of mercury might be present in the resulting medicine, with obvious safety concerns.

The tests on the finished medicinal product that the company was required to carry out, for instance the verification that there was no bacterial or heavy metal contamination, were the same as those required for any other natural health product, with one notable exception: for homeopathic medicines, there was no analytic testing of quantity of medicinal ingredient in the finished product. The starting, raw material had to be tested for identity, rather than the starting material’s immaterial presence in the finished product. Partly because of this, the Unit’s evaluators, qualified in the biological sciences, evaluated the quality of homeopathic medicines themselves:

> We do our own quality, because of a lack of understanding on the part of the chemists [who usually did quality assessment]. For instance, even HPLC would not help identify the finished ingredient [in a homeopathic product].

As was the case in other assessment units, some barometers of product quality that the scientists would apply in their lives outside the NHPD as practitioners or consumers were irrelevant in the regulatory evaluation of quality. For instance, one homeopath felt that succussing the medicinal preparations by hand, on a book, gave the medicines a different quality from medicines succussed by machine.

In sum: In many ways, the quality assessment of homeopathic medicines was fully commensurable with that of other types of natural health products – the same analytical tests were required of the finished product. But the one notable exception – that there was no "material" amount of medicinal ingredient, as understood in the biomedical paradigm – meant that, organizationally, the quality assessment of homeopathic medicines was made incommensurable with that of other medicine types, because the unit's biologists, rather than outside chemists, wrote the quality assessment report.[11]

Safety

In the Homeopathic Medicines Unit, the evaluators had two types of safety concerns: toxicological and homeopathic. Both concerns centred on dose. While the first concern was fully commensurable with concerns of other units, the second was incommensurable.

The evaluators' primary safety concern, and the one shared with other all other units at the NHPD, was toxicological. Because of the serial dilution process with homeopathics, toxicological concern entered only when homeopathic medicines were of low potency, e.g., when the medicinal ingredient was not serially diluted and succussed. In low potency homeopathics, the starting material may be present in the finished product in what the scientists referred to as "material doses." This was a heightened concern when the application was for a homeopathic medicine containing: restricted ingredients such as prescription drugs, biologics, and

tobacco; potential poisons *Aristolochia spp.* and *Asarum spp.* and so on; or pathogens such as the nosodes, isodes, sarcodes, and allersodes.[12] To address this concern, scientists at the NHPD required that homeopathic medicines made from such substances be potentized to 12CH or higher (Health Canada - NHPD 2006b:1).[13] The "CH" in "12CH" stands for a 100, meaning that one drop of starting material is put in 99 drops of diluent and succussed. The "12" in "12CH" means that this dilution process is sequentially done 12 times. At a potency of 12CH, there is a reasonable likelihood of only one molecule of starting material present in the finished medicine; at any higher potency, there is little likelihood of any molecules present. There are various dilution scales used in homeopathy, some of which are reproduced in Figure 9-1.

Figure 9-1: Dilution Scales
adapted from *Evidence for Homeopathic Medicines* (Health Canada 2006b:52)

Scale	**Designation Equivalence**
Decimal (1/10)	X = D = DH
Centesimal (1/100)	CH = C = CK = K
Fifty Millesimal (1/50 000)	LM = Q

Scientists required this minimal potency of 12CH to ensure there would be no "material dose" in the finished medicine; a few paraphrased Paracelsus' "all things are poison and nothing is without poison, only the dose decides" in this regard.

The scientists' other safety concern, was homeopathic. This concern makes no sense within biomedicine, because it is the concern over noxiously high potencies,

in other words, concern over extreme dilutions. Some of the Unit's homeopaths were particularly concerned about high potencies when the label recommended frequent dosing[14]. Within the paradigm of homeopathy, I was told, nosodes are considered "risky," and so some evaluators felt that the dosing regimens for nosodes should be of limited frequency.[15]

Unless the pharmacopoeia referred to by the applicant contained clear limits, however, assessment officers were unsure whether they would be able to enforce upper limits for potency, and, during the time of my fieldwork, were discussing the matter. For instance, I observed one assessment officer assessing multiple versions of the same homeopathic medicinal ingredient, but of very variable potency. She felt comfortable, it seemed, recommending a licence for the medicine with a potency of 30CH and with limited frequency of use. But unease set in with another file for the same medicine but with potency of D2, and with a third file with a potency of D200, without limiting the frequency of use. She had hoped to have a discussion of the issue in a unit meeting, but because of absences in the unit, the meeting had been postponed; she therefore drafted a memo for the unit calling for a discussion of whether there should be a limit on the range of acceptable potencies.[16] Like in the Traditional Medicines Unit, when evaluators did not think something made sense "within the paradigm of homeopathy," their actions were quite similar: bring the issue to the attention of one's colleagues in general, an expert colleague in particular, or perhaps the unit head; and if there were discrepancies in opinion, arrange for a discussion of the issue, in hopes that a

reasonable unit-wide decision can be reached, and that the decision would subsequently be supported by upper management.

Efficacy

In the logic of current health protection: medicines designed for self-care, as natural health products were originally conceptualized, generally require clear label claims so consumers can make an informed choice.[17]

Many homeopathic medicines, however, are not produced for self-care, but for use upon the recommendation of a homeopath. Homeopathy, as a rule, requires that a homeopath carefully tailor the treatment regime to the individual patient. The directorate's homeopaths explained to me that as health practitioners, they would spend upwards of an hour enquiring about the patient's complaints, personality, sensibilities, desires, and so on, to select the appropriate, often singular remedy for a patient. The ideal remedy would reflect the patient's totality of being, rather than any generic disease. Homeopathic medicines used in the context of a practitioner-patient relationship therefore cannot have claims in the usual sense of their "efficacy for anyone with such-and-such-disorder in the population," as efficacy has been constructed in biomedicine.

To allow for homeopathic practice, the Directorate therefore divided homeopathic medicines into two types for its assessment purposes: (1) homeopathic medicines that are intended for use in consultation with a homeopath, and thus having no

condition-specific label claim, and (2) homeopathic medicines designed for self-medication, with specific claims. I will describe each in turn.[18]

At the time of my fieldwork, this exception regarding label claims was largely specific to homeopathic medicines, because, as I mentioned, normally all natural health products were expected to have a specific label claim so the 'consumer' could make an informed decision.[19] Yet Product Licence Applications for homeopathic medicines without specific efficacy claims were permitted – even required in the case of homeopathic medicines with only one ingredient. *En lieu* of a label claim for a product's efficacy, these medicines were required to include one of the following "non-specific uses or purposes" on the label: "Homeopathic Medicine," "Homeopathic Remedy," "Homeopathic Preparation," or "Homeopathic Drug." These homeopathic medicines without specific label claims were eventually processed in a special assessment stream using a Homeopathic Medicines Labeling Standard, analogous to assessment in the Compendial stream, and the pharmacopoeial stream in the Traditional Medicines Unit, that have been described in earlier chapters.[20] Before the inception of the Natural Health Products Directorate, the Therapeutic Products Directorate licenced homeopathic medicines by the spreadsheet, using a similar rationale, and thus the evaluation of these single-ingredient homeopathic medicines in Canada had remained stable for at least a decade despite various changes in organizational context. Scientists' judgements about the efficacy of these products is a judgement about the existence of a medicine within the textual standards of a paradigm – whether that

be for homeopathic medicines, traditional medicines, or vitamin and mineral supplements.

The remainder of this section discusses the assessment of specific label claims. Condition-specific label claims could only be made if there were more than one medicinal ingredient in a homeopathic medicine. The NHPD required that applicants submit evidence for the efficacy of a label claim. As for traditional medicines, evidence for a homeopathic medicine's efficacy was expected to be textual – ideally pharmacopoeial – and clearly reproduced in the Product Licence Application:

> Evidence must be submitted as photocopies of relevant text that makes reference to the recommended use or purpose. It is the responsibility of the product licence applicant to underline (not highlight) the exact information being referenced in order to ensure clarity after photocopying. Applications containing evidence that is not underlined may take longer to assess than those where relevant sections have been clearly marked (Health Canada – NHPD 2006d.)

In the NHPD's five-layered hierarchy of evidence, pharmacopoeial evidence had a lowly position, way down at level four. Section 8 of the homeopathic guidance document encouraged:

> the use of level I-III evidence [well-designed meta-analyses, clinical trials, and observational studies] where it exists. Scientific evidence from Levels I-III may be used to support novel conditions of use which are not supported by homeopathic provings or references such as the homeopathic *material medica*. Homeopathic *material medica* and homeopathic provings are the most commonly available evidence, and are accepted as Level IV evidence (Health Canada – NHPD 2007a.)

Like in the Traditional Medicine Assessment Stream, there were several limits placed on health claims in the Homeopathic Assessment Stream, because of the lowly ranking of pharmacopoeia in the hierarchy of evidence. The label claims of homeopathic medicines had to contain the qualifier “homeopathic medicine” or “used in homeopathy for…”, because, according to one assessment officer**,** an upper manager was “worried companies [were] trying to slip stuff through” the Homeopathic Assessment Stream.[21] When the homeopathic medicines had specific label claims, the claims had to be suitable for self-care (Health Canada – NHPD 2006b:4and16); medicines assessed as homeopathic medicines could not make claims for any Schedule A (serious) disease.

Efficacy in assessment work and private opinion

To return to one of my original research questions: how was efficacy constituted in the pre-market assessment of homeopathic medicines?

There are, of course, several ways of answering this question. To summarize what efficacy was *in practice*, as outlined above: it is clear that efficacy was different things depending on whether a claim was being made. For proposed single ingredient homeopathic medicines, there were no generic health or treatment claims and no concept of efficacy outside of a homeopath’s practice; therefore all that was evaluated was whether, indeed, a medicine was a “homeopathic medicine” according to a pharmacopoeia and that various quality and labeling

standards had been met. For proposed homeopathic medicines with specific claims, although the evaluation of efficacy could be based on published studies (like for any other natural health product), the proposed medicine had to be included in a standard homeopathic pharmacopoeia – or the proposed medicines could be deemed to fall outside the paradigm of homeopathy.[22] In other words, pharmacopoeial standards were de facto evidence of the existence of homeopathic medicines, and therefore their safety and efficacy; without a medicine's documentation in the pharmacopoeia, "there is the question of safety and efficacy" for the evaluators (Candy). The efficacy of homeopathic medicines was loosely given *a priori*, by pharmacopoeia; there was little discussion of the meaning of efficacy in the daily assessment work.

The official, Directorate definition of "efficacy" in the context of homeopathic medicines was no different than the official Directorate's definition of "efficacy" of all medicine types. The Directorate's Guidance Document "Evidence for Homeopathic Medicines" defines efficacy uses wording that would not be out of place in a Cochrane Collaboration publication:

> The extent to which a specific intervention, procedure, regiment or service produces a beneficial result under ideal conditions. In other words, it is the ability for a NHP [natural health product] to produce the desired health outcome, which it is used according to the Recommended Conditions of Use, under ideal conditions. (Health Canada – NHPD 2007a:34)

Keen readers will notice this definition combines two ways of approaching efficacy: first, as the *extent to which* a medicine works, and second, as *whether* a medicine

works. These two approaches were also often mashed together in the scientists' individual opinions.

Homeopaths' opinions regarding efficacy

The official definition of efficacy contrasted with that found in the private opinions of the Directorate's homeopaths. Saffron, a homeopath, told me that the hierarchy of evidence-based medicine – with randomized clinical trials near the pinnacle of establishing efficacy – was of little importance to her understanding of efficacy:

> It comes back to weight, the weight of the evidence: For a scientist, randomized clinical trials are worth more than [homeopathic] provings; but for me clinical evidence [homeopathic proving] is worth more than clinical trials. Homeopathics have been working for 200 years. I think that has more weight.

Candy made a similar statement:

> You get a lot of people [scientific staff at the NHPD] that are more scientist, and they feel that they need the science to backup the product. It is not that we [homeopaths] don't feel the science would be useful … we'd love to see efficacy studies, because, you know, we're open. But because we've seen them [the homeopathic remedies] work ourselves, we can work without the science necessarily having to be there.

For the homeopaths, the efficacy of homeopathy was already proven, based on the personal experience of healing in themselves or others:

> When a remedy has been shown to work at least once, then the "homeopathy does not work" [myth] is already smashed. So now, the questions become: To what extent does it work? How is it best used? Etcetera (Olive).

In all my interviews with homeopaths, what emerged most strongly was their emphasis on practical experience for determining "efficacy," or, as it was even more strongly framed by several homeopaths, "reality." Candy explained:

> By nature, I am very adventurous. I take my own stuff. For many products, I have bought them, taken them, given them to family… so I see the reality …
>
> Science is not the reality of healing, the experience of giving, to a person and seeing the healing… therefore scientists do not understand products…. [In the] Directorate, the chemists, masters, and PhDs outnumber the practitioners. The former types deal with what they understand to be the nature of the product – they have the materials, looking at the toxicology, the quality. But they do not have the reality of a human who has been healed. Not clinical trials, not adverse reactions, but healed, in health, healed. That is the difference between a paper review and an actual understanding.
>
> I'm happy we [at the NHPD] have lots of practitioners. How do you explain to a scientist[23] how to balance chi, pitta? [laughs]. This is the clinical effect versus efficacy.

The homeopaths all believed clinical experience was a "huge asset" in the regulatory assessment of homeopathic medicines. Candy felt that other scientists could be trained to understand homeopathic medicines, but she hedged that it took homeopaths three years in school after a bachelor's degree to get their knowledge. While Olive felt that naturopaths, because of their training in homeopathy, have some understanding of the homeopathic paradigm, Saffron opined that even a naturopath would be inappropriate for the unit, because of the importance of "day after day after day after day of seeing" the workings of homeopathy. Regardless of their views on appropriate training, I believe it is safe to say that for these homeopath evaluators, efficacy was inseparable from "reality," the experience of healing, when they were asked their personal views. One homeopath, Wendy, when asked what she brought to the NHPD, replied:

> I can offer an objective perspective when people ask about homeopathy, by saying “this is how it works” and “*this is how it is*”; so I can bring caring for the community.

In sum, in interviews, the homeopaths expressed utter conviction in the efficacy of homeopathy, with the overriding efficacy being experienced clinical effect (as opposed to randomized clinical trials).

Homeopaths’ conviction did not necessarily extend to products in applications

Even though the assessment of homeopathic medicines was conducted by homeopaths with clinical experience and who expressed conviction that homeopathy “worked”, in many ways the homeopathic preparations proposed in Product Licence Application forms did not correspond to the homeopaths’ practice of, and experience with, homeopathy. As Candy explained, it “is sometimes difficult working here because we’re reviewing products that kind of go against the way we’ve been trained.” For instance, while I was observing one homeopath at work, she opened a file with a Product Licence Application, looked at the contents, and sighed, telling me:

> Ugh. Here, it is a combo remedy, and they are putting in an antidote to other remedies. In part, it is a European approach. In part, it is just the company making up its own approaches – and they just have to provide an explanation or rationale.

In other words, this homeopath had to assess whether a company’s combination remedy met the NHPD’s regulatory requirements, even though she claimed she would never use such a product in her practice. Indeed, when it came to assessing homeopathic medicines with claims, it was rare that these practicing homeopaths’

beliefs regarding homeopathy aligned with the proposed product, because of the population-based nature of product claims. Most homeopaths believed that a homeopathic remedy should be carefully selected for the individual patient, whereas label claims declare the medicine's use for any patient (which made little sense in the homeopathic paradigm). (But note that several homeopaths in the unit were advocates for the use of homeopathic preparations in first aid situations, situations in which the preparation is not tailored to the individual patient).[24] Therefore these homeopaths largely understood their clinical experience to enter the NHPD's scientific assessment of homeopathic medicines only in terms of general "understanding"; their clinical experience was not written into the Safety and Efficacy Assessment Report directly. In many cases homeopath's expressed convictions regarding the efficacy of homeopathic medicine in practice was entirely irrelevant to the evaluation of homeopathic medicines with generic health claims.

The opinions of non-homeopath scientists regarding homeopathy

In interviews, non-homeopath scientists expressed a range of convictions regarding homeopathy – that it works, that it does not work, that it sometimes works. These convictions were not always one-sided, as in the case of a scientist who ridiculed homeopathy because he found the mechanism of action unbelievable, but who was nevertheless convinced that a homeopathic remedy had cured him of an ailment.

Despite the range of expressed personal opinions on the subject of homeopathy's efficacy, vocalizing disbelief *in work settings* regarding homeopathy's efficacy was neither common nor consistent with etiquette in the Directorate. Outright and overt disbelief in the entire paradigm was interpreted by many scientists at the NHPD – homeopath or not, with a range of convictions regarding the efficacy of homeopathy – as a serious faux pas. (Many homeopaths appeared to additionally experience this as a personal affront). There was one story of such a *faux pas* that seemed to serve as a morality tale. When, in interviews, I stated my particular research interest in the evaluation of traditional and homeopathic medicines, several non-homeopath scientists recounted a saga that had happened prior to my fieldwork. The saga's plot goes:

> Once upon a time, there was an evaluator in the Clinical Trials Unit. She was assigned to evaluate an application for a clinical trial of a homeopathic medicine. She firmly believed that homeopathy had been scientifically proven not to work. So she marshaled that bastion of evidence-based medicine, the systematic review, to support her position that as a scientist she simply could not recommend any clinical trial of homeopathy, never mind the particular one sitting on her desk.
>
> All the systematic reviews in the world could not save her from her fate. She was promptly relieved of her duties evaluating that particular application and was not given any more files pertaining to homeopathic medicine to assess.

One of the scientists who recounted this event to me in interview, Violet, opined:

> Scientifically, I can see where she was coming from. I mean, she used Cochrane reviews & all that… But there are problems with systematic reviews, too.

While Violet could empathize with the assessing scientists' perspective, her account, and the accounts of other scientists, left me with the unambiguous impression that she believed the evaluator's reasoning was totally inappropriate within the Directorate. Louise was emphatic in her disapproval of the scientist making the faux pas:

> That's not what you do when you're at the NHPD. Being open-minded regardless of your own beliefs, is what you have to do. People leave prejudice at the door, right, basically.

That incident in the Clinical Trials Unit was not the only instance of homeopathy being discounted within the walls of the NHPD, at least according to the homeopaths. Several homeopaths were highly indignant about an incident in which a manager requested that a licensed homeopath not recommend treatments in the workplace. Saffron, one homeopath who recounted this story to me, interpreted this intervention as an indication of management's disbelief: "they [management] don't believe in what we're doing – because I mean it's okay for someone to come ask for a [conventional pain-relieving pill] but it's not okay to come and ask for something else." This homeopath also felt she had a moral obligation to help her workplace colleagues with first aid, within her scope of practice.[25] Other actions by management were likewise interpreted in terms of management's disbelief in the efficacy of homeopathy, such as one of the Director Generals' statement that certain health claims were "too strong for a homeopathic." These negative

relationships were apparently in the minority, however. Saffron estimated that in her experience interacting with non-homeopath scientists,

> 50% respected homeopathy, 40% tolerated it, and 10% disrespected it. Some people [scientists & managers] are right in tune; others smile and nod; and 10% say “that’s just not possible” or “snake oil.” And, for instance, one manager argued that homeopathy cannot change the physical properties of water; but at the same time stated that homeopathy works and heals people. So some disrespect is not intentional, they just do not understand.

The point that I would like to make is that, generally, neither homeopaths nor non-homeopaths seemed to fundamentally care about their colleagues’ *beliefs*. Essentially, these personal convictions were irrelevant to what was considered good assessment work at the NHPD. What *was* criticized, was bringing personal convictions into the workplace through actions, including through statements. Irrespective of personal beliefs, scientists and their managers were required to act as properly socialized participants in the assessment process.

Another way of understanding this requirement of proper socialization, is to say that scientists and their managers were required, in their work, to respect etiquette. Breach of etiquette was experienced by many as a sign of disrespect, and incorrect reasoning. I have given a negative example, that of the faux pas. Let me turn to two positive examples, of non-homeopath scientists commended by homeopath as well as non-homeopath peers, to further characterize the etiquette required of scientists and their managers.

Acting as if you believe

Olive, a homeopath, commended one manager's work with the Homeopathic Medicines Unit, stating he was "good with understanding" of homeopathy, because:

> *He acts as if he believes* it [homeopathy], and internalizes it. It is so nice that someone without training [in homeopathy] can think about it, talk intelligently about the issues; has made the effort. Especially from management. [emphasis added]

What was salient for Olive was not that this manager actually believed in the efficacy of homeopathy, but rather that he *acted as if* he believed. I argue that Olive's statement encapsulates the required etiquette, that obviated the importance of personal belief at the NHPD: one had to *act as if one believed*.

To flesh out this etiquette, I present several interview excerpts regarding the evaluations done by non-homeopath scientists in the Clinical Trials Unit.

Scientists *acting as if they believed* in the Clinical Trials Unit

> You definitely need to keep an open mind. Like I said, I come from a [laboratory science] background, so as you can imagine, the whole concept of homeopathy is very different from what I've been trained to believe. But regardless of that, I will assess a homeopathic medicine with the understanding that these things do in fact have an effect – how they have an effect is not really important. The point is that you have to respect all people, so I think that is the bottom line. (Louise)

Nearly all the scientists in the Clinical Trials Unit, whom I quote here (Ariella, Violet, and Louise), had strong backgrounds (e.g., doctorates) in a biomedically-relevant laboratory science. In individual interviews, one of these scientists described coming to believe in homeopathy, "because I've used it and it works," while another

was a committed skeptic. Regardless of their private opinions on the matter, however, a mandatory ethic of regulatory pragmatism appeared to pervade the Unit's work.

When I asked Ariella to tell me about a homeopathic trial, she responded:

> Well it was interesting, I mean because you don't think of homeopathics as needing clinical trials, but they do….

The interview continued, with my interjections in italic typeface:

> *Did anyone ever say, well, you can't do a clinical trial of homeopathy?*
>
> No. [laughs]
>
> *OK*
>
> I think … I don't… I've never heard that. I think that people realize that they have to be done. There has to be that … leap, you know. There's obviously design disadvantages, but it still has to be done….
>
> We're taking something that is very, very, well I don't know, personally, personally oriented: homeopathic medicine is based on individuals. So you're taking that out of the clinical setting and you're putting it into a clinical trial. So in a sense you're compromising some of the principles that a homeopathic practitioner would follow. But that was not really the main emphasis of our review.
>
> *OK*
>
> Because when it comes down to it, what we authorize is based on safety and efficacy [laughs squirmishly]. So. That's the goal.

While another scientist, Violet, had remarked that "some people say that you cannot have a clinical trial for homeopathy – the paradigm is just too different" precisely because of homeopathy's focus on the individual, Violet also argued that

there was still a need for clinical trials of homeopathic medicine, for instance to test higher potencies than had been documented in pharmacopoeia.

These evaluators clearly felt that part of their work in the evaluation of a clinical trial for homeopathy involved learning about "the paradigm of homeopathy," and running with that paradigm in their reasoning. These scientists explained that when felt they did not understand something, for instance the relevance of the homeopathic provings submitted with an application for a clinical trial, they consulted with one of the Directorate's homeopaths. In interview and in observation I got no sense of insurmountable barriers or conceptual incommensurabilities. The interviewees, instead, detailed additional considerations they needed to keep in mind in their assessment of trials of homeopathic medicines. One such consideration was the healing crisis in homeopathy:

> They [in homeopathy] have this thing called a "healing crisis." The idea is that before you get better you get worse. So you have to tell patients to hang in there, although it seems that you're getting worse for a week or two. (Violet)

> In homeopathic practice, a person can react to the homeopathic medicine but it's considered to be a *good* reaction, not an adverse reaction. It's called a healing crisis… That could be misinterpreted, you know, from a traditional clinical trial setting… We wanted to make sure the subjects would be aware of what a healing crisis was, and that it would not necessarily be an adverse reaction in a traditional sense. (Ariella)

These descriptions of the concept of a "healing crisis" were delivered very matter-of-factly. I never got the sense that these differences were anything but part of the regular, expected reasoning work of evaluators.

Following etiquette did not mean that one's disciplined desires disappeared. For instance, the desire of ex-laboratory scientists to discover mechanisms of action was articulated by Ariella in interview:

> It's tempting to make them [the applicants] include more things [when applying to conduct a clinical trial] that would be useful because not very much is known about, you know, not very much is known about the mechanisms of how these products act.
>
> But when it comes down to it, we don't have the authorization to do that [laughing]. So basically we have to stick to the protocol.
>
> Though it is tempting to try beyond what is, what is, uh [laughing squirmishly], recommended….

What was required of scientists – as competent assessment officers in the Directorate – was that they be able to temper or tame such disciplined desires through a disposition towards regulatory pragmatism, and to follow etiquette.

Difference as "real and do-able": regulatory pragmatism

Wendy, a homeopath, told me that before she arrived in the Directorate she was unable to imagine how she would go about her new work as a scientist evaluating homeopathic medicines:

> Originally, I asked, how is this job going to work? Assessing homeopathic files scientifically?

This imagination was no longer needed at the time of the interview:

> … and then, now I'm doing it. I feel a lot of the job is bringing up issues, which go [up the chain of command].

I found that a theoretical, hypothetical, or typical incommensurability of so-called logics of homeopathy and science (or biomedicine) were, to put it bluntly, irrelevant in the practice of assessment at the NHPD. Such incommensurability only occurred in instances prior to practice. In practice, differences became workable. (They had to be for the regulatory project to succeed). And differences became workable despite (or perhaps because of) the configuration of various medical 'paradigms.'

I suspect that the differences were "real and doable," to use the language of social studies of science scholar Helen Verran, for at least two reasons. The first: difference was not approached as an end in and of itself – as a philosophical or other boundary-making exercise. Rather, these scientists approached difference only *en route* to goals of their mundane (work) day. If this were a philosophical dissertation, I believe I would argue that this tangentiality to purpose is what made differences utterly workable, i.e. obviated theoretical incommensurability. To take but one other example from the social studies of science: that of Helen Verran's study of number in Nigeria's educational system (2001). Verran, who was interested in students' learning of number, had such difficulty writing of the partial differences in English and Yoruba approaches to number that she had to rewrite a book three times. In the published book, she explains that her student teachers and their students were uninterested in differences or boundaries between Yoruba and English number *per se,* although, in the successful math lessons, these students delighted in learning something new about number and playing with partial differences between ways of numbering. While some differences were real –

some elementary school students, for instance, mastered two ways of approaching division – Verran's student teachers laughed out loud at one of her initial drafts of the book, which essentially presented two types of number, English and Yoruba, as incommensurable. Because of this reaction, Verran found she could not maintain either of her original, 'fundamentalist' approaches to number: universalist and relativist. Verran argues that in her refusal to imagine an ultimate division between English and Yoruba logic, however, she did

> not want to imply that opportunities for choice and deliberation over logic do not exist…. It seems that my students [bilingual "student" teachers] made choices between banal routines; selections between and among what were little more than alternative, familiar sequences of gestures with hands, words, and stuff. Sometimes they deliberately joined the banal routines in innovative ways, and often the lessons that emerged when they did this were especially successful (2001:29)

The "familiar and banal experience" is what Verran felt was missed by her original two analyses of her fieldwork, analyses that she calls "foundational."[26]

"Familiar and banal experience," is exactly what I argue was going on among homeopath and non-homeopath scientists at the NHPD. The issue was not about belief in one system or another, or belief that two systems were parts of a whole, but rather about competence with the Directorate's etiquette and style of reasoning. There was little that could not be overcome with learning, with making reasoning about the safety and efficacy of homeopathic medicines into a "familiar and banal experience." One homeopath remarked of the Clinical Trial Unit's evaluators, that they "might have felt there were a lot of issues" with evaluating a clinical trial for homeopathy, "because they're not used to it." But, Olive continued,

“if they understand and are willing to work with the paradigm, all is fine.” And most scientists with whom I spoke were in fact eager to learn, stating that they enjoyed ‘learning new things,’ whether they considered these ‘new things’ science-based or not. Violet explained that “what I really like about the work is working and learning from all these people [practitioners] about these difficult things”; however, she then hedged “but on a personal level, everyone tries but succeeds to different extents.”

Verran found that schoolchildren were able to play with Yoruba and English logics of numbering, without any earth shattering outcomes of presumed incommensurability. This is consistent with my findings regarding the work of scientists and homeopaths in their evaluations of homeopathic medicines, pre-market. Shifts between logics (and their disciplined dispositions) did not go unnoticed. Verran remarks that students occasionally found the use of both logics funny. Mildly uncomfortable laughter – that sensation that Verran observes was indicative of such shifts for herself and among students – was also evident in my interviews with Ph.D. scientists evaluating homeopathic medicines, as in the interview with Ariela above.

Verran maintains her interest in the “generative tension” of difference – and again, I would specify that this tension is likely only generative when the difference is not approached as a end in and of itself – and explains how this generative difference “enabled connection as easily as it allowed separation, and presumably it allowed both in multiple ways” (Verran 2001:30). This contingent separation and connection

– providing the “possibilities for doing different” – is exactly what I observed officers at the NHPD doing in their assessment work. Well-respected officers (and the bilingual schoolchildren studied by Verran) were able to (partially) change “registers.” As Verran points out, this register-changing is not unique to bilinguals – monolinguals are similarly able to do so. But these separations and connections were neither idiosyncratic nor absolute. To take the case of the NHPD: there was a shared style of reasoning among scientific staff, which, in the case of homeopathic medicines, did require certain types of separations and connections, or to use another term, required changes in register to, for instance, recognizing the healing crisis. And both bilinguals and monolinguals, can change register inappropriately or badly. Indeed, some officer’s attempts to use a particular register (e.g., that of universalist systematic reviews) were clearly deemed inappropriate, as faux pas.

The second reason why I suspect difference in the Directorate was simultaneously “real and doable,” was the specific affective work expected of these scientists as public servants. As I have detailed, competent assessment officers had to *act as if they believed* in the paradigm of homeopathy (or, in the case of homeopaths, in the possibility of efficacious but non-individually prescribed homeopathic medicines) in their pre-market evaluations of homeopathic medicines. Although at first glance this is strikingly different than the case of the Nigerian schoolchildren and teachers, for whom belief was not at issue (how does one believe, or not, in numbers? One simply uses them or does not) – perhaps the difference is only superficial. I argue

that, likewise, for the assessment officers, belief was not really relevant to their work.

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1 From the NHPD's homepage, at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php , accessed March 16, 2009. Emphasis added.

2 1111 of the total 22,229 Product Licence Applications received and registered at the NHPD by August 16, 2007.

3 Unlike companies submitting applications for traditional medicines, most of the companies submitting applications for homeopathic medicines were based in Quebec and/ or were subsidiaries of European companies. This small market size is not unusual for North America. Homeopathic pharmacopoeia were also enshrined in a US American Act in 1938. When the US Food and Drug Administration (FDA) assessed the size of the market for homeopathic drugs after the second world war – and identified only five homeopathic pharmacies in the entire US (two in Los Angeles and three in the Bronx) – the FDA decided to omit homeopathics from its review of over-the-counter products (Peter Barton Hutt in Daemmrich et al. eds. 2007:140-141).

I suspect this option of ignoring homeopathic medicines would not be politically viable for a federal Canadian government directorate; in Canada, it was generally recognized that homeopathic medicines were more important in the province of Quebec (a province with separatist undercurrents, and with strong block representation federally) than they were in the rest of Canada.

4 According to an internal document (DIN_HM Transfer Project July 8, 2005; Record of Decision (DRAFT) with document listing last update as July 11, 2005) TPD's processing of homeopathic medicines was termed a "compliance project": "For the 1997 compliance project, led by TPD, an electronic application form on a diskette was used by the applicants to input their product information (typically attestation to HPUS for dilutions, etc.) 42 companies were involved. Each application only took a few minutes to complete for each product…. TPD evaluators were involved in the review of the information."

5 Although in all likelihood simply new "issues" will arise. Olive, when detailing the many issues that had been resolved over the first 3 or 4 years of the NHPD's operations, predicted:

> Maybe now will be a new round [of issues]. Now it is the definition … maybe we just need to create another paradigm/ unit for them [isopathy etc.]…
>
> Every one little thing been a "little thing" which can be complicated, because we need too ensure our decisions do not affect documents or decisions elsewhere.

Figuring out how to deal with issues without setting an undesired precedent, took time.

This is right out of Herzfeld's observations: "The concern with precedent, however, reveals the authorities' intense concern with creating a history that will ideally end by overwhelming itself – by, again, converting a temporal sequence into eternal fiat – and each act … draws on this underlying logic. The alternative is chaos." (1992: 165)

The Unit's thorough approach to solving these issues also meant that the Homeopathic Medicines Unit did not churn out licences at a quick rate for the first few years of operation. Of the 1111 Homeopathic Product Licence Applications received and registered, only 172 had been licenced, and 160 refused by August 16th, 2007. The numbers thereafter jumped, perhaps because of several focused "blitzes" during the time of my fieldwork. At least one of these blitzes was to "get the numbers cleaned up" for a meeting with the main lobby group for homeopathics, the CHPA, which, at the time, met with NHPD management twice yearly. One scientist explained, a blitz was held "because we [the NHPD] can only say we're short of resources for so long. The blitz helped get many IRNs [Information Request Notices, following initial assessments] out."

6 "Young" = no older than early forties.

7 The full names are: *Homeopathic Pharmacopoiea of the United States* (HPUS); *German Homeopathic Pharmacopoeia* (GHP) and the original German version; *Pharmacopee francaise* (PhF), *European Pharmacopoeia* (Ph.Eur.), and the *Encyclopedia of Homeopathic Pharmacopoeia* (EHP). The last one, the EHP, was added with the second version of the guidance document in November 2006 (Health Canada – NHPD 2006b). The original guidance document had also included the British pharmacopoeia.

8 The methods of preparation for homeopathic medicines often involve a process of serial dilution accompanied by vigorous shaking ('succussing') at each stage of dilution. In other words, to make a homeopathic medicine, one takes a starting material (say aloe), mixes it with diluent (water, sugar or alcohol) and vigorously shakes ('succusses') the mixture. One would then take a single drop of that mixture and place it in 10 or 100 drops of diluent and succuss; one would then take a single drop of that second, more dilute mixture and place it in 10 or 100 drops of diluent and succuss, so on, usually repeating this dilution process twelve to thirty times. Usually, but not always, there is no "material", i.e. quantifiable, amount of starting material like aloe in the final homeopathic product.

9 Refusing the whole lot – perhaps the simplest action – would not have melded with the Directorate's commitment to philosophical diversity and promoting consumers' freedom of choice. Although scientists ultimately decided that non-pharmacopoeial medicinal ingredients could not be assessed in the Homeopathic Assessment Stream, evaluators recognized that:

> these products would not do well in the non-traditional stream [the default assessment stream], because there is insufficient evidence. There are hundreds of files in this situation. (Candy)

10 The challenges experienced by the Homeopathic Medicines Unit were strikingly similar to those faced by the Traditional Medicines Unit; Candy's explanation of the "challenge" posed by isopathy in the Homeopathic Medicines Unit was nearly identical, word-for-word, to Ampan's explanation of the "challenge" posed by aromatherapy in the Traditional Medicines Unit (see Chapter 8). This is perhaps unsurprising for two reasons. One, these challenges arise because of the reliance on pharmacopoeial standards. Two, because "homeopathic medicine" and "traditional medicine" are defined in the NHPD's guidance documents rather than in the Regulations, which have the force of law. Therefore, industry can directly pressure the NHPD to change (usually widen) the definitions.

11 Upper management used the Unit as testing ground for several new assessment processes (blitzes, comparative approach, safety and efficacy assessment officers also doing quality assessment); presumably this was fostered by the isolation of the Homeopathic Medicines Unit and smaller, and well-defined, numbers of applications in this assessment stream.

12 Allersodes are made from substances which could induce the formation of antigens, for instance toxins, venins, proteins. Isodes are made from substances that are believed to have produced an imbalance in the body, and can be made from pharmaceutical drugs. Nosodes are made from pathology itself: from bacteria, parasites, viruses, and human excretions, secretions, pathological organs etc. For example, source of the medicinal ingredient could be "bacteria isolated from patients suffering from streptococcal diseases." A sarcode is prepared from healthy persons' organs, tissues etc.

13 Note that homeopathic medicines derived from radiopharmaceuticals (Schedule C of the Food and Drugs Act) or restricted narcotics (from Schedules 1-IV of the Controlled Drugs and Substances Act) were not considered licensable by the NHPD (GD 2006b: 52).

14 One scientist stated a medium-high potency is 200C.

15 Nosodes are made from pathology itself: from bacteria, parasites, viruses, and human excretions, secretions, pathological organs etc.

16 It seems that some applicants also tried to 'sneak' in medicines as homeopathic medicines, perhaps thinking there would less attention paid to the safety. For instance, while I was observing one officer, she had an application for a homeopathic medicine with a potency of D0: "I do not know what that means. If it is a tincture, then it might be acceptable in another [assessment] stream."

17 See the Regulatory Impact Analysis Statement in the *Canada Gazette II* (SOR2003/196):

> The NHPD's intention in including the margin of safety criterion in the proposed Regulations at CGI [Canada Gazette I] was to allow the Regulations to apply to those substances that can be safely used for self-care, i.e., products that can be selected and used by consumers without requiring practitioner intervention.

18 This division is documented in Section 1.3 of the NHPD's Guidance Document *Evidence for Homeopathic Medicines* (Health Canada – NHPD 2007a).

19 This was an artifact of the premarket assessment of homeopathic medicines being transferred to the NHPD, a Directorate originally intended to oversee only medicines intended for self-medication. The Directorate, however, did not want to unduly restrict market access to homeopathic medicines prescribed by homeopaths (remember, the practice of any healing art is under provincial jurisdiction) and thus needed to provide some pre-market clearance for homeopathic remedies that are used in homeopathic practice.

20 This labeling standard emerged after my fieldwork, with the standard dated November 26, 2007 (Health Canada – NHPD 2007b).

21 Such qualifiers were made mandatory by the Director General during the time of my fieldwork.

22 Of the homeopathic pharmacopoeias, I was told that only the EHP contains claims.

23 Candy's last statement of course elides the fact that she is hired as scientific staff herself; of course, identifying as a scientist is another matter entirely. I remember PhDs, unsurprisingly, explicitly identifying themselves as scientists, along with a few other non-practitioners. In terms of social groupings at the NHPD, it is safe to say that many health care practitioners tended to self-assort, separately from other scientists. This was so much the case that several non-practitioner scientists thought I was a health care practitioner, because, I assume, I occasionally lunched with practitioners, or because perhaps the scientists registered the "other" of the anthropologist as a more typical "other", a health care practitioner.

24 A clear exception to the emphasis on the importance of tailoring treatment to the individual, for nearly all these homeopaths, was the use of homeopathic remedies for first aid. The homeopaths' conviction on this matter (as well as my & my non-homeopath colleagues' subsequent experience) was persuasive. (There are only two self-medication "natural remedies" that I have begun using because of my experience at the NHPD, and one is homeopathic first aid for wound healing. The other, likewise adopted because of the very strong conviction of several assessment officers, was the inclusion, into my previously vegetarian diet, of fish because of the remarkable (according to these scientists' convictions) health-conferring properties of the oils in fish).

25 Saffron also took issue with the manager's reported statement that helping was considered a conflict of interest: "I can understand someone not wanting you to recommend a specific product – but if you're not telling to go with certain product line, then…."

26 One, what Verran calls universalist, that assumed a fundamental unity of English and Yoruba number, and one, that she calls relativist, that assumed a fundamental division of English and Yoruba number. Both foundationalist approaches, she argues, assume that "the world, knowers, and knowledge are a priori separate and that these three given entities would feature in and constitute [her] explanation," without recognizing the three figures as tropes (2001: 34).

For very similar conclusions addressing the role of emotional dispositions – but on a more psychological, rather than sociological level – see an account of acupuncture and commensurability by Thagard and Zhu (2003).

Part IV. The Directorate's particular mandate and its scientists' everyday reasoning

Ah, they'll never, they'll never ever reach the moon,
at least not the one that we're after

> from Leonard Cohen's "Sing Another Song Boys," on the album *Songs of Love and Hate* (1970)

Chapter 10
Scientists' opinions on the science and cultural and philosophical diversity in their work

My original goal

I originally understood my research project to be to respond, via ethnographic description, to the puzzle of how a science-based organization would go about "respecting philosophical and cultural diversity," as described in the NHPD's mandate:

> « Through the Natural Health Products Directorate, Health Canada ensures that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.» [1]

I had understood this mandate as going to the core of key discussions in medical anthropology about the (in)commensurability of medical traditions. Gilbert Lewis' characterization of a paradox he encountered as a medical anthropologist and physician in another society was, I thought, going to be the paradox writ small in the NHPD, although the language that Lewis used nearly two decades ago is no longer the language of the day:

> We note cultural differences; we meet the relativity of points of view. Why should we apply our critical standards to their treatments? We expect certain standards of safety and effectiveness in treatment we might receive ourselves – should we ask for the same to be applied to the practice of

> alternative medicine? Or do we have double-standards – one lot for them, another for ourselves? (1993:190).[2]

Lewis' concern with the catch-22 – *one standard or a double-standard?* – while relevant to my research area, was and is part of a varied and larger discussion in medical anthropology (see Kleinman 1980, Pigg 2001, Adams et al. 2005) and anthropology as a whole (see Strathern 2004a, cf. Evans-Pritchard 1976) about how to make appropriate cross-cultural comparisons.[3]

Prior to my fieldwork, I had understood the NHPD's mandate as lying at the intersection of two important trends in medicine in Anglophone countries at the start of the twenty-first century: (1) the rise of evidence-based medicine, and (2) the increased mainstream recognition of traditional, alternative, natural, complementary medicines.[4][5] Despite the recognition of these two trends, this intersection, to me, was uncharted territory *by definition*: inherent in a mash-up of, on the one hand, a universalizing approach to knowledge epitomized by science and evidence-based medicine that argues "[t]here are no other ways of knowing" (CMAJ 2001:613; cf Verran's (2001) discussion of generalizing logics) and, on the other hand, the recognition of contextualized knowledge or "cultural and philosophical diversity." At the close of the 20th century, many Anglophone governments were creating high-level commissions, committees, centres, and reports tasked with investigating how to make "scientifically rigorous yet contextually sensitive'" decisions (from Jonas[6] 2002:39) and accomodate pluralism (Straus[7] 2003) in medicine and medical care.

There are at least two ways of approaching the incommensurability of medicines in this context. The first is philosophically. This approach is featured in many discussions within medical anthropology as well as beyond. There is a growing body of literature on the question of the application of evidence-based medicine (EBM) to complementary, alternative and traditional medicines (CAM), philosophically speaking (e.g., Borgerson 2005, Evans 2008). EBM is currently being applied to CAM, many authors have "rais[ed] questions about the suitability of the EBM approach" for alternative medicines – because evidence may "hing[e] on a very different notion of therapeutic efficacy" (Barry 2006:2657).[8] Often, philosophical approaches provide a prescriptive or normative answer to the question of whether, and how, traditions of medicines might be (in)commensurable (e.g., Thagard and Zhu 2003). Other researchers point to the incomplete advance of EBM *in practice*, explaining that the most trusted sources of information among patients was nearly an inversion of the EBM hierarchy (e.g., Verhoef *et al.* 2002), and noting difficulties in the actual application of EBM to state policy (e.g., Keshet 2009). This discussion, while interesting *theoretically*, has little place in an ethnographic account of scientists' reasoning in the NHPD. There is mention of the hierarchies of evidence-based medicine in the public representations of the NHPD, which could be analyzed rhetorically, but little mention of EBM in scientists' everyday work inside the Directorate.[9]

Because of the vastness and potentially unwieldy considerations in commensurability, the dissertation research was tailored to approach only the

literal meaning of commensurability. For two things to be commensurable in a literal sense they must be measurable by the same standard, both divisible by some quantity, or somehow be proportionate to each other. Conversely, two things are incommensurable if they are “not comparable in respect of magnitude,” “incapable of being measured (in comparison with),” or, in math, “having no common factor, integral or fractional” (*Oxford modern English dictionary* 1992.).

This project focussed on the use of measures in making medicines commensurable, documenting how various healing traditions were, or were not, made commensurable when a federal regulatory body evaluated the efficacy of medicines ‘while respecting cultural diversity.’ I had believed that to reconcile its two mandates, the Directorate’s scientists would have to: (1) find common measures for medicines from various medical traditions (configure commensurability), and (2) identify unique measures for medicines from various traditions (configure incommensurability). My central research objective was to investigate the development and use of these measures, and their implications for the tension between the commensurability and incommensurability of medicines. Because I assumed the reconciliation would feature measures with *numbers*, I had anticipated my research would be primarily focussed on methodological innovations in clinical studies’ statistical design.[10]

I was wrong.[11]

My attention to measures and methodological (statistical) innovation was misplaced. I found that while numerical standards were used in the assessment of quality, other textual standards characterized the evaluation of safety and efficacy as I explained in the section Textual Standards in Practice. I did not find any calculations that opened new worlds of comparison. (Except, of course, my eyes were unhappily opened to the particularly generic world of managerialism, with its counts of tasks completed, and measures used to reckon the organization's positioning in "the swamp" that was the backlog, as discussed in Part V.) In a regulatory agency like the NHPD, scientists can only assess what has been submitted by applicants. Minkah summed up the quandary as I had originally perceived it, and its pragmatic obviation in the regulatory context, in interview:

> And the only way that I can see … traditional medicines being unified is really having something that everyone can agree on, in terms of the criteria... and the only the thing that can really unify, that is the principle of scientific investigation. But that requires that you create, um, sort of, you know, methods and, um methods that are basically consistent with whatever that healing paradigm regards as being essential in demonstrating efficacy. You know.
>
> *Have you seen any files like that?*
>
> Any studies? Not in files, but in research ya, it is quite possible to do and there are many well-published studies that look at that.

It was not that the NHPD did not meet its mandate. It did. Rather than using statistical innovation to meet the mandate, the use of standards was paramount.[12] Where I expected statistical reasoning, I found reasoning through taxonomy and comparison. My examination of "respect for cultural diversity" followed the scientists' perception of this respect and therefore focused on the assessment of

traditional medicines in the Traditional Medicines Unit (Chapter 8); my examination of "respect for philosophical diversity" follows the scientists' perception of this respect and therefore focused on the assessment of homeopathic medicines in the Homeopathic Medicines Unit (Chapter 9). Conceptually, creating separate "healing paradigms" and organizational units devoted to those paradigms enabled an imaginary in which this respect for diversity could be localized in specific evaluation units, in separate forks of the algorithm.

In this logic, *efficacy* was consistency between the product (and its dosage, claims, and so on) with the documentary evidence supporting the medicines' use in a "paradigm." "You have to provide *evidence* that it [the medicine] will do what you are claiming to do *within that paradigm*," explained Robin Marles. As long as suitable, authoritative and pertinent references to traditional use were provided, scientific staff explained: "We're not questioning *efficacy*, because we're using reliable sources" (Ommy); "We just check the logic in that paradigm" (Tommy). Ampah stated that the Traditional Medicines Unit essentially takes appropriate documentation as a "barometer of efficacy"; there are no specific "measures," per se, he clarified, in response to my search for measures.

My ethnographic findings are an old story in a new context; Evans-Pritchard remarked that among the early 20th century Azande, apparent contradictions in beliefs regarding witchcraft were likewise non-problematic for Azande, for whom there was no need to acknowledge or register the contradictions because the

contradictions were segregated in different activities or spheres of life, or were explained away in “secondary elaborations” (1976). While the contradictions I investigated among scientists had little to do with beliefs, the same dynamics still held, regarding the apparent irrelevance of contradictions that were apparent to the anthropologist. While I heard NHPD management state in public presentations that if scientific evidence were to overwhelmingly contradict a traditional use, then this would be taken into consideration in assessment. But again, this was a theoretical, not practical, statement. Practically, given NHPD’s channelled and separated processes at the time of my fieldwork it was difficult to see how such a juxtaposition of “overwhelming scientific evidence” and traditional evidence would ever happen in the Traditional Assessment Stream, except perhaps as an ad hoc Issue. These scientists did not register the tensions of the catch-22 *one standard or double-standard?* or any contradiction *in practice* because of the segregation of activities into separate work units, procedural steps, or explained away the contradictions in pragmatic terms, or by making every element of the decision explicit (in the current culture of transparency and accountability) to the extent that the exact content became irrelevant. Textual Standards in Practice, focussing on scientists’ mundane work, explicated how the scientists did conduct science-based evaluations of traditional medicines while respecting philosophical and cultural diversity; this chapter describes scientists’ answers when I asked them individually in interview and in a survey, how the Directorate’s mandate to “respect cultural and philosophical diversity” came into play in their daily evaluation work.

Mandate operationalized, but not top-of-mind

Because reference to the NHPD's mandate was very rare in the mundane workaday world of scientists, I asked them in interview and a survey: *How does the NHPD's role in "respecting cultural and philosophical diversity" come into play in your work?* An important prefacing note is that many scientists looked at me rather like I was mad or a very dull child when I asked this question. Scientists' most common response to my interview question was a statement to the effect of Zahra's reply:

> It hasn't. But I've not worked in traditional or homeopathic medicines. In the non-traditional [assessment] stream, [it is] all science-based, so I have no experience.

In response to the survey question, more respondents answered "yes" than "no" (a few answered both yes and no) but the more frequent rationale offered in response to the survey question was a classic scientific rationale: "no, because science-based assessment is objective."

It is important that I explain not only what was *not* present in the fieldsite (the mandate in mundane work), but scientists' opinion regarding the dual mandate.

Science and paradigms

First, I must explain scientists' perception of the relationship between science and philosophical and cultural diversity. The premarket evaluation of traditional and homeopathic medicines (as defined by the NHPD) was seldom if ever

spontaneously characterized as science. The evaluation of these two categories of medicine was often described in counterpoint to science, if only implicitly, like in Zahra's response (above) to my interview question, and sometimes explicitly as "the other side," to use the words of another scientist in Non-Traditional Assessment (Abigail). Even a homeopath, Candy, said in passing: "we [homeopaths] have our evidence, but very little scientific evidence." The implication of many responses I received was: that the evaluation of homeopathic medicines had philosophical diversity, the evaluation of traditional medicines had cultural diversity, and the evaluation of other medicine types had science.

This opposition of *science* to *paradigms* was never clear in practice, always muddled. I will return to a discussion of scientists' opinions regarding science and respect for cultural diversity and of the muddle of practice below, but first, let me introduce a definition of biomedicine from the scholarly literature to help untangle it from other facets of science at the NHPD.

A sociohistorical definition of biomedicine

For analytical clarity, let me introduce a sociohistorical definition of biomedicine from the social studies of science perspective.[13] Biomedicine, according to Cambrosio *et al.* (2006), is "a material, institutional and epistemic configuration that cannot be reduced to medicine (the pathological) or biology (the normal)." Biomedicine, they argue, emerged in the middle of the twentieth century.

*Bio*medicine, to use the term technically, fundamentally intertwines clinical phenomena with biological processes investigated and quantified in the laboratory. Because of this fusion of the clinical and the laboratory, Keating and Cambrosio argue that biomedicine interacts with "not the [human] body per se, … but, rather, models of the body" (2003: 20), often quantifiable and biochemical. Following Canguilhem, they argue that the quantification of pathology and biology is, quite literally, what made the normal and the pathological commensurable: the defining characteristic of biomedicine (Keating and Cambrosio 2005).

Some premarket evaluation of medicines at Health Canada is fully consistent with this definition of biomedicine, its models of the body, and its styles of quantification. For instance the procedure for the pre-market evaluation of *novel* chemical medicines (new conventional pharmaceuticals), is resolutely biomedical. In the Therapeutic Products Directorate, an evaluator would likely never authorize a clinical trial of a *novel* chemical entity without: (1) reports detailing laboratory (in vitro and in animals) tests of the chemical entity, *and* (2) a *plausible biochemical mechanism* for the chemical's efficacy in humans. The randomized clinical trial required for market authorization plays a key role in biomedical approaches to efficacy; but a mandatory precursor to this clinical trial is a (conjectured) biochemical mechanism of action.[14] These randomized clinical trials are what many of NHPD's scientific staff referred to as science, as we will see below; however for clarity in analysis I will refer to them as biomedicine.

NHPD did not require plausible biochemical mechanisms of action

From a historical perspective, what was particularly striking in the NHPD's evaluation of medicines was its unmooring from the laboratory, its detachment from any plausible biochemical mechanism of action. Scientific management at the NHPD explicitly rejected using a biomedical (pharmacological) model as the basis for the evaluation of natural health products. In cases where a medicinal substance had a history of use in humans, there was no requirement for its laboratory testing *in vitro* or *in vivo*. Nor was a *plausible biochemical mechanism* for a medicine's efficacy required prior to authorizing a clinical trial or licencing a product for market. The models of the body with which scientists reasoned such as models involving pitta, chi, or vital energy were not always those used in biomedicine.

This rejection did not mean that biomedicine was altogether irrelevant in the NHPD's evaluation of medicines. There were many instances of evaluations fully consistent with the biomedical model, especially in the Non-Traditional Assessment Stream, but also, as I explained in Chapter 8, when the medicine was considered traditional, although scientists did not necessarily recognize it as such. (As I have explained, the *Pharmacopoeia of the People's Republic of China* is resolutely biomedical). Furthermore, for a wide variety of medicine types, companies often couched their applications in the language of biomedicine, even if NHPD scientists were not recommending licensing on the basis of explanations in that language. For instance, applicants flooded the Traditional Assessment Stream with purported biochemical mechanisms for traditional medicines, rather than providing scientists

with what they actually needed in the Traditional Assessment Stream: evidence of traditional use.

Even though traditional medicines and homeopathic medicine were treated as *paradigms* in the Directorate, there was an important difference between the relationship of traditional and homeopathic medicines to efficacy as generally operationalized in biomedicine. Even when scientists assumed the efficacy of traditional medicines to be uncertain, the medicine's (potential) efficacy could be rationalized through hypothesized biological mechanisms – the biological mechanisms could be treated as uncharted territory that would eventually be discovered with scientific progress. This was not the case for homeopathic medicines. I never heard a Directorate scientist justify the efficacy of homeopathic medications through a biochemical mechanism of action.[15] Nor did anyone within my hearing or sight imply, that future laboratory research would elucidate such mechanisms. In these senses, homeopathy at the NHPD truly constituted an alternative, rather than a complement, to biomedicine.[16] This is also why the evaluation of homeopathic medicines at the NHPD provided an opportunity to explore how scientists made science-based decisions while respecting philosophical diversity.

But is it science?

In interviews, I asked 20 NHPD scientists the purposely naïve question: *Is what you do as an assessment officer, science?*[17] In response, approximately half the scientists (11) stated that their assessment work *is* science, and the remainder (9) avoiding answering directly and instead argued their work is *science-based*. Regardless, most respondents (15) devoted much of their reply to my purposely naïve question to complexifying science by presenting me with definitions and typologies of science, or by discussing the relationship of scientific literature and methods to their work. I provide a thematic analysis of the responses here so that the relationships of science: non-traditional product assessment :: tradition: traditional product assessment, might be nuanced in the ways understood by the scientists themselves.

Of the 11 scientists who answered yes to my question of whether their assessment work is science, seven scientists provided an unambiguous yes. Most of these unambiguous yeses provided a rationale in line with Abigail's:

> It [assessment] is definitely science. It is a logical, reasoned interpretation of the data. It uses statistics to make a decision. It is well-written articles with certain standards to them.
>
> I'm talking about non-traditional assessment: there is a big difference between supporting something based from clinical data and based on traditional data… the clinical trials are the science.[18]

For Abigail, assessment simultaneously *is* science because of its style of reasoning, and *uses* science in the form of clinical trial results.[19] An additional four respondents to this question initially answered the question with yes, but subsequently qualified that yes by stating that the work was "science-based" or by

otherwise complexifying science. Sharon stated that yes, assessment work was science, and in the same breath she declared her work to be “truly a science-based assessment” because assessment officers were required to include “probability values and statistical significance, and sample sizes” in their reports. Other scientists also stated the use of toxicological uncertainty factors and analysis of methodology and tests was science.

Of the many who did not answer my question with a yes or a no, at least three respondents used the distinction between *science* and *science-based* to effectively sidestep my question. “We review the scientific evidence, yes,” answered Hildegaard, and Noor provided the diplomatic “Well I think that the organization tries to have a science-based *approach*.” Reiko explained “I think we’re trying the hardest we can to ask for good science to be the evidence for the efficacy of these products. I think there are products supported by science – good science – but others I think sort of stretch the limits a bit.” Several respondents explored typologies of science. One assessment officer, Richard, began his answer by saying yes, but after a long explanation of how science could be divided into two categories, basic and applied, he realized that the NHPD did neither; he concluded that the ‘bottom line’ was: “we do not really do science, but look at scientific evidence.” (But, as the previous paragraph shows, many respondents felt that looking at scientific evidence made the work science.)

To give a better sense of the responses, here is Minkah's entire response to my question:

> [Assessment] is science; now there are various levels of science. Because not a lot of this [assessment] gets into the actual testing, I think it's a review of science, it's not actually/ I don't know, I guess for lack of a better word, it's not actually science in action,[20] but rather a review of it, you know, I suppose. But that being said, there are a lot of position papers and IASs [issue analysis summaries] that are written which would be comparable to what you would do in any scientific institution when you do a review of literature. So from that angle, yes, this is definitely science. From the point of view of um regulating products, it is science but it is more of a regulatory approach … as opposed to um, I guess an analysis of actual products, you know, in terms of the chemistry, phytochemistry and whatnot.

Although Minkah gave an unambiguous yes to my question, his response jives with the responses of the nine interviewees who did not provide an unambiguous yes or no:

> Partly. We're using scientific journals. But this is where it gets complicated... (Emmanuel)

> …What is scientific? Drug people think: randomized controlled trial. But we can see epidemiological studies as scientific evidence (Hildegaard)

> I don't know. Maybe it is a little bit of science, but it's mostly regulatory. It is based on science – it has to be – but it is a regulatory job… (Binta)

> I don't know. I guess it depends on how you define science ….I think there are scientific *aspects* to a lot of what we do, but whether it is pure science – I think it is really applied in a lot of cases …. There are *aspects* of science in assessment, but there is a lot of administrative work in assessment. There's a lot of sort of regulatory science, however you want to define that …. In [comparative assessment], I think there is very little science – the science is assumed based on the [standard]. The only science would be [identifying] misleading claims: being able to pick out misleading claims, based on having a background in science….You certainly wouldn't know "a statement to the effect of" if you didn't have a background in science. So – some of that is science. I think being comfortable and capable and using that language, that language of science – um. Whether it is actually science I don't know. (Naavah)

Seven respondents to the question spontaneously mentioned the assessment of traditional products, although none were in the unit that assessed those products. Five of those seven respondents said that they did not think what went on in traditional assessment was science – even if they were unsure whether regular assessment was. The other two respondents explained that the assessment of traditional products, while not *exactly* science, had parallels. Dorrie thought that when assessment officers read traditional pharmacopoeias for dosages the scientists were doing a "history-based science. But then they're also trying to check it [the application] against the evidence [to discover whether] there is some evidence in the science literature that [the traditional dosage] causes adverse effects." Robin Marles provided a diplomatic answer to my question:

> I would say the vast majority of what we do, is based on science, but there are areas where it is based on more a *rigorous* application of certain principles, in terms of research and documentation, with respect to other healing paradigms. So, we are not forcing homeopathic medicine to meet pharmacological standards of evidence. Nevertheless, in the review of the homeopathic medicine, you can expect there to be accurate documentation of rigorous quality control. So, there are scientific aspects to the assessment of every product, but we don't *limit* ourselves to the scientific information.

In sum: not all scientific staff members were sure that what they were doing *was* science, but those that were not sure conceded that assessment is *based on* science. I believe that had I asked a sample of scientific staff a comparably ridiculous question, *Is the work of assessment officers in evaluating traditional medicines, tradition?,* I would have received many generous, patient answers along the same lines that I received to my question of "Is what you do as an assessment officer, science?"[21] The responses would have been generated to humour the anthropologist, rather than address a pre-existing concern or everyday

reflection. Keeping in mind this lack of spontaneous discussion of the NHPD's mandate in scientists mundane work, let me turn to their responses on the second part of the mandate.

Back to the question: *How does the NHPD's role in "respecting cultural and philosophical diversity" come into play in <u>your</u> work?*

To return to the question I asked of nearly every NHPD scientist I interviewed: *how does respecting cultural and philosophical diversity come into play in **your** day-to-day work*?

Approximately half of scientists, in response to the question either in interview or in survey, said it did not come into play at all, because what they did was science-based. As Namir explained to me, "when it comes to philosophy and the cultural thing, I mean no matter where you are, the rock is still going to fall to the ground." Likewise, Buck replied:

> In day-to-day work – in non-traditional [assessment] – we do not really care about culture, or philosophy, we just need evidence. If we were in traditional [assessment], it would be different, but I think we're also a little behind with tradition, in terms of cultural and philosophical [diversity because the NHPD's definition is based on regionally-defined cultures…]

Carolyn wanted to be clear that scientists had to "be careful" when assessing isolates in the Non-Traditional Assessment Stream; scientists should not to look at the products as traditional:

> People try to portray [isolates] as traditional products, but when you really look: there is a higher dose, it is concentrated, an isolate – you cannot think of it that way, and have to be careful. Sometimes when I get a file I say – "Oh, I take that product! Oh, there's no evidence behind it!" So I stick to the science behind it. It is amazing what you find when you go back to the

> original research. Summaries, reviews and meta-analyses are not always accurate.

Many scientists, especially those with no experience in the evaluation of traditional medicines (as defined by the NHPD), linked "cultural diversity" to the evaluation of traditional medicines in particular. Nevertheless, not all scientists who had worked in the Traditional Medicines Unit linked the NHPD's mandate to the Traditional Assessment Stream. There was one such scientist, Molly, who I effectively forced to address the issue in our exchange following my generic interview question:

> [long pause]. It is a diverse work environment. There are many different people from different backgrounds.
>
> *[pause, waiting] In any other way?*
>
> No.
>
> *[pause, waiting] How about when doing traditional files?*
>
> Yes.
>
> I guess because of my previous training […] and exposure to all of that stuff it just wasn't – I just didn't really think about it. I just/ that's just what I do. I don't know. It doesn't seem [pause] different. Because you have to have a different way of thinking when you are assessing those files. You can't look at it from,
>
> I enjoy doing those files. I like assessing TCM [traditional Chinese medicine] files, I find it really interesting.
>
> *What is it about it?*
>
> Just the whole [pause] I guess it kind of shows you how new conventional medicine is, and how the conventional medical establishment thinks it is the be-all and end-all and then here are all these cultural healing systems that have existed for thousands and thousands of years. And that describe exactly the same thing you're talking about. From thousands of years ago, they prescribe these things to help make it better, and a lot of [the] time

> without side effects. So it is just a/ I don't know, I kind of understand that way of thinking, I guess. I always really enjoyed it, because it made sense.
>
> *I only asked about the traditional files because a lot of people have answered [the question about cultural diversity] by saying "oh maybe over on the traditional unit'"– it is always elsewhere.*
>
> Maybe if it were a new way of thinking for you – if you weren't used to seeing the terminology, or seeing the,
>
> Because it is a totally different culture in there, of medicine, because you know the words that are used are totally different from what we use. So in that sense, maybe it would/
>
> I can't remember what it was like when I first looked at TCM, it must have been really hard to wrap your head around. Now I find it easier. Simpler. There's black and white, hot and cold, ying and yang. Internalized.

Emma replied to my question with an unambiguous "definitely yes, it is very refreshing, actually" because

> For example, we do accept studies from all kinds of countries and journals that maybe other scientists would not consider as rigorous. And using different paradigms, you know, that sort of thing…

Scientists who did reply yes,[22] that respect for cultural and philosophical diversity did come into play in their work, were often as likely to mention diversity among colleagues as they were to mention the evaluation of traditional medicines.[23] In the survey responses, common rationales for yes were: because the view of traditional Chinese medicine is taken into account (9 replies), because people working at the NHPD are diverse (9 replies), because there are diverse ideas and this is a positive thing (4 replies), because assessment is 'objective' (3 replies).[24]

Justine initially worked through her interview reply in general NHPD terms: “Obviously in [the assessment of] TCM, but I do not understand Chinese.” She became sure her answer was yes when she continued, speaking of linguistic and cultural diversity among staff:

> I think so. In the review, we try to account for different traditions and paradigms.
>
> Actually I definitely think so. We even try to get [hire] people who can read articles in different languages. The group is really diverse in terms of gender and religion.
>
> So beyond the products, it is the way we do work: respect for diversity. Issues, if they arise, are **usually** dealt with. That is the other huge positive thing about the NHPD: I feel we can approach others and ask questions. I love that about the place. I’ve heard it is not like that elsewhere.

In his reply to my question, Richard summarized a recent radio discussion on tolerance (on the subject “Have we as Canadians become too tolerant for our own good?”) and then stated he felt he could “come to work, and to not feel any sort of discrimination, overt or subtle. Think of it. Not cultural or racial.” Malik also replied in terms of the diversity of scientists’ background:

> It is very obvious at the NHPD: scientists from India and Quebec and [either Mauritius or Maritimes (Atlantic Canada), tape unclear]. It is a real, real government atmosphere: we do not see one race, two races, but each individual person, from a different country, with a different race and background, and science background.
>
> The atmosphere is really distinctive at the NHPD. This is a typical Canadian environment. What is most important is that people have to adapt to work in diversity. Most are okay, one or two people could not work in this atmosphere. Most people are happy to work and anxious to do work.

Scientists’ replies in terms of the diversity of scientific staff did not always mean that the respondent agreed that respect for philosophical and cultural diversity was

relevant in his or her workaday world. Frank answered my question with a emphatic “no,” and then linked the diverse workforce to market forces, not respect for diversity:

> *No.*
>
> There are different people, but that does not make any difference.
>
> Everyone does that nowadays. Management says you have to have so many green and black heads, and hire so many First Nations. These things are going to change over time anyways because sooner [there will be] more mixing so [it will be] hard to differentiate.
>
> Why do you think customs, foods have changed over the last fifteen to twenty years? And in TV programming, the comedians etcetera? There are changes in the styles, gradual changes of how reality is, in movies. And all these changes are market-driven. A lot of the changes are market-driven.
>
> The same thing [is happening] with the workforce, based on availability, and population changes.
>
> Look at [fast-food chain for carnivores], bringing out the green stuff, the salads: market-driven. People get different exposure and try things out, develop a taste and then [get] hooked.
>
> If we were born in China we’d eat snake. You are where you grow.

For many scientists, the diversity of the NHPD’s scientific staff was unremarkable. As one scientist responded – and he was worried that his initial joking response about being “the token white guy” would be an identifying detail (it was not) –

> There is a lot of diversity, which is kind of cool, but [pause] I guess everywhere I’ve worked there is that kind of diversity, because half were from other countries, like China, Japan, the Middle East and stuff. So [pause] ya, you just deal with it. Ya. Not really something you think about so much. (Darren)[25]

Conclusions

Binta wished that she had more reason to respect cultural and philosophical diversity in her work:

> We're all divided [into units]. For instance for TCM and Indian medicine, specific people do that. I would like to explore much more.

Which leads me to my conclusion: to some extent, scientists' professed experience of "respect for cultural and philosophical diversity" coming into play in their everyday work – when there was any such experience – was experienced as a feature of organizational structure or specific work units, or of diversity among scientific staff. In their responses, some scientists distinguished organizational structure or processes from the diversity in staff; others felt that the diversity among staff was what allowed the NHPD to respect cultural and philosophical diversity in its evaluation of medicines. Of course, still other scientists redirected my line of questioning about the relevance of the NHPD's mandate. As Olive corrected what she thought was my misguided question:

> The whole point of the mandate is to respect *consumers' choice*. By the NHPD being here, it gives the option.
>
> Diversity within the NHPD has more to do with the mandate of the public service: being representative of the population.

Neither my interviews nor my survey was designed to provide a truly representative sample of scientific staff at the NHPD. The purpose of my sampling in interviews was to maximize the range of opinion by maximizing diversity among the scientists I interviewed – diversity in terms of scientific background, extent of formal education, organizational position, practitioner status, as well as personal factors that I had learned or inferred (age, birthplace, current family status and

responsibilities, attitude towards performance standards, and so on). The purpose of the voluntary survey was to document the range of scientists' birthplaces and languages, so I would not need to include a bland statement such as "the NHPD had a relatively diverse scientific workforce" which could mean different things to different readers. Given that I aimed to elicit the widest range of experiences and replies, my strategy was successful in the sense that scientists' answers of yes and no were split nearly 50-50. (And unsuccessful, in the sense that as Richard remarked in interview: "I do not understand how you're going to take everyone's opinions [in interviews] into account.") I have included this analysis of the scientists' diverse replies to two structured research questions for three reasons. First, for the record – like much of the detail in this ethnographic account, I include scientists' responses because access into the community of regulatory scientists in the premarket evaluation is limited, and because unless the researcher is known personally, I suspect scientists' responses (if one could get responses from multiple scientists) would likely be entirely the generic, cautious statements of public relations. One of the original purposes of ethnography – to provide description and detail to those who could not visit a community – still has its place; even though global travel is in some ways easier now than a century prior, this glosses over the fact that there are many communities with such strong insider-outsider distinctions that it is not always possible to gain entrance. (This entry is a distinguishing feature of several notable medical anthropologists' works, for instance those of Petryna (2002) and Young (1995a).) Second, the variety of opinion expressed in interview makes the striking uniformity in scientists' reasoning in the practice of the pre-

market evaluation of medicines the more striking. Third, because, despite the nearly 50-50 split in yes or no responses, there were only a limited number of themes in scientists' rationales. Notably, three quarters of the scientists to whom I asked the question, *Is what you do as assessment officer, science?* replied by complexifying science, drawing from conventional as well as idiosyncratic distinctions among facets of science. With respect to the question pertaining to philosophical and cultural diversity, there were three main themes in scientists' replies:

> (1) No: assessment is objective and therefore respect for cultural diversity does not come into play
>
> (2) Yes, and: respect for cultural and philosophical diversity is synonymous with either: 1. traditional Chinese medicine, or 2. the Traditional and Homeopathic Assessment Streams, *by scientists not working in those assessment streams;*
>
> (3) Yes: because of the diversity of the scientific workforce at the NHPD.

From the perspective of many assessment officers, whether their daily work was science or involved "respect for cultural and philosophical diversity" – was not self-evident.

Nevertheless, the mandate was key for those outside the Directorate. One manager stated:

> We heard many times from stakeholders during the consultations and info sessions their concern that, with changes in personnel at NHPD, core values such as respect for cultural and philosophical diversity in health care choices might be diluted, misdirected, or lost.[26]

At the time of my fieldwork, the particular interpretation of respect for cultural and philosophical diversity was anchored in key algorithmic standards and key personnel; as stable as anything in government, I suppose, until, of course, the texts get lost on the shared N:/ drive, and the key staff leave the NHPD.[27]

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[1] From the NHPD's homepage, at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php , accessed March 16th, 2009. Emphasis added.

[2] Margaret Lock and Mark Nichter (2002) and Marina Roseman (2002) date the interest in medical anthropologists' interest in medical pluralism to the 1970s, captured in 1976 with the publication of Charles Leslie's edited *Asian Medical Systems* and Arthur Kleinman *et al.*'s *Medicine in Chinese cultures: Comparative Studies of Health Care in Chinese and Other Societies*.

[3] Although, I should note, the subtext in these discussions is often how to *avoid* making *inappropriate* comparisons or contrasts, which is not quite the same thing as a discussion of appropriateness.

[4] Evidence-based medicine is a movement that gained prominence through the 1980s and 1990s (see Cochrane 1971 for the movement's central reference, and Daly 2005 for a history of the movement). Publications containing the phrase 'evidence-based medicine' have increased almost exponentially since a 1992 article using the term in the medical journal *JAMA* (see Weisz 2005: 382). Evidence-based medicine is embraced by regulators (if not clinicians) as an instrument for scientific and impartial regulation (e.g., Marles 2003, WHO 2005). The movement privileges quantitative methods in the evaluation of medicines and health services, and arranges types of evidence supporting efficacy in a hierarchy (see Hunt 1997 for a history; for analyses by social scientists of controversies over the quantitative evaluation of medicines see Richards 1988, Epstein 1997, 2004, Healy 1997, Hess 1999). An example of this hierarchy is below in Figure 10-1:

Figure 10-1: " Strength of Evidence Grading System" taken from Health Canada's *Evidence for Safety and Efficacy of Finished Natural Health Products* (2003: 29).

Levels of Evidence	Type of Evidence from Human Studies
I	Well-designed systematic reviews and meta-analyses of randomized controlled trials or other clinical trials, or at least one well-designed randomized controlled trial (preferably multicentred)
II	Well-designed clinical trials without randomization and/or control groups
III	Well-designed descriptive and observational studies, such as correlational studies, cohort studies and case-control studies
IV	Peer-reviewed published articles, conclusions of other reputable regulatory agencies or previous marketing experience, expert opinion reports.
V	References to a traditional use

([5] continued from above) At the time I prepared for my fieldwork (2006), the anthropology of evidence-based medicine was in its inception, invoked in articles as context (Adams 2005) or as an interesting locus for future anthropological work (Rock 2005, Lambert forthcoming).

Complementary and alternative medicine
Simultaneously, "complementary and alternative medicine" (CAM) has been increasingly addressed by national and international regulatory bodies, because of a perception of increased use (e.g., Eisenberg et al. 1993, 1998, 2001; WHO 2005:iii). In many cases these regulatory bodies frame their programs addressing CAM as part of the institution's recognition of "traditional medicine" or medical pluralism. For anthropological perspectives through the past two decades see: Unschuld 1980, Lock 1990, Sharma 1993, Adler 2002, Baer 2002, 2005, Micozzi *et al.* 2002 as well as the rest of that issue of *Medical Anthropology Quarterly*. For regulatory situations in various countries, for Canada see Volpe 1998; for UK see Mills 2001, Smallwood 2005; for US see M. Miles 1998, Jonas 2002, Sheehan and Brenton eds 2002, Straus 2003, Gordon 2004, Meenan and Vuckovic 2004. This institutional recognition of medical pluralism should be kept distinct from the long-history of de facto medical pluralism in Anglophone countries (for Canada see Crellin et al. eds 1997, Crellin 2004; for US see Starr 1982, Goldstein 2004).

An outcome of these two concurrent trends in biomedicine is that "evidence-based medicine" is increasingly used to evaluate complementary and alternative medicine (e.g., Smallwood 2005), as well as traditional, alternative, natural, complementary, integrative, or ethno- medicines (Marles 2003, Liu 2004, Borgerson 2005, WHO 2005, Barry 2006). But how to make these medicines commensurable? What exactly is to be taken as evidence and measured? How will the measuring proceed? Who gets to make these decisions? The stakes may be high in some cases, as entire medical traditions (and their practitioners) may be on trial in the quantitative evaluation of a medicine (cf. Adams et al. 2005).

Although these were guiding ideas in my proposal, neither evidence-based medicine nor multiculturalism provided the overriding political motivation for the creation of the Natural Health Products Directorate nor its particular mandate, at least if my research into their creation is any indication.

[6] Joseph J. Jacobs was the first Director (non-acting) of the Office of Alternative Medicine in the US, in his post from 1992-1994.

[7] Stephen E. Straus was the first Director (non-acting) of the US National Center on Complementary and Alternative Medicine (NCCAM), in his post from 1999.

[8] e.g., Smallwood 2005, Liu 2004, Gagnier *et al.* 2006, Linde & Willich 2003, Kelner *et al.* 2004a,b.

[9] For discussions of EBM and alternative medicine by a rhetorician, see Derkatch 2008, 2005.

[10] In preparation for my fieldwork, I took graduate-level courses on statistical methods, including analyzing clinical trials, and clinical trials of alternative and complementary medicines. I perused journals for methodological innovations in studies of traditional medicines. I attended a two-day workshop on systematic reviews of natural health products; I attended multiple science- and social science-based conferences and symposia that might shed light on the ways in which scientific approaches to traditional medicines were tailored to understandings of health, the body, and healing in the tradition or system of medicine. While this was a useful educational experience, and gave me a certain proficiency as assessment officer at the NHPD and confidence for my anthropological fieldwork (and I did not have to spend fieldwork time learning the science 'lingo,' only the government 'lingo') – these training activities turned out to be largely irrelevant for my anthropological fieldwork at the NHPD. While methodological processes such as n-of-1 trials (see Hart and Sutton 2003, Kravitz et al. 2008) were touted by NHPD officials in public fora as research strategies that might respect the individual focus of certain healing paradigms, they were irrelevant in mundane practice – for regulators to see such innovations, applicants would have to submit them for evaluation.

[11] There are at least two reasons why it is important to showcase my original research objectives and my failure to achieve them. First of all, methodologically speaking, it is important to point out what I was looking for and did not find (numbers of science), and what I was not looking for but that it is important for me to write about in this ethnography because it was so important to the community studied (numbers of management). Second, this anthropological approach to number now joins other research projects in anthropology that – in general, and this is the most important point – have failed to find or follow the numbers in question (Adams 2005, Kohrman 2003, Lock 1998, Rock 2005). I had envisaged this difficulty before setting out to do my research, noting that, based on this previous work in anthropology, there was an extent to which medical statistics may be unapproachable – not in a 'black box' or 'forbidding' sense, but in the sense that as one approaches the numbers they are no longer there; in looking closely at number, one slips to the other side of the looking glass. This observation will be explored in more detail in the next chapter.

[12] Had I properly listened to my supervisor's suggestion that I expand my research objectives from measures and statistical techniques to standards and procedures as well – my expectations might have been more properly re-oriented. My many thanks to my supervisor for suggesting I write "standards" into my research objectives in addition to my original "numbers." More than ten years of supervision and never incorrect.

[13] For an introduction to the social studies of science perspective, see Golinski.

[14] The clinical trial itself lies at the intersection of at least three sources of expertise in recent medicine, as identified by historians and social scientists: (1) The clinician (prestige of healing experience), (2) The bacteriologist (prestige of laboratory), and 3. The statistician (prestige of quantification) (e.g., Matthews 1995; see also Young 1995).

[15] I did inquire whether the action of homeopathic medicines was discussed in terms of "vital force" (as an alternative to biomedical mechanisms of action). Candy noted that scientists in the Homeopathic Medicines Unit did speak of patients' strength or force "however you want to perceive it" in discussions:

> The point of homeopathy is to stimulate the vital force, and so in discussions it come up in terms of how we as homeopaths see the administration of a product. It is rare to see the term used by companies. Some companies talk about strengthening force, but not vital force.

[16] Theoretically, there are many ways in which homeopathy could be considered utterly separate from biomedicine; here, I derive this distinction from the Directorate's policy decisions and activities.

With respect to homeopathy, with the clinical decoupled from the laboratory, we are no longer technically speaking of biomedicine. But that does not mean we can no longer speak of (medical) science, as Saffron pointed out.

[17] When the scientist was not currently an assessment officer, I asked a variation of the question. Example variant questions were: *Do you think that the work that you did as an assessment officer was science?; Do you think the work you do in product licencing/ assessment is science?*

[18] Two respondents in this category explained that assessment was science "because we require clinical trials or evidence from journals" (Miel's words). Two others felt that the decision processes had a science to them because they involved risk management (Emma) and the precautionary principle (Amélie). Two other scientists responding with an unambiguous yes, gave other reasons. Carolyn stated that what assessment officers do is science because "anything else is emotion" especially in the context of alternative medicines. Namir answered yes "because the science does not change depending on who is doing the assessment."

[19] See also Lim 2007 for a similar perspective from a reviewer in Health Canada's Therapeutic Products Directorate.

[20] To my knowledge, none of my interviewees were familiar with the discipline of the social studies of science or the work of Bruno Latour; given that I spent a year with the group, I suspect familiarity with the discipline would have been mentioned in conversation at some point.

[21] I suspect some would have replied that their work was "tradition" in the sense that the scientists respected previous decisions, as well as the traditional healing paradigm, and have to analyze interactions in complex mixtures according to this paradigm, while others would have replied that the assessment was at least *based* on tradition, or "the tradition of the scientific method." I suspect there would have been an additional, substantial contingent who argued 'no', because the assessment was not in the context of a traditional healer-patient relationship, and that it incorporated several elements from the scientific literature.

[22]Half the respondents in interview said the mandate did come into play; roughly 70 percent of those who answered the question in the survey said the mandate did come into play (some answered both yes and no.)

[23] Similar considerations were evident in one scientists' 'no' answer: "No. My unit is not culturally diverse at all. I have not had a file that is culturally diverse" (Patti).

[24] There were also a few considerations mentioned only once or twice in the 'yes' answers: because both English and French languages were respected (survey response #12); because [a third] language helped with networking in government (survey response #36); because the industry is worldwide (survey responses #5, #20); and because "we have to allow the doctors their good clinical practice, like not to overstep the bounds, stepping on their professional image" (interview, with scientist in Clinical Trials Unit).

[25] That scientist was more concerned about the predominance of women scientists and its effect on lunchtime discussion topics: "You really have to watch like in the lunchroom too sometimes, because the conversation veers off into lace … and you don't necessarily want to be a guy at a table in here."

[26] From an internal NHPD e-mail dated 1/07/2006 with subject "Traditional Risk Information." The correspondence was forwarded to me in 2007 for the purposes of my research.

[27] What is interesting here is how "key stakeholders" (industry lobby groups) are concerned about staff turnover; which again leads to the question of why the constant high turnover, discussed in Chapter 17.

Chapter 11
And where is multiculturalism?

Multiculturalism, missing in action

One of my research objectives was to explore how the NHPD came to its mandate to respect "cultural diversity," and also how "cultural diversity" and "multiculturalism" were manifest in everyday activities in the Directorate. To my surprise, neither "respect for cultural diversity" nor "multiculturalism" was mentioned during everyday activities in the Directorate. Chapter 10 explored scientists' opinions regarding cultural diversity in their everyday work, expressed in direct response to my interview question on the subject. The only time I remember the use of the term "multiculturalism," was when an interviewee used the term to paraphrase what he saw as my interests, and then move on to what was of importance to him: the personal attributes generally expected in a Canadian bureaucracy versus those expected in hierarchical organizations in another country. My anthropological object was missing in action.

There are two other terms used at the NHPD that I think obviated any use of the term "multiculturalism" among staff. The first is "fairness," central to moral reasoning in the Canadian public service as a whole.[1] Although issues of fairness were discussed regularly in work meetings and lunch and watercooler discussions, these discussions were never hypothetical, but very concrete regarding at least one named entity (e.g., culture, healing paradigm, person), in a specific context. For example, evaluators wanted to make sure they did not give an advantage to

homeopathic companies versus other companies, or to hold the lack of English or French skills against applicants based in China. It is difficult to imagine how multiculturalism could be used in such concrete terms, as it describes a possible structure of relationships among cultures, not actual instances of relationships. The second term was "access," within the NHPD's mandate along with respect for freedom of choice:

> Through the Natural Health Products Directorate, Health Canada ensures that *all Canadians have ready access* to natural health products that are safe, effective and of high quality, *while respecting freedom of choice* and philosophical and cultural diversity.

The fact that the term "multiculturalism" was not used is a strong argument for totally ignoring multiculturalism in this ethnographic analysis. Indeed, I strongly suggest to the reader without interest in Canada or multiculturalism per se to skip this chapter in its entirety. There are three reasons why I still feel compelled to address multiculturalism, however. The first is that the evaluation of natural health products has been justified on a *political* level as part of Canada's multiculturalism. Appeals to multiculturalism were made, especially by advocates for traditional Chinese medicines, in the hearings of the House of Commons' Standing Committee on Health's consideration of natural health products, for instance by Mr. Lin-Hoi Yu, chairman of the Canadian Chinese Herbal Professional and Merchants Association, who argued that any "[r]estriction of the use of herbs is against the principles of multiculturalism and the Charter of Rights and Freedoms in Canada" (testimony February 19, 1998). The second reason for my discussion of multiculturalism is because scientists' concern for fairness and access is arguably

part of an ethos of multiculturalism manifest at the NHPD, although it is not explicitly stated as such.[2] The third is pragmatic: if I do not discuss multiculturalism explicitly I believe readers might (perfectly reasonably) gloss my discussion of the NHPD's mandate as a discussion of multiculturalism. Because of the many general resonances of the mandate to Canadian policy of multiculturalism, is it important that I explicate the lack of apparent direct genealogical relationship between the policy of multiculturalism and the NHPD's mandate, as well as the extent to which scientists made no mention of multiculturalism in their daily work or in interview. The chapter is devoted to those projects.

Definitions and analyses of multiculturalism in Canada

Multiculturalism has played an important role in imaginaries of Canadian nationalist projects (cf Anderson 1991) for the past four decades. The term itself, "multiculturalism," dates to the 1960s.[3] The *Oxford English Dictionary* (2010) defines multiculturalism as: "The characteristics of a multicultural society; (also) the policy or process whereby the distinctive identities of the cultural groups within such a society are maintained or supported." In analyses of Canadian multiculturalism, many authors jump between discussing multiculturalism as: (1) an ideal, pertaining to social organization, (2) a de facto description of society and (3) a specific law or policy. Furthermore, given the vagueness of "culture," and the number of relationships that could be described with the prefix "multi-," it is no surprise that "multiculturalism" can be interpreted in many ways in each of those

three domains. The flexibility and polyvocality of multiculturalism is perhaps one of its greatest assets as an ideological tool of the state. Here, I am restricting my overview of multiculturalism to policy and law enacted by the Canadian federal government.

Canadian policy and law

The term "multicultural" is first found in the Canadian record in 1964, when, in his inaugral speech as senator, Paul Yuzyk advocated for the increased recognition of "third element" (ie. non-English, non-French) ethnic groups in Canada such as Ukranian-Canadians; he argued that, given this third element accounting for "almost one-third of the population, Canada has become multicultural in fact" (1964:12).[4] *Multiculturalism*, rather than simply the adjective *multicultural*, was proposed as an alternative to biculturalism by the Canadian Royal Commission on Bilingualism and Biculturalism; when the Commission subsequently used the term "multiculturalism" in a report in 1969, the term garnered wider readership.[5]

Political analysts link the emergence and uptake of multiculturalism to two things. First, to the term's usefulness in shifting attention away from biculturalism and independence movements in the province of Quebec. The federal government's focus did shift from "bilingualism and biculturalism" to "bilingualism and multiculturalism," and the province of Quebec has since contested this shift as well as the model of multiculturalism more broadly. Second, the 1960s saw the emerging discourses of human rights and postcolonial independence movements.

It was no longer politically possible for the government to ignore the quarter of Canadians of neither French nor English heritage.

Canada's official multiculturalism policy dates to 1971 when it was proclaimed by the federal government; governments in Australia and the European Union subsequently developed similar official policies. Through the 1970s, the policy of multiculturalism in Canada seems to have meant funds for cultural preservation; the policy was operationalized through federal grants for cultural community centres, language programs, and the "folk arts." Multiculturalism became enough of an organizing symbol to the federal state that the *Canadian Multiculturalism Act* was passed in 1988, declaring multiculturalism a "fundamental characteristic of Canadian society."[6]

Simultaneously, the federal government has pursued some work against discrimination based on ethnicity, birthplace, race, language, and religion under the rubric of its policy of multiculturalism. For example, the *Multiculturalism Act* states that the Minister of Multiculturalism may assist "ethno-cultural minority communities to conduct activities with a view to overcoming any discriminatory barrier and, in particular, discrimination based on race or national or ethnic origin" (5:1g). The federal government's anti-racism initiatives in the 1970s and 1980s are partially related to Canada's official policy of multiculturalism. The government established a point-based system for incoming immigrants in the 1970s in the *Immigration Act*, which did not explicitly favour immigrants from Europe and the US as did the prior

system of quotas based on country of origin, although as Li (2003) points out, the reason for this new system may have been related to concerns other than abolishing discrimination. Anti-discrimination clauses were included in the *Canadian Charter of Rights and Freedoms,* and several federal committees were formed through the 1980s to address racism, including a Race Relations Unit in 1982 (Warburton 2007).[7] In 1986, parliament passed an *Employment Equity Act*, stating employers may not deny employment for reasons unrelated to ability, and must correct workplace disadvantages for "visible minorities" as well as for women, Aboriginal people, and people with disabilities.[8]

Two-pronged policy in the **Act**

The multiculturalism policy, as outlined in section 3 of the *Multiculturalism Act*, is two-pronged. The first part addresses the preservation and enhancement of multiculturalism in society writ large; the second part addresses multiculturalism in federal institutions.[9] I hypothesize *how* each of these prongs of Canadian multiculturalism policy *could* apply to the NHPD's evaluation of medicine from many medical traditions. It is all conjecture – none of these arguments was "found" in my fieldwork site.

i. Multiculturalism as equal benefit of public health protection?

The *Multiculturalism Act* states that the Canadian government should: "ensure that all individuals receive equal treatment and equal protection under the law, while

respecting and valuing their diversity" (3:1e.) My theoretical excursion regarding the relevance of multiculturalism in the NHPD's evaluation focuses on this section of the *Act*, which mirrors a section of the *Charter*. Providing *equal*, but *different*, treatment is of course something that depends on perspective.

Therein lies an apparent historical conundrum of the federal department of health.[10] The original purpose of the Canadian federal drug patrol was to ensure that medicines were safe and did not have fraudulent claims. (The purpose is ostensibly largely the same today, although now the mandate is interpreted in the language of risk management, no longer absolute, cf. Hacking 1990.) By evaluating traditional medicines used by ethnocultural communities in Canada according to the same standards of for pharmaceutical drugs, the government would essentially prevent individuals from accessing medications from their cultural heritage, because many of these medications could never meet the standards for conventional pharmaceuticals due to prohibitive costs of clinical trials and new drug submissions for non-patentable products, unsuitability of non-chemical medications to the standardization required, incommensurable diagnoses, and so on. For many years, the government presumably used this rationale to ignore these medications – not evaluating them, but not ordering them off the market.[11] But by turning a blind eye to these medicines, individuals from certain "cultural communities" more prone to using medicines packaged in a non-English and non-French language are less protected by law, contrary to the *Multiculturalism Act*. There was also the de facto concern that companies could make claims for their product in a non-English, non-

French language that contravened Canadian law. The “problem” of traditional herbal medicines (read: traditional Chinese medicines) became the focus of expert advisory group after expert advisory group through the 1980s in the Health Protection Branch of the federal department of health as described in Chapter 3. The conundrum returned to: how to provide *equal*, but *different*, public health protection?

This conundrum was also the source of complaint by industry. David Bader, a non-Asian co-owner of an American-style natural health food store in Vancouver, complained that his company was subject to compliance action by the Health Protection Branch’s Inspectorate, whereas the Asian-style stores down the street with the same Chinese products of apparent concern to the Inspectorate were not subject to compliance action. Bosco’s complaint was rejected by the first human rights tribunal in 1996, but on the technical point that his business (Don Bosco Agencies Ltd.) could not have a race, and therefore it was not altogether within the jurisdiction of the *Canadian Human Rights Act* to comment.[12] Furthermore, although the tribunal found discrimation, they found the department had a defence of bona fide justification:

> The original tribunal found that, while the Department’s policy of not enforcing regulations against the Chinese ethnic community was based on assumptions, these assumptions were not unfounded. The Department’s assessment that there was a low risk when ethnic retailers were selling Chinese products was based on the assumption that ethnic retailers were selling only to their own community, and that consumers in the ethnic community were knowledgeable about the proper use of these products (Canadian Human Rights Commission 1998).

A review tribunal subsequently overturned that judgement, stating that the "impressionistic" evidence offered by the department was insufficient for a bona fide defence. The review tribunal also developed a "sufficiently direct and immediate" test for the relationship between discriminatory action against a corporation closely owned by an individual, reversing the previous decision regarding the scope of the tribunal's judgement. (In the review tribunal, the Canadian Human Rights Commission was also an appellant.) The review tribunal also made explicit links between herbal medicines and ethnicity, and public health protection:

> The original tribunal also failed to address evidence of the lack of good faith by the Health Protection Branch in its treatment of ethnic Chinese herbal products in general, and in particular of the herb dong quai. The evidence showed that many of the herbal products of ethnic Chinese importers and retailers contained injurious substances such as lead, arsenic, and codeine. In view of the serious health hazards in some of the Chinese herbal products, "it was difficult to ascribe to the policies and practices of [the Health Protection Branch] a sincerely held belief that those policies and practices were imposed in the interests of adequate enforcement of the Food and Drug Act and regulations." In adopting its so-called "low-risk" policy, the Health Protection Branch was not acting in the interests of the general public, including the ethnic Chinese community (ibid).

That review tribunal, in March 1998, ordered that Health Canada establish new policies, ones that would not have discriminatory effects on certain merchants because of their ethnicity. Bader was not awarded personal damages. Because of the significance of the remedies ordered, and the presumable link to making "natural health products" top of mind, I quote the remedies and orders of the review tribunal at length. It is notable that not one single government official mentioned this case to me; I believe most scientists were unaware of it, and I did not interview

policy analysts who may have been made aware of the issue as a political consideration. From the decision rendered March 11, 1998, from the Human Rights Tribunal:

> In this case discrimination as found by the original Tribunal and confirmed by the Review Tribunal has occurred in an agency of government which has a mandate to protect the health of the general public.
>
> Moreover our findings indicate that the mandate of the HPB [Health Protection Branch] was subject to, and was influenced by, pressure groups. There is also evidence of political pressure at higher levels and we have accepted that those pressures caused HPB to adopt policies and practices inconsistent with its mandate.
>
> For those reasons we are inclined to accept the broad remedies proposed by counsel for the Commission in the hope that they will provide guidance to the Department of Health and Welfare and HPB leading to the uniform enforcement of the Act and thereby achieving a level playing field and also for the protection and welfare of the general public….
>
> The Review Tribunal ORDERS that the Department of National Health and Welfare and more particularly, the Health Protection Branch, adopt, subscribe to and put in place the following policies, practices and measures, namely:
>
> 1. (a) Cease differentiating on the basis of prohibited grounds, that is to say, that it cease treating herb and botanical dealers, whether importer, distributor, wholesaler, merchant or retailer or all or any of the foregoing, differently according to their race, national or ethnic origin when enforcing compliance with the Food and Drug Act and Regulations;
>   (b) That is cease the unequal enforcement of the Food and Drug Act based on the ethnicity of importers and retailers in the herb and botanical health food industry;
>   (c) That it cease the unequal enforcement of the Food and Drug Act based on the so-called ethnicity of the product as between ethnic and non-ethnic or Western products; and
>   (d) That it cease unequal enforcement based on ethnicity of user or consumer of the product.
>
> 2. That the Minister cause to be carried out on a national scale a system review of its enforcement policies, practices and compliance strategies relating to herbs and botanicals in order to identify and eliminate unsound distinctions previously relied upon or which are based upon ethnicity of dealer, ethnicity of product, ethnicity of user/consumer, with

particular emphasis upon eliminating differential treatment between groups which have in the past been defined by Health Canada and HPB as Chinese, ethnic Chinese, traditional, Western herbal, Western health food and non-ethnic sectors of the herbal botanical industry.

3. (a) That Health Canada devise a racially neutral compliance enforcement strategy in order that prevailing distinctions by racial sector in the herbal and botanical industry be eliminated so as to achieve a level playing field for all participants in the industry.
(b) That Health Canada devise compliance strategies which are truly product oriented in as much as enforcement is related to the magnitude of the risk to human health, inherent in the product itself, regardless of its origin or the ethnicity of the dealer or consumer,
(c) That the compliance strategy of Health Canada as above noted, shall be national in scope and uniform in its application.
3. That Health Canada formulate and disseminate by Letter to Trade and by other means (following a review on a national scale as described in paragraph 2 above) within 90 days of this decision a clear cut written policy statement containing a commitment ot a uniform national approach to the regulation and enforcement of the Act and the regulations with regard to herbal and botanical products, irrespective of where sold or by whom imported … [13]

Although the decision was rendered on March 11, 1998, the hearings listed in the decision were from June 1996, November 1996, and March 1997. As mentioned in Chapter 3, the Standing Commission on Health was tasked with the examination of Natural Health Products in the fall of 1997.

On the heels of this period came the creation of the Office of Natural Health Products in 1999, in accordance with the recommendations of a Parliamentary committee, and accepted by the House of Commons. Any genealogical relationship between multiculturalism as instantiated in the decision of the human rights tribunal, and the Office of the Natural Health Products, likely happened at a level to which I did not find documentary evidence – or there was no such relationship. I suspect the proposal for natural health products fell on political or upper

managerial ears that needed a solution to many simultaneous “issues,” and for which a regulatory regime for natural health products might fit the bill. I do not know, nor will I ever know.

Rather than unambiguous change in interventions per se, there is a certain element of change in narrative, and attribution as evident in the new mandate (as likewise remarked in Chivens 2004.) While many medicine types were evaluated similarly before and after the creation of this Office, there are a few major differences.[14] One major difference is the fact that traditional Chinese and Ayurvedic medicines are evaluated against the pharmacopoeial standards of the People’s Republic of China and that of India, respectively. But again, to my knowledge, this was never really related to Canada’s official policy of multiculturalism, but rather bureaucratic ideas of expediency in an era of backlogs requiring “Smart Regulations.”[15] Another major difference was that any capacity to effectively monitor natural health products on the market from a laboratory perspective had been cut;[16] the effect of the pre-marketing endeavour outside the Directorate was therefore unclear and possibly impossible to determine. [17]

Multiculturalism as institutional requirement: as diversity among evaluators?

Diversity in the cultural background of employees is an institutional requirement for the NHPD for at least two reasons. The first is law; the second is credibility.

According to the *Employment Equity Act* and the *Multiculturalism Act*, federal governments must provide equal opportunities for employment and also correct any current barriers to employment for four groups, including visible minorities. At the time of the Standing Committee on Health's hearings in the 1990s, several public servant scientists had brought, or were continuing to bring, allegations of racism and systemic racism (most found to be substantiated) in the Health Protection Branch to human rights tribunals. At least one tribunal's found blatant as well as non-blatant racism, and issued of an edict requiring the Branch to take certain remedial affirmative action measures (see Al-Waqfi & Jain 2008 for a summary.)[18]

What is the relationship between these facets of law (*Employment Equity Act* and human rights tribunal edicts) and staffing at the NHPD? Again, I do not know – if there is one, that would be something that politically astute upper managers would know, and likely not mention to an anthropologist. In any event, it would be both too cynical and incorrect to imply that the NHPD was created to deal with previous systemic racism in the Health Protection Branch. The complaints involving systemic racism pertained to the promotion of visible minority scientists to management positions; not their employment in the first place.

Beyond its obligation to follow the law, the NHPD has an even more compelling institutional reason for a diverse workplace is especially: its credibility as an organization. As noted by a bureaucrat involved with the first committee

considering the regulation of traditional ethnic medicines in the 1980s (and also a bureaucrat mentioned in racism complaints):

> Many respondents ["stakeholders"] accept and recognize the importance of a certain amount of government control, but are willing to accept it only if herbalists are involved in its organization and application (Liston 1987:16).

NHPD's mandate, as a federal institution responsible for evaluating medicines while "respecting philosophical and cultural diversity," requires a polyglot, cosmopolitan scientific staff with expertise in various healing traditions. Whenever the authority of the Directorate was challenged, management would speak of these qualifications. It makes NHPD the poster-child institution for multiculturalism.

***

I do not want to mix these political imperatives with the warm, fuzzy kind of multiculturalism experienced by some staff. In many ways, the NHPD's evaluators expressed a success story regarding the warm-fuzzy kind of nationalizing multiculturalism worthy of a poster-child institution. Indeed, the NHPD – like many scientific bureaux in the more recent versions of Health Canada's Health Protection Branch – had a very diverse staff in terms of ethnicity, birthplace, and cultural background among scientific staff (and there were more women than men). In participant-observation and interviews, scientific staff reported being genuinely happy to learn from each other. One of the things that evaluators consistently answered unprompted by my interview question "what do you most like about your work," was that they enjoy learning from others: from those based in other scientific disciplines and healing paradigms, and with different backgrounds, perspectives,

and cultures. I do not believe this was contrived. This curiosity, openness and propensity for learning is perhaps cultivated in the enculturation process of the sciences. It may also be selected for by virtue of immigration to Canada. It is also consistent with the spirit of the *Multiculturalism Act.* I do not think many NHPD scientists were familiar with the *Multiculturalism Act*, had even ever looked at the *Act*, or possibly even knew of the existence of the *Act*; this despite their answers to my question about philosophical and cultural diversity were in tune with official Canadian government policy.

The NHPD's mandate is a curious nationalistic project, in spirit perhaps linkable to the state policy of multiculturalism, although this state policy has little or no direct relationship, genealogically speaking, to the main impetus for the formation of the Natural Health Products Directorate, as found in documentary traces. (The wording proposed in the NHPD's mandate comes from members of trade lobbies, as far as I have been able to determine).[19]

What is this nationalism? It is not about natural resources or indigenous knowledge. "Natural health products" are generally assumed to be largely imported, not indigenous to Canada. While the marketing of traditional medicines as both "modern" and "traditional," "natural" and "scientific" to a middle-class consumer "wanting the best of both worlds" is as present in Canada as Lock and Nichter review in other countries (2002:13),[20] in Canada this marketing is frequently unlinked to the traditional medicines of Canada's First Nations, Inuit and

Métis groups (cf. Miles 1998a, 1998b). It is not really clear whether licenced natural health products even gain support from the Canadian state, akin to what Kuo argues for East Asian medicines, which "seem to gain support from the states they are derived."[21] The Natural Health Products Directorate's interest was not directly linked with nationalistic projects related to health care provision (see, e.g., Brotherton 2003)[22] nor national herbal heritage[23] (see, e.g., Hayden 2003: As Cori Hayden found in Mexico, I found that private concerns and scientists sought out "public materials" as evidence of safety and efficacy, obviating charges of appropriation or bioprospecting. See also Greene 2004, Nigh 2002.)

The evidence on which the Directorate's scientists base their judgements of a medicine's safety and efficacy is often submitted by businesses. Unless a company makes an application to market a medicine as a commodity, there is no evaluation. Therefore, what is evaluated at the NHPD is what is important to the commodities market, not necessarily that which is important to any given medical tradition. Ewen, in response to my question about whether respect for different traditions of medicine came into play in his work as AO, stated:

> It is not relevant in my area because I do non-traditional assessment. I guess we respect the tradition of the scientific method.
>
> The NHPD is an interesting place, because traditions are respected up to a point, if they are well-documented. Although technically speaking they [applications] can have expert opinion reports, and testimony of elders, I have never heard of that actually happening.
>
> How many companies have *any* connection to cultures?
>
> [Pause: thinking]

> Perhaps in TCM [traditional Chinese medicine].
>
> [Pause: thinking]
>
> I mean look at [he names a heavily marketed product in Canada at the time, whose advertising and packaging featured a photo of an early 20th-century American Indian]: these are not Indians, but Europeans.

One could be cynical and state that the effect of the regulations is to respect "cultural and philosophical diversity" in terms of business practice, rather than medical tradition. On the other hand, such a cynic would not emphasize the centrality commerce has generally held in many traditions of medicine.

It seems that multiculturalism serves as formative if hazy *pre-idea*, to use Ludwik Fleck's (1979) terminology, for the mandate framing the NHPD scientists' activities in the pre-market evaluation of medicines.

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[1] The *Values and Ethics Code for the Public Service* lists four types of values: democratic, professional, ethical and people. The people values entail "[d]emonstrating respect, fairness and courtesy in their dealings with both citizens and fellow public servants" (Minister of Public Works and Services 2003:10)

[2] Warburton mentions that thirty years previously, in the mid-1970s, "although Canadians were not familiar with the policy [of multiculturalism, from 1971], there was fairly wide support for the multicultural notion of promoting and sharing Canada's cultural diversity" (2007:279); so it may be unremarkable for the word to not be used, but the notion remaining in full currency. My point in stating that my "object was missing in action" was that there was no explicit or clear, direct genealogical link between the NHPD's processes and official policies of multiculturalism.

[3] There is at least one use of *multiculturalism* that predates the 1960s, according to the *OED* (2010), which lists a 1957 use of multiculturalism as a "key to successful living" in New Mexico and Switzerland. Furthermore, the adjective *multicultural* appears to have a slightly longer international heritage than multiculturalism. The term's increased used is largely associated with its establishment in Canadian policy.

[4] The full sentence, to highlight that Yuzyk did not presume intragroup unity, is: “In reality Canada never was bicultural; the Indians and Eskimos have been with us throughout our history; the British group is multicultural – English, Scots, Irish, Welsh; and with the settling of other ethnic groups, which now make up almost one-third of the population, Canada has become multicultural in fact” (1964:12).

[5] This high-profile commission investigated the relationship of French and English Canada through the 1960s. There is a direct link to the senator, Paul Yuzyk, who used the term; he made several presentations to the Royal Commission, on the contributions of people of Ukranian origins to the creation of Canada.

[6] Wording taken from the Justice Canada website at http://laws.justice.gc.ca/eng/C-18.7/index.html ; accessed July 30th, 2010. See also the description of multiculturalism-in-action in Mackey’s description and analysis of the celebrations of the 125th anniversary of Canada’s formation of a nation state in 1992 (1997).

[7] Section 15: “(1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability. (2) Subsection (1) does not preclude any law, program or activity that has as its object the amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability; [….][Section 27:] This Charter shall be interpreted in a manner consistent with the preservation and enhancement of the multicultural heritage of Canadians.”

[8] According to the Act, “employment equity means more than treating persons in the same way but also requires special measures and the accommodation of differences.” The process is based on self-identification: ”Only those employees who identify themselves to an employer, or agree to be identified by an employer, as aboriginal peoples, members of visible minorities or persons with disabilities are to be counted as members of those designated groups for the purposes of implementing employment equity” (section 9(2)).

According to Li (2003:128-9), the term “visible minority” was brought into offical discourse in 1984 by Commissioner Rosalie S. Abella, and was subsequently included in the *Employment Equity Act*. (Li also outlines how Statistics Canada operationalized the category of visible minorities in the 1986 and subsequent censuses). Li argues that between 1971 and 1991, the percentage of Canadians of neither British nor French origins remained relatively stable at just over 25% --*but* this percentage was increasingly representative of those of non-European origins (2003:133).

[9] The complete “multiculturalism policy,” or section 3 of the *Canadian Multiculturalism Act*, is:

> (1) It is hereby declared to be the policy of the Government of Canada to
>
> (a) recognize and promote the understanding that multiculturalism reflects the cultural and racial diversity of Canadian society and acknowledges the freedom of all members of Canadian society to preserve, enhance and share their cultural heritage;
> (b) recognize and promote the understanding that multiculturalism is a fundamental characteristic of the Canadian heritage and identity and that it provides an invaluable resource in the shaping of Canada’s future;
> (c) promote the full and equitable participation of individuals and communities of all origins in the continuing evolution and shaping of all aspects of Canadian society and assist them in the elimination of any barrier to that participation;
> (d) recognize the existence of communities whose members share a common origin and their historic contribution to Canadian society, and enhance their development;
> (e) ensure that all individuals receive equal treatment and equal protection under the law, while respecting and valuing their diversity;
> (f) encourage and assist the social, cultural, economic and political institutions of Canada to be both respectful and inclusive of Canada’s multicultural character;
> (g) promote the understanding and creativity that arise from the interaction between individuals and communities of different origins;
> (h) foster the recognition and appreciation of the diverse cultures of Canadian society and promote the reflection and the evolving expressions of those cultures;
> (i) preserve and enhance the use of languages other than English and French, while strengthening the status and use of the official languages of Canada; and
> (j) advance multiculturalism throughout Canada in harmony with the national commitment to the official languages of Canada.
>
> (2) It is further declared to be the policy of the Government of Canada that all federal institutions shall
>
> (a) ensure that Canadians of all origins have an equal opportunity to obtain employment and advancement in those institutions;
> (b) promote policies, programs and practices that enhance the ability of individuals and communities of all origins to contribute to the continuing evolution of Canada;
> (c) promote policies, programs and practices that enhance the understanding of and respect for the diversity of the members of Canadian society;
> (d) collect statistical data in order to enable the development of policies, programs and practices that are sensitive and responsive to the multicultural reality of Canada;
> (e) make use, as appropriate, of the language skills and cultural understanding of individuals of all origins; and
> (f) generally, carry on their activities in a manner that is sensitive and responsive to the multicultural reality of Canada.

Taken from the Justice Canada website (see endnote 6 this chapter), July 30, 2010.

The *Canadian Multiculturalism Act* does not apply to governments in the Yukon or Indian bands (Warburton 2007:284).

[10] Young et al. provide a general formulation of the nationally-specific contradictions inherent in multicultural states' recognition of minority medical traditions:

> China's contradiction involves a desire to preserve cultural diversity while eliminating those 'backward tendencies' which work against the economic and social development of the country as a whole. Canada's contradiction is a slightly different one, involving a desire to preserve cultural diversity while maintaining an emphasis on equality of rights and responsibilities for all Canadians. Behind these differences in ideology, however, there is a more basic structural contradiction – namely, that cultural pluralism, while considered an asset as long as it is restricted to preserving unique cultural traditions, is nevertheless a threat to strong central government if interpreted to imply the power to set policy at the local level in areas such as health policy (1995:498).

[11] A less generous assumption is perhaps federal government officials simply did not care to protect the health of those using medications unconventional by British standards. Medicines from Asia were screened for narcotics until the 1950s and then occasionally contamination, but otherwise ignored until the late 1980s.

[12] The 1996 decision of the initial tribunal hearing *Bader v Department of National Health & Welfare* is available on the website of the Canadian Human Rights Tribunal. A summary is found in the Commission's 1996 *Annual Report* on the topic of case work, under the heading "Jurisdictional and procedural questions." (Accessed August 18, 2010).

[13] The decision can be found on the website of the Canadian Human Rights Tribunal in the section "Decisions Rulings" (search for "Bader"); accessed August 18, 2010.

[14] Homeopathics are still a special category unto themselves among evaluators, and vitamins and minerals are largely regulated according to the same standards as they were previously at TPD [the Therapeutic Products Directorate, that used to assess all drugs at Health Canada].

[15] For an anthropologist's commentary on the phenomenon of Health Canada's "smart regulations" see Graham 2005.

[16] This was also the period in which management decided to close the internationally-recognized Natural Products Laboratory in the Health Protection Branch's Bureau of Drug Research in 1991, amid formal international outcry at the stupidity of closing an internationally-recognized laboratory, and informal grumblings of racism, because the position of the research scientist who had worked in the position for more than twenty years was also cut. As Awang pointed out, with the closure of that laboratory, there was little chance that years later Health Canada would be able to solve "the hairy baby story," an incident that required expert detective work including contact with the Chinese Institute of Materia Medica to get reference standards to determine that what was supposed to be ginseng was in fact the toxic Chinese silk vine. (Testimony by Dennis Awang to the Standing Committee on Health on March 12, 1998.)

[17] It is difficult to say how much of Health Canada's pre-market evaluation addresses my main public health fairness concerns – ensuring the absence of poisons (pesticides, solvent residues, chemical 'spikes') in plant-based medicines, and ensuring the identity of the substances. This concern cannot be addressed by an all-paper evaluation. It requires laboratory testing.

[18] In 1997, the Canadian Human Rights Commission found significant under-representation of minorities in senior management jobs at Health Canada, under-representation that could not otherwise be explained. (When the lawsuit was filed in 1992, only 1 of 118 executive-managers was also a "minority"; in 1997, 4 out of 167 senior managers at HC were also minorities). The tribunal did not blame individual senior managers but blamed the discrimination on the net effect of staffing policies. The tribunal ordered a course of affirmative action (Kondro 1997). There had been at least one founded case of blatant racism, however, which apparently resulted in at least one senior manager (Liston) disappearing from his post when the problem was confronted (see decisions by the Canadian Human Rights Tribunal with the appellants "National Capital Alliance on Race Relations" or "Chopra," or, for a memoir, Chopra 2009).

[19] While some "interests," as science studies scholars might say, were clearly involved in the everyday shaping of this hodgepodge of tradition – for instance I could argue that the high proportion of applications for traditional Chinese medicines in particular, may have made traditional Chinese medicines top-of-mind among regulators – there were other elements of the pragmatic hodgepodge that seemed to have little outside "interest" associated with their adoption. For instance, some definition needed to be used and I got the impression that the WHO definition was seen as a definition as good as any, perhaps even more so because of the organization's moral authority, and, most importantly, one that was ready-made and did not contradict the direction the NHPD wished to take. Of course, once the definition was in place, it shaped the way in which tradition was enacted and reasoned with as a tool in the evaluation of medicines (cf Hacking 1991)

[20] Lock and Nichter referring to van der Geest and White 1989, Leslie 1989, Miles 1998a&b.

[21] From a presentation originally entitled "A Racial Science/Business? Putting Kampo in the Context of Asian Regulatory Culture" made by Wen-Hua Kuo made at the annual conference of the Society for Social Studies of Science in Montreal on Saturday, October 13th 2007. His main argument was, that in states such as Vietnam and Japan, East Asian medicines are linked to the nation-state, whereas in Europe and North America, East Asian medicines are linked to race or culture or ethnicity.

[22] Brotherton (2003) discusses of the Cuban state's promotion of traditional and natural medicine in the "special period.". Brotherton argues that the "emergence of a state-sanctioned medical pluralism in Cuba's health sector", at least insofar as research into traditional and natural medicines in the 1990s, must be understood in economic context. It came at a time after the period of Soviet aid, and during a time when the US blockade prevented many medical supplied entering the country (2003:245-7.) He points out that the state was adamant that traditional and natural medicine did not constitute second-rate therapy provided only because of the scarcity of pharmaceuticals. The Program for the development and generalization of natural and traditional medicine, begun in 1991, "include[d] the search for active medicinal principals of plants, their clinical testing, and the subsequent generalization of the results so that they can be progressively incorportated into the techniques and procedures of the East Asian medical tradition" (from a 1996 executive report issued by the MINSAP entitled "Analysis of the Health Sector in Cuba," as quoted in Brotherton 2003: 247.) One physician Brotherton interviewed, stated that Chinese, Vietnamese, Korean "and some Canadian" advisors came to in the previous decade to help to "exploit the positive characteristics" of "both traditional and Western medicine (ibid: 250). Traditional and natural medicine was billed as a scientific research topic, and documents about "green medicine" circulated by the state to practitioners in the country presented pharmacological information about traditional medicines (2003: 249).

The economic embeddedness are of course not confined to the Cuban situation. Goldstein argues that changing relationships between state- and privately-operated health institutions in the US mean that "the economic forces driving the delivery of health care now frequently find themselves with a direct economic interest in moving the narrative of health and illness away from its traditional control by physicians" (2003: 50).

[23] Although the *Multiculturalism Act* talks about the right to cultural heritage, are natural health products heritage? These medications are, by definition, used in a traditional system of medicine – but it is only the commodified product that is evaluated (cf Lock 1990). Because of the ambit of federal versus provincial jurisdiction in Canada, the regulation of commodities (medications) is separated from that of medical or health practice. The federal government's Food and Drug Regulations (including Natural Health Products Regulations) address medications as commodities: conditions for the import, sale, packaging, etc. of medications. The Regulations do not apply to the *practice* of medicine or pharmacy, and as such what doctors, healers, and other practitioners choose to do in their practice or compound for their patients. That falls under provincial jurisdiction. The NHPD also has no regulatory authority to assess home remedies, or foods prepared for health-related purposes – anything that is not commodified. Many important cultural or subcultural practices related to health, such as the preparation of specific soups and other food, using honey against evil, prayer, qi gong and anything considered spiritual, are beyond the ambit of the NHPD.

Furthermore, any medicine with a "mind-altering" component is generally illegal in Canada by virtue of its inclusion the *Controlled Substances Act*. Such a medicine is therefore removed, at least in law, from the category of regular medicines. Nevertheless, it is generally recognized that substances such as peyote and khat can be used for spiritual/ community purposes related to healing or social wellness in the broad sense; therefore, although generally criminalized in Canada, psychoactive plant matter can be legally obtained, possessed and used by ethnically-based groups for "religious ceremonies" on particular dates should the proper, formal permission be obtained from Health Canada.

Chapter 12
Appropriate reasoners
Good reasoning in the Directorate

From dichotomies to diversity

A concern of Gilbert Lewis, as well as many other anthropologists in the 1980s and 1990s, was the paradox ensuing from the imperative to use “standards appropriate to the context, and not assume that only our own are true. Double standards? More than just double?” (Lewis 1993: 191). The question was one of commensurability. Whose standard(s) to use? How? This question calls for, and enables, literal accounting.

Nearly twenty years later, is it possible, as an exercise, to do such literal accounting. I could argue that at the NHPD, certain medications, or traditions of medicine, were made commensurable, in the literal sense. Common standards and measures ranged from: licences (NPN numbers), quality tests, safety requirements and, on a superficial level, evidence of efficacy as adequate documentation. But I could also argue that those same medications, or traditions of medicine, were made incommensurable, in the literal sense. Incommensurable judgements or efficacies resulted from internal organizational complexity and the use of different evidential standards for efficacy for medicines in different assessment streams. Using either argument with its literal accounting, I could try and persuade the reader that the placement of certain medicines in these accounts were fair or unfair. This would be partially misleading. With so many standards involved in any pre-market assessment of medicine, the question of commensurability becomes

difficult to use for meaningful analysis, although not for lack of standards. This point is borne out in a comparative analysis of the Directorate's approach to change in two different medical paradigms.

Commensurable changes? Change in Traditional Chinese Medicine versus Western Herbalism

First, a caveat. While the term "Western Herbalism" had been used by the NHPD for several years, in the middle of my fieldwork the term was abandoned as a contentious term. As I was briefed in a unit meeting, "herbal medicine" was the new name, decided by NHPD management, for the specific paradigm previously known as Western Herbalism. The change was because the term "Western Herbalism" had become controversial in the NHPD's two external advisory committees.[1] This change in titles was not necessarily consistent with the stance of the Traditional Medicines Unit, which had taken great care to distinguish between the "traditional use of a herbal medicine" and "traditional medicine" for its regulatory efforts; nevertheless, the decision was taken at a higher level.[2]

There are several reasons why NHPD's approaches to traditional Chinese medicine, and the tradition formerly known as Western Herbalism, were largely incommensurable. The first reason is that, while the NHPD to some extent relied on a foreign government's standard for traditional Chinese medicines, the NHPD had extensive *in-house* regulatory standards (monographs) for medicines with claims "Traditionally used in Western Herbalism for…" At the time of writing, the

NHPD, in its *Compendium of Monographs*, had published just over one hundred monographs for single medicinal ingredients, of which sixty contained claims beginning with the phrase “Traditionally used.”[3] The vast majority (52) of these sixty monographs with traditional claims contained claims based in Western Herbalism (subsequently, called Herbal Medicine).

Product Licence Applications attesting to these sixty in-house standards were assessed in the Compendial Assessment Stream, not in the Traditional Assessment Stream.[4] As I described in Chapter 6, if the NHPD received a Product Licence Application with information that attested to, and matched, a monograph in the *Compendium*, the NHPD was obliged to licence or refuse the application to market medicine within 60 calendar days. There was no regulatory calendar limit in the Traditional Assessment Stream.

These “traditional” in-house standards were developed not by the Traditional Medicines Unit, but by the Monograph Development Unit. Although there was some overlap and exchange of personnel between units and assessment streams, there were no regular meetings on the topic of traditional medicines with all affected scientific staff. The upshot was that there appeared to be different relationships between the regulations and these two types of traditional medicines. With traditional Chinese medicine, at least one assessment officer felt “We’re trying to mold a different paradigm to our regs [regulations]”; Western Herbalism, which later morphed into Herbal Medicine, was, in a sense, *built into* the regulations

through the official regulatory Compendium of Monographs. There were a few monographs containing claims prefaced by “traditionally used in traditional Asian medicine…”, but these were few and far between.

Perhaps because of the differences in process between the Traditional Assessment Stream and the Compendial Assessment Stream, some challenges experienced by the Traditional Medicines Unit were obviated in the Compendial Assessment Stream’s processes. The first “challenge” I described in Chapter 8 – the substitution of medicinal ingredients in multi-ingredient medicines – would likely have been an issue also in the Compendial Assessment Stream but for the fact that in the Compendial Assessment Stream, substitutions were outright prohibited. The third “challenge” I described – medical syncretism – was also recognized as a challenge in the unit developing the monographs. That unit also had difficulty in clearly documenting 50 years of use of mixing or syncretism, required for a traditional use claim:

> The mixing of different therapeutic paradigms – New World, Old World, Ayurvedic, Traditional Asian – creates a difficult situation for the regulation of products, as these new applications of traditional botanicals are not supported by the available literature. E.g. Adrenal tonic made up of Ashwaganda (Ayurvedic tradition), Licorice (Traditional Asian tradition), Siberian ginseng (Traditional Asian tradition) and Borage (Old World tradition).[5]

Nevertheless, this problem was, in a sense, a hypothetical one for the Monograph Development Unit, because the problem was not so much in the development of monographs: monographs could not be developed without appropriate evidence in documentation. The “problem” – the general slowdown of assessment in the Non-

Traditional Assessment Stream (the catch-all "other" category) – would be encountered by other assessment units, whose assessment officers ended up having to evaluate such "syncretic" products according to appropriate standards.[6]

Because the NHPD was writing and editing the *Compendium of Monographs*, the in-house standards, its scientists could include "changes" or "modernization" into the monographs or associated internal standards in one of many ways. According to an issue sheet developed by the Monograph Development Unit,[7]

> There is a gap between the Traditional Use and the Modern Use categories on the current Compendium of Monographs; the introduction of the Western Herbalism classification would address the issue.

While Modern Use was for indications "supported by clinical trial data," and Traditional Use was based on at least fifty years of documented use in an ethnically-defined setting, the new, proposed category, Western Herbalism was for those "supported by modern practitioners like NDs [licenced naturopathic doctors] or registered herbalists," but that differed from Traditional Use in:

> Intent – e.g. Black cohosh was not traditionally used for menopause; this indication appeared in the 1950s in Germany.
> Dosage – e.g. Feverfew tinctures were not traditionally used in practice.
> Paradigm – Echinacea and Goldenseal were not traditionally combined; these two herbs have different geographical and ethnobotanical origins. [8]

The NHPD's Feverfew Monograph contained three types of claims, as opposed to the usual two types of claims, that for traditional use and that for science-based use. To distinguish Western Herbalism's evidentiary base from the two usually types of claims – "Traditionally used.." and, from that at the other end of the spectrum, the unqualified, purportedly science-based "Used for.." claim – there

emerged an additional type of qualifier for the claim: “Used in Western Herbalism.” This “Used in Western Herbalism…” qualification formally recognized the changing nature of a non-biomedical health practice, indexing documented practices without needing clear parameters regarding the indigeneity of the cultural group as required in the Traditional Assessment Stream.

Thus, there tended to be different approaches to change in traditional Chinese medicines (evaluated in the Traditional Medicines Unit) and in Western Herbalism (evaluated in the Monograph Development Unit and Monograph Management Unit). Separate Units, in separate Bureaux, were working with different purposes and objectives. The comparison between the approaches was more mereographic than oppositional; they were not entirely framed as a complete opposition, or a whole encompassing its parts. The tension inherent in the Orientalist (cf Said 1978) de facto result – of a changing and adapting traditional Western Herbalism, and an unchanging, typified and classified traditional Chinese medicine – however, remained. I would argue that this was partially, but not entirely, a product of available discourses at the beginning of the 21st century.

Institutional standards

The question posed by Gilbert Lewis has shifted, slightly. At the NHPD, scientists spoke of “multiple healing paradigms,” shared tips on pharmacopoieal standards for absence of microbial contamination, and debated whether *energy* could be substituted for the *chi* (or *qi*) in health claims (it was decided no). When an

assessment officer stated that homeopathy simply did not work – backing up her statement with systematic reviews from that bastion of evidence-based medicine, the Cochrane Collaboration, there was no doubt among other assessment officers that her reasoning was faulty for within the Directorate, in addition to her having committed a faux pas. The contextual reasoning assumed by Gilbert is occurring, so the question shifts from *how to* go about such the contextualized reasoning, to *how does* this contextualized reasoning proceed and made to seem appropriate, fair.

It is not unusual for contemporary professionals in large organizations to be making judgements with attention to "respect for diversity." Grégoire Mallard et al. (2009) examined panellists' accounts of their reasoning and judgement on a multidisciplinary fellowship committee in the US. These panellists were concerned with being fair. In their analysis, Mallard et al. distinguish between two types of fairness: distributive and procedural (2009:576-577). They characterize distributive fairness as a merit-based, universal, Mertonian-type fairness; as relying on one standard. That was not the fairness of concern to the panellists. The other type of fairness outlined by Mallard and colleagues, the procedural, "linked fair evaluation less to the application of *general* criteria than to the application of *appropriate* criteria, that is, to "contextualized cognition," defined as the application of the epistemological styles most relevant to the field or discipline from which a research proposal emanates" (2009:576). Because I am using their term "appropriate" in the chapter title, their explanation of reviewer's fairness bears mention:

> Reviewers evaluate fairly when they use standards that are most appropriate to the object of evaluation. Rather than applying a single universal criterion indiscriminately, they specify which criteria, or lenses, are most appropriate to assess the strengths and weaknesses of the object under evaluation. This requires locating the object, which in this case are grant proposals, within specific fields of expertise, including within the intellectual conventions and epistemological styles that prevail within these fields. The fairest criteria are thus not the most widely shared criteria but the standards deemed most appropriate given the distinctive features of a particular object (Mallard et al. 2009: 578).

Appropriate reasoning at the Natural Health Products Directorate

In both Traditional and Non-Traditional assessment, scientists could follow the assessment processes to the letter and do the assessment badly or masterfully, in ways that other assessment officers would generally recognize. In the pre-market assessment of medicines, there were so many possible characterizations of the medicine and comparisons to the evidence that could be made. An appropriate judgement is the one made with respect to the most salient standards. Both the reasoning and the judgement could be more or less elegant (cf. Verran 2001).[9] What was this fairness, this appropriateness, this mastery, this elegance?

I will approach this mastery in two ways, drawing cumulatively from scientists' characterization of "good reasoning" in various types of assessment: as discernment, and as possibly indicative of abductive reasoning.

I first consider scientists' descriptions of "good reasoning" in the traditional and homeopathic assessment streams. In those assessment streams, scientists had to

reason with the “logics of the paradigms” concerned, as well as other regulatory standards. The dynamic of this reasoning is akin to Lewis’ suggestion of “multiple standards,” as there were still definitive standards within each “paradigm.” Elegant judgements included standards, yes, but the elegance came from the way in which the scientists wielded the standards, were able to discern and articulate meaningful comparisons and contrasts.

I then consider scientists’ reasoning in the non-traditional assessment stream, an assessment stream in which they needed to consider the “totality of evidence.” In these evaluation activities, scientists’ characterizations of the medicine and of the evidence proceeded simultaneously; neither was entirely determined at the outset. In some cases scientists characterized their reasoning as detective work. I characterize scientists’ reasoning as “abductive,” while retaining my emphasis on observable features of reasoning.

Discerning standards

Like in any style of reasoning, I suspect, there was nothing precluding the creative use of standards for particularly successful judgements; there were, however, many ways of using standards incorrectly or incoherently. Scientists often readily recognized their lack of expertise in certain areas. In the words of one self-described “hard-core science-type”:

> When I actually considered [working at the NHPD] …. my biggest challenge was in getting over my, uh, prejudice, I guess, or I’d say, or maybe, ignorance about things like naturopathic medicine, and homeopathy, which [pause] I still haven’t overcome yet.

> But I …I think I've started to appreciate a little bit more, sort of the holistic um, approach, so [pause] I guess that's a good thing.
>
> It's still a work in progress, because I'm in the Non-Traditional [Assessment] Stream with products that are based on scientific evidence, so it's not, I think, like history of use, and that kind of stuff, it's really based on the science …(Sharva)

While Sharva was still, in her own avowal, working through her prejudices, I have no doubt that she would have considered the following variant Standard Line, sent to an applicant as part of an assessment of a traditional Chinese medicine, as (1) professional and likely appropriate reasoning, and (2) involving a distinction she herself would be unable to make:

> The claim is neither specific nor clear. "Remove accumulation and stagnation, used for stagnant blood" is too general. There are different patterns of accumulation and stagnation; stagnant blood can have very different symptoms according to the patterns and organs involved. The formulae used for different patterns are different. As per Chapter 8 of the Evidence for Safety and Efficacy of Finished Natural Health Products guidance document, please be specific for the claim and ensure the rationale for the combination is clearly addressed.[10]

Clearly, the extent to which the assessment officers could assess the appropriateness of a claim in a medical paradigm like traditional Chinese medicine depended on their level of expertise with that paradigm. This expertise was not determined by "belief." I suspect that Sharon could neither believe in, or not believe in, various stagnations. She could not discern them. Her inability to discern the differences in those types of stagnation were what made her inadequate to the task of evaluation the file. This inability to discern the differences did not mean they did not exist; I doubt that, even given her prejudices, that she thought her colleagues

who wrote such standard lines to be deluded. Sharon could, hypothetically, learn to discern among stagnations.

Most scientists were eager to learn in general, including to see from other's perspectives and to learn to discern new standards, generally garnering experience from their expert colleagues.[11] For some scientists this involved actively "embracing the weirdness," as they characterized it, perhaps in a spirit of cosmopolitanism (cf Rabinow 1996: 56 in Zhang 2007) or Orientalism (cf Said 1978).[12] As Violet pointed out in her discussion of homeopathy (see Chapter 9):

> What I really like about the work is working and learning from all these people [practitioners] about these difficult things. [pause]
>
> But on a personal level, everyone tries but succeeds to different extents.

For the vast majority of scientists who had regularly evaluated medicines according to evidence from a particular paradigm, however, what they were discerning was not difficult, just different. They were neither mysterious nor obscure. Take the following interview exchange with Dorrie:

> Essentially that is what we have to do: well there's traditional evidence, and there's modern evidence. And the modern evidence is CT [clinical trial] data.
>
> *Do you enjoy working with both types of evidence?*
>
> Yes, but it is difficult to tease out useable, matching dosages from both. Sometimes it is a real challenge for traditional sources, I mean some of the stuff goes back centuries, so it is difficult to see what it was then and what it is now.
>
> *Do you feel equally confident with both types of evidence?*

> They're very different, you can't compare them. … They are just so different. Quite often CTs are done with isolates or standardized compounds. They are so very different an approach than the traditional [medicine] which is quite often a, herbal tea or an extract or dried powdered herb, but it is a whole herb preparation….The scholar in me finds advantages and disadvantages to both, but is highly intellectually stimulating.

Another scientist, Baek, was more blunt about the extent to which the "difficult things" as experienced by the non-practitioner scientist Violet, were as mundane as evaluating the science:

> I've worked in both [assessment] steams. The bottom line is the same: we guarantee safety and efficacy. The only difference is the requirement. We use TCM [traditional Chinese medicine] knowledge consistent with TCM theory. For the new products it's is the same thing but the evidence is based on CT [clinical trials] or something – if the controls are appropriate, if there is adequate sample size, if the R [randomization] is real R or there is something behind it.
>
> I cannot I say enjoy one or the other. If I go there, I work; if there, work.

Mundane an achievement

The degree to which many scientists in the traditional and homeopathic medicines units considered their evaluation of traditional and homeopathic medicines unremarkable, utterly mundane, is perhaps a notable achievement of the bureaucracy. Within the Canadian federal department of health, this has not always been the case. NHPD scientists caricaturized the ways in which scientific and medical staff in sister directorates managed to prevent this mundane consideration of natural health products. In some cases herbals were simply ignored: *TPD used the 10% rule, saying that herbs under 10% could be ignored*. *MHPD asked: who would use this ridiculous product anyways? to justify ignoring it.* In other cases the mundane consideration of herbals was prevented by unachievable evidentiary and

quality standards (for natural, non-isolated non-prescription medicines): *TPD treated ginseng as a "new drug," requiring all sorts of randomized clinical trials for evidence of safety. MHPD, from a toxicology perspective, sees many spices as quite toxic*. Of course, there are so many types of medicines grouped in the category of natural health products (cf. Chapter 3) that simple comparisons and contrasts are impossible between the work of the NHPD and that of its sister and precursor directorates. TPD had licenced many herbals and homeopathic medicines in the 1990s using much the same types of evidence that the NHPD was using a decade later.[13] One difference was that while the NHPD stated it was evaluating efficacy, in some cases, TPD had stated it was not.[14] There was no concern expressed for "outmoded" (e.g., non-scientific) terminology in the new Directorate, although there had been a decade previously at TPD.[15]

Scientists at the NHPD *who worked in the evaluation* of these medicines generally embraced this mundane approach. Even a Clinical Trial Application for a randomized trial of a traditional Chinese medicine – with more than fifty medicinal ingredients listed in the Application – was addressed like any other medicine at the NHPD; scientists' only comment was that it took a *very* long time to go through all the required reasoning for each of the fifty medicinal ingredients.

Paradigms

Boundary-work between paradigms was only pursued when necessary for evaluation work, and never, to my knowledge as an end in and of itself; the important thing was for scientists use the most salient and appropriate standards

for the evaluation at hand (cf Sagli 2001, in Bivins 2007). Medicines' safety and efficacy in different assessment streams were therefore not always commensurable, even if there was a uniform style of reasoning, because different considerations were brought to the fore. If one is examining discourse, paying attention to rhetorical differences between categories, one must do "paradigms" in the European epistemological tradition; this is, however, a different project than reasoning with those categories to a different end or activity in which the rhetorical differences might not be especially salient when reasoning. This is similar to the distinction made by Stanley Tambiah (1990:125-127) between approaching commensurability as "finding a common measure," such as grouping different traditions of medicines under the common rubric of "paradigm" which introduces particular constraints, and approaching commensurability as "making proportionate" by examining the relationships of the parts to the whole.[16] Several Issues emerging in the evaluation of traditional and homeopathic medicines at the NHPD, were less due to particularities of those traditions of medicine, than institutional constraints involved in approaching these traditions of medicine as "paradigms." Despite the seeming comparability of paradigms, the Homeopathic Medicines Unit did not perceived itself to work with the Traditional Medicines Unit more than other assessment units, or vice versa. Paradigms, standards, were not, strictly speaking, comparable, because scientists recognized both organizational and contextual reasons for that which was most important in some judgements, to be irrelevant in others. [17]

Expertise, discernment, abduction

Part of what enabled the NHPD to take this mundane approach was *who* was doing the assessment: professionals with sufficient expertise to discern these differences.[18] There had been an explicit place for expertise maintained: there was both room for scientists' expertise in decision-making according to standards, and in changing the overall algorithm determining the standards used. Scientists recognized that what was most important in one paradigm was not always the most important in another (cf Strathern 1991), and so a range of expertise was needed. Rather than analyzing scientists' work in terms of incommensurability, then, it is perhaps more apt in my analysis to speak of the ability to discern. Except perhaps for medicines in the Compendial Assessment Stream – when the parameters for the comparison were set in advance by the standard of the NHPD's published monograph – the efficacy of various medicines was neither entirely commensurable nor incommensurable. Using Strathern's framing, scientists were most interested in what was made whole.

Given the multiple, partially connected (cf Strathern 2004) standards and paradigms, how did scientists discern among them? The selection of the appropriate standard appeared to be a hodgepodge of experience, mantras, organizational context, as well as many other things: only so much of this selection was accessible to the fieldworker, or likely even to an articulate consciousness of the scientist him or herself. One was to characterize the selection of standards is abduction, as described by C.S. Peirce:

> upon finding himself confronted with a phenomenon unlike what he would have expected under the circumstances he looks over its features and notices come remarkable character or relation among them, which he at once recognizes as being characteristic of some conception with which his mind is already stored, so that a theory is suggestion which would *explain* (that is, render necessary) that which is surprising in the phenomenon…. Abduction is the process of forming an explanatory hypothesis…. Abduction merely suggests that something *may be*…. A [hu]man must be downright crazy to deny that science has made many true discoveries. But every single item of scientific theory which stands established today has been due to Abduction (Harrowitz 1983:181).

While Peirce looks to "some conception with which his mind is already stored," there is no reason to approach abduction any differently than other reasoning. In the case of this dissertation, that is via the thought collective's socially and materially situated activities. The work of assessment officers like Alex described in Chaper 5 required perpetual attentiveness required to ensure "a match" to an appropriate standard. I suspect scientists' leaning back, stretching, expressions of annoyance are part of this casting about for some standard to use, and, concomitantly, how to shape the problem. This would be from past activities, perhaps, or recent conversations or cubicle décor: experience. Most are inseparable from experience, but as Harrowitz points out, "experience can be either public or private" (1983:185). Furthermore,

> Noticing the observed fact is the first step. A rule then suggests itself to explain the origin of the observed fact. The observed fact is consequently read through the hypothetically posited rule [note that Pierce uses 'experience,' 'general truth,' and 'law of nature' as rules] and the case is abducted. The rule, then, generates the intelligibility of the observed fact, and the observed fact is read through the rule (Harrowitz 1983:90,182)

This is why Harrowitz states that abduction works not only forwards but backwards, chronologically (1983:190).[19] I believe this model of ratiocination is plausible, and

consistent with Fleck's characterization of styles of reasoning within thought collectives, without having to infer the mental cogitation of others. In Chapters 14 to 18 I describe how.

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[1] In 2007, the NHPD's Expert Advisory Committee and the Management Advisory Committee engaged in intra-and inter-committee debate over what to call the herbalism that "is currently practiced in Canada." The following is an account of the debate as it filtered down to me as scientific staff member.

At least one member of the Expert Advisory Committee (whose members were mostly professors) found the use of the term "Western" to be problematic: did the term encompass Europe and/or North America, and given that much of the North American eclectic tradition is originally drawn from First Nations medicines, did using the term "Western" obscure the contributions of First Nations to the tradition? Alternatives considered were "contemporary herbalism" or "modern herbalism" but this lost the traditional element. The committee suggested that, rather than the term "Western," the cultural context of a traditional medicines' use be derived from the nation state in which there was documented use; it recommended the use of qualifiers like "Traditionally used in British Herbalism…" and "Traditionally used in American Herbalism…" Medicines without an ethnocultural context, e.g., called phytotherapies and phytomedicines, would be more appropriately assessed in the Non-Traditional Assessment Stream.

The Management Advisory Committee (an industry committee) strongly disagreed with the Expert Advisory Committee's recommendations. The industry committee argued that these distinctions were meaningless to consumers, because all such herbal medicines fall in the same paradigm, and in any event NHPD should be focusing on the products, rather than the practice, of herbalism.

NHPD management decided that the approach it would take 'would be the approach the Therapeutic Products' Directorate had taken,' before the NHPD existed: "to avoid the whole controversy," and use the term "herbal medicine."

(The Expert Advisory Committee (EAC) also commented on other terminology; for instance, I had recorded in the meeting minutes from January 19th, 2007: "EAC would like us to consider labelling our TCM monographs as TAM (Traditional Asian M[edicine]) monographs.")

[2] From a presentation "An Overview: Evidence for Safety and Efficacy of Traditional Medicines" delivered April 10, 2007 at an internal training session; slide 61. "Traditional herbal medicine" is ambiguously related to "traditional medicine" in WHO's definitions:

> Traditional use of herbal medicines refers to the long historical use of these medicines. Their use is well established and widely acknowledged to be safe and effective, and may be accepted by national authorities. (http://www.who.int/medicines/areas/traditional/definitions/en/index.html; accessed March 10, 2009.)

The Traditional Medicines Unit interpreted this to mean that *traditional use* of herbal medicine is not necessarily *traditional medicine*.

[3] The NHPD's *Compendium of Monographs* contained, as of March 2009, over 100 pharmacopoeial-like monographs for single medicinal ingredients, and 14 product (multi-ingredient) monographs, the most frequently-cited monograph probably being the multi-vitamin/multi-mineral supplement monograph. Count taken from the Single Ingredient Monographs available at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_list-eng.php , accessed March 7, 2009.

[4] In the Compendial Assessment Stream, applicants did not have to provide any evidence for safety and efficacy if their packaged product conformed *exactly* to the specifications of the monograph, including dose, claims, etc. Rather than provide their own specification sheet for quality assessment, the applicants in this stream simply attested to the Compendium of Monographs' specifications. The process of Compendial Assessment – comparative assessment werein the standard for safety and efficacy is the NHPD's own published monograph for a medicine – has already been described in Chapter 6.

[5] From an issue sheet developed by a monograph author from the Monograph Development Unit, document titled "Botanical Monograph Category "Western Herbalism"" dated 2007-03-08.

[6] As I mentioned in Chapter 8, this phenomenon was also found in the Traditional Medicines Unit. While several members of the Traditional Medicines Unit had commented in passing that "modern Traditional Chinese Medicine" and "modern Chinese medicine" should yield interesting health claims; this was a comment in passing, because such claims were not suited to evaluation in the Traditional Assessment Stream, and so were irrelevant to actual work.

[7] Document titled "Botanical Monograph Category 'Western Herbalism'," dated 2007-03-08.

[8] From document titled "Botanical Monograph Category 'Western Herbalism'," dated 2007-03-08.

[9] For example, Helen Verran's study of student teachers in Nigeria (2001) described the way in which one teacher, Mr. Ojeniyi, taught division. Rather than teaching division as the reverse of multiplication – which is what Verran expected – Mr. Ojeniyi presented "division as definitive of whole number," declaring to the class of elementary students "You will not understand a number unless you understand the many ways it can be divided." The lesson involved a game of students translating between English number names (and the base-ten system) and the Yoruba number names – describing a number as a multiple of twenty plus or minus various factors of twenty, which could be done in many ways, some more elegant than others.

[10] The statement was taken from one scientist's variant standard lines document (see Chapter 5 for a characterization of those documents). My thanks to the scientist who must remain unnamed.

[11] For instance, one scientist, Noor, explained that when she needed to establish a medicine's safety based on food use outside of Canada,

> I guess a guiding factor is respect for cultural diversity. Especially when, you know, almost everything is a little bit toxic, and you're trying/ So you could potentially say, 'oh, well, this substance contains these three chemicals which at very high dose might cause trouble.' But you recognize the fact that it has been used for a long time in some other culture, and that it's actually relished as a special food.
>
> We use rhubarb and rotten cow's milk. *Rotten cow's milk?* Cheese. *Oh!* I think we have a habit of trying to see it from another person's perspective.
>
> I guess the main thing is having experts from other cultures who are doing evaluations [for medicines] from these traditions, some of the traditions, and helping create the monographs, is a reasonable approach to allowing cultural diversity and yet/ But also trying to keep tabs on things to avoid dangerous products from other traditions, that could injure or kill someone.
>
> I think the approach is just about right.

Likewise, Reiko explained

> There are product that I come across that I ...personally would never take. But I have to respect the fact that others might want to take it, and therefore I have to take all the evidence into account, to see if it is risky or not.

[12] One lunchtime discussion among a group of scientists was on the topic of travel. One scientist wondered why her dreams were very different in a foreign country. Another scientist hypothesized food differences, and I hypothesized an antimalarial drug, but these practical suggestions did not seem to be relevant to her experience. "Now you're all going to think I'm weird," said the scientist who had shared her experience. Another scientist countered: "This is the NHPD: nobody is going to think you're weird."

[13] Although as Liora Salter notes in her discussion of debates over Canadian standards used to limit environmental pollutants and contaminants, "[a]ttention was directed away from the standard itself and toward the manner in which government handled its regulatory responsibilities" (1988: 165).

[14] An online question and answer forum by TPD documents the different perspectives as to the relationship between efficacy and pharmacopoeia in the pre-market evaluation of homeopathic medicines:

> Question: Are homeopathic preparations subject to regulation in Canada?
>
> Answer: Because homeopathic preparations are used in the treatment of disease, they are classified by the *Food and Drugs Act* and *Regulations*. They must therefore have a DIN on the label prior to sale.
>
> Question: Are homeopathic preparations subject to the same evaluation process as other drugs?
>
> Answer: No, the evaluation process reflects the unique nature of these preparations.
>
> DINs are issued for homeopathic preparations that are considered to be non-toxic; however, there is no assessment of the efficacy of these products.
>
> A homeopathic preparation may contain only an ingredient or combination of ingredients for which a monograph as a homeopathic medicinal ingredient is defined in the current editions of the *Homeopathic Pharmacopeia of the United States (HPUS)* or the *Pharmacopée Française (PhH)* and which is offered for sale in a dosage form defined by, and prepared in accordance with, the procedures prescribed by these compendia. Ingredients that are otherwise prohibited from drugs may not be present in homeopathics.
>
> The labelling of the product must identify it as a homeopathic preparation. It must also indicate that the product is to be used only on the advice of a physician or homeopathic practitioner. No therapeutic claims, explicit or implied, may be made for the product. Labelling is not subject to pre-market review by HPB. Responsibility for conforming to labelling guidelines as outlined in the Drugs Directorate Guidelines entitled *Homeopathic Preparations: Application for Drug Identification Numbers* rests with the manufacturer. However, a homeopathic preparation must comply with Good Manufacturing Practices (Division 2 of the *Food and Drug Regulations*). (Canada. Health and Welfare Canada 1991:44).

[15] Health Canada's *Drugs Directorate Guideline: Traditional Herbal Medicines* in force a decade earlier, beginning in October 1995, required proposed claims "be based on modern concepts of therapy, avoiding terms such as "tonic" […] and other similar words that are outmoded" (Health Canada – HPB 1995b:11).

[16] Anthropologists have long discussed how to make comparisons between cultures. Comparison is always explicitly or implicitly at the core of the ethnographic project. (Implicitly because an ethnographer is at least using the language of a particular cultural context to write about another). There are pitfalls in assuming or recognizing too much similarity, or conversely too much difference, in the comparison. It is clearly inappropriate to assume that there are no differences, saying that everything is a variation of one culture. What is most important in one culture (e.g., 'religion') may be present in another culture, but in the second culture it may have little central importance. This can make structuralist comparisons – that arrange cultural differences within cross-cultural categories – misleading. On the other hand, it is also generally inappropriate to assume that it is impossible to say anything about another culture, because it is so completely different, and not coeval. This goes against common sense. People regularly speak more than one language, engage with more than one cultural group, and travel without major problems. Anthropologists have long observed that humans do manage to meaningfully communicate across, between, and with plural cultural traditions:

> translation implies *some* measure of comparability, and comparability in turn implies *some* measure of *commensurability*. But this inference has brought us to the threshold of the thorny and contested issue of how we are to understand *commensurability* and *comparison* (Tambiah 1990:125).

Nevertheless, there are important differences cross-culturally that need to be acknowledged, and sometimes cause major misunderstandings. How to recognize difference appropriately? There are many ways in which these comparisons and contrasts have been configured. Stanley Tambiah outlines two styles. He argues in one, that style that compares through common measures, can, for instance, "group Indian caste, together with systems of social class in the industrialized West, racial discrimination and domination in the United States, European feudalism, under the common rubric of *Social Stratification*" (1990:126). I would argue that the NHPD did the same thing, grouping various traditions of health and healing under the common rubric of *healing paradigm.* Another style, one that Tambiah loosely termed structuralist, strives to treat systems as wholes and to describe, from within the tradition itself (say the Indian caste system). In this second method, the "differential valuation given to parts and functions according to their contribution to the whole"; only after "the totalities have been constructed", can comparisons be made (1990:126-127).

Marilyn Strathern, introduces the idea of "more than one, but less than many" to overcome this conceptual stalemate (2004a [1991]). This idea is meant to overcome the idea of singularity – one culture – and also the idea of totally separate cultures – plural cultures. To put it in Haraway's terms (1991), either of those ideas requires a "God trick." Following Haraway, Strathern argues that the cultures as described in an ethnography are always partial, situated, and more than one, less than many. She focuses on the relationships between cultures from the perspective of the situated anthropologist. These relationships are "doable" (Verran 2001), as opposed to theoretical. But there is not necessarily an a priori whole of any culture. The whole that makes a person, a culture, an anthropologist is developed through particular, historical relationships (Strathern 2004b).One can read the anthropology of things (e.g., Appadurai ed. 1986) and the history of objects (e.g., Daston ed. 2000), as genealogies of the wholes that are created, and thus directly speaking to the question of commensurability. (This observation is from Povinelli, who specifically mentions body parts in organ trafficking, 2001:325) These approaches are examinations of tensions when something is made whole and becomes a common measure (standard) that *moves* through space and time; and when it becomes another whole. While these approaches directly speak to the question of commensurability, they simultaneously move away from that question. In genealogy, there is no easy way of speaking of commensurability and incommensurability, which require a common measure or a common time, against some form of stable background.

[17] Marilyn Strathern's "partial connections" (2004[1991]) and Haraway's "situated knowledges" (1991) are frequently used tropes to configure comparisons in anthropology. The central issue discussed in *Partial Connections* (Strathern 2004) is that of comparison in anthropology, and how to keep a sense of proportion in relationships of unequal importance or effect to both parties. This attention is reflected in contemporaneous ethnographies of science. Sharon Traweek notes that Japanese physicists are acutely aware of the American physicists, although the reverse does not seem true (1988); this flow of remarks to the ethnographer about North America while in Japan is also true in *Encounters with Aging* (Lock 1993).

[18] If etiquette is as important as I suspect it is in the entire Canadian Public Service, then clearly *who* is employed determined the considerations and expertise at hand.

[19] See also Eco (1983), who suggests there are at least three different types of abduction.

Part V. Numerical standards in practice

Measured judgements, managed judgements

Chapter 13
Numbers of science

In social anthropology, there is a tradition of comparative work on measurement, number and arithmetic (e.g., Tylor 1913, Hallpike 1979, Reed and Lave 1979, Lave 1988).[1] Recent authors conclude that number is neither a matter of individual psychology nor of collective symbolism, but is rather an *activity*, which depends on the problem to be solved and the materials at hand for the solution (Hallpike 1979, Lave 1988, Verran 2001).[2][3] This approach is also the approach I am taking to scientists' reasoning more broadly. This chapter inventories the numbers scientists used in the pre-market assessment of medicines, and argues that the way in which scientists reasoned with numbers and statistics was little different than the way in which they reasoned with other textual standards. Scientists reasoned with number through taxonomy and comparison, in a non-linear, material, and embodied way; in situations of uncertainty, scientists consulted with expert colleagues. Scientists transformed opportunities for calculation into opportunities for comparison.

Numbers and statistics pull that disappearing trick

After some of my coworkers heard me describe my research focus – the numbers and statistics used in the evaluation of natural health products – they reportedly joked "What does she mean – the submission numbers written on the files?"

To find out what numbers assessment officers were transforming, I asked every scientist-interviewee, towards the end of the interview, what they did with their

calculator. The answers varied depending by assessment unit, but the majority of scientists said they used their calculator to determine the total daily dose provided by a medication, or to do sample size and power calculations.[4]

Staff often professed having very little knowledge of statistics. This was often not true, and in the course of the conversation that followed they would describe the statistics they observed in their day to day work. As a rule, however, the regulatory scientists did not verify the correctness of the statistical test used in a clinical trial. Scientists in product assessment at the NHPD were nearly always working with published results from clinical trials, publications that they assumed were already peer reviewed. In the non-traditional assessment stream the evaluators would often state in their assessment report whether the results of a clinical trial were reportedly significant, but this was not necessarily the only number of interest, or even the most important number in their evaluations.[5] Namir explained that although he mostly looked at “the p-values, that sort of thing,” those numbers were only “one of the important things” that he looked for: “but not a make or break thing.” Especially because with statistics, Richard opined, “Basically, you can get your results to say what you want.”

I suspect the reason they claimed to have little knowledge of statistics is because their reasoning with statistics was with instruments: with their variable “stashes” of statistics and calculatory abilities on the computer, in piles of paper, and of course, among their acquaintances. There *was* substantial expertise and working with

numbers, and they did calculate. It was less that the numbers or statistics disappeared, but rather their transformation (through counting, calculating) disappeared. This chapter explains the varied ways in which they were disappeared. But first, I inventory the numbers found.

Numbers found[6]

I inventoried the numbers used by assessment officers, grouping them into those used as part of: serials, comparisons, calculations, and counts.[7] The counts – counts of productivity (i.e. quotas), of the number of days the submission had been with the NHPD or back with the applicant – will be discussed in the next chapter.

The numbers used as part of serialization were the numbers that my colleagues had made a joke about: the submission and file and licence numbers, as well as the cube and phone and fax and employee identification numbers, employee position and rank numbers, date of monograph, sequential sections of SOPs (standard operating procedures), number of information request notices (IRNs) sent. These numbers were the numbers associated with bureaucracies; they could be poked fun of because they were administrative place markers, without ontological significance and without any connection to science. Nevertheless, the actual *digits* were important in these numbers and could not be altered in the least.[8] Furthermore, sometimes the actual digits in such numbers revealed substantial information to the socialized and observant member of the thought

collective.[9] These were numbers useful within a stable system in which all the other parameters were established. With the other numbers that I will describe, the digits themselves were less important.

In pre-market assessment, I argue, that every opportunity for calculation was reworked into an opportunity for comparison.[10] There were opportunities for calculation, and scientists did calculate. I inventoried the calculations I did, observed, or that scientists told me they did in addition to daily dose and sample size; these included calculations to find equivalencies for: bodyweight, crude dried plant matter, combination medicines, vitamin A – beta-carotene conversions, percentages, and the weight of the placebo versus intervention medicine in a clinical trial. However, whenever possible these opportunities were turned into opportunities for comparison; indeed, the entire point of the calculation was to make the information presented in the submission comparable to some standard, or vice versa (see Chapter 6 for a discussion of the importance of comparison).

For most calculation types, electronic spreadsheets or other tables were created as calculation templates for the specific operation, to the scientist could plug in a number (e.g., the amount of beta-carotene), hit “enter,” and the required number for comparison purposes (e.g., the amount of vitamin A) would (magically) appear. In other cases, scientists used online converters or calculators, such as ones for the determination of a reasonable sample size for a clinical trial.[11] I came to see these ready-made tables for specific tasks as “stashes” of calculation (cf. Lave

1988) used to reshape a number into one amenable to the required comparison. Stashes were organized not only by type of calculation, but also degrees of uncertainty. For instance, one scientist in the clinical trials unit had a link on the desktop web browser to a sample size calculator for everyday use, and then "the statistics pile" of papers (replete with take-out menus) stashed in the corner of the scientist's cubicle. This scientist would refer to the pile of papers with references, studies,[12] notes from coursework,[13] and links when the sample or the analysis proposed in a clinical trial was less obvious. These stashes moved number away from being generic, in the sense that school-taught addition and subtraction are part of a generalizing logic (Verran 2001). When they needed to do a particular calculation, or even count, scientists often went to the appropriate stash.

It was the scientists working in assessment streams using monographs and pharmacopoeia who appeared to do the most calculations. While this initially seems out of place – calculation has associations with science, and comparative assessment was considered the least "scientific" of all assessment streams – it is in fact consistent with the use of calculation in many everyday situations, as discussed by the anthropologist Jean Lave (1986). She found that the problem and solution was determined dialectically in setting; individuals only resorted to calculation when a choice on other grounds was unreasonable. Likewise, in the non-traditional assessment streams, scientists could obviate calculation by coproducing the "problem" and the "solution." Frequently, calculation was obviated because it was clear to scientists that a more fundamental mismatch between the

proposed medicine and evidence for its safety for efficacy, existed, a mismatch that precluded any meaningful calculation: different medicinal ingredients, different daily doses, different claims, and so on.

It was only when the proposed medicine was sufficiently comparable to the evidentiary standard that any calculation could occur. In the non-traditional stream, this frequently only happened after multiple assessments had already been completed on the proposed medicine, with the applicant having reshaped the application so that the scientists' reasoning through taxonomy and comparison could proceed. Even when the application was reshaped, calculation was not necessarily an obvious activity. For instance, one assessment officer was working on a proposed weight-loss aid in which the evidence was the company's own data on the product (i.e. the study clearly corresponded to the proposed product), but in her first assessment she did not redo the statistics herself, but rather dismissed the study as providing insufficient evidence, stating that although there might have been a slight statistical difference, the difference was not clinically relevant. The applicant contested her judgement, so she consulted a statistician from another part of Health Canada who wrote a report, including redoing the applicant's calculations, the result of which there was not even any statistical significance, independent of the questionable clinical significance. For a regulatory scientist to get involved in calculation in such an instance, not only did an application had to have provided numbers to look at, but also those numbers had to be clinically relevant (or contestably so), and furthermore those clinically relevant numbers had

to affect the scientists' determination of safety or efficacy. Only if all those conditions were met was there a need for the scientists to calculate.

In the comparative assessment streams, and in quality assessment, the standard for comparison (the monograph, the pharmacopoeial entry, the specifications template) was already determined. It was possible for scientists to reduce the amount of calculation by working from both sides simultaneously to establish if one side was more or less than the other: on the one side, the number in application, and on the other side, the number in textual standard.[14] Another strategy that was not strictly calculation was "eyeballing" a number in the Product Licence Application form to make sure it fell within the acceptable range of the pharmacopoeial or other textual standard (in quality assessment, for instance, generally 80-120% of any declared amount). Nevertheless, with only one option for the evidentiary standard, the structured matching often immediately required calculation. This was true not only of the regulatory scientists but also the applicants. The requirement in the Compendial Assessment Stream that the proposed medicine correspond exactly to the published monograph sometimes encouraged rather creative calculation on the part of applicants determined to have their proposed medications evaluated in that stream.[15]

Calculation was also required whenever dealing with plant-based extracts, especially those specified in monographs or pharmacopoeia, because the extraction ratios, quantity of medicinal ingredient and quantity dried crude

equivalent had to be declared on the label and it was easy to become muddled, even if the principles were clear.[16] The solution to this was generally to use template tables, heuristics, to as much as possible make the calculation into a comparison.

An example observation with calculation: Pat

At 8:52 am, Pat begins her assessment of a file by saving a copy of an Assessment Report template into the electronic file workbooks on the shared computer drive. She then proceeds to compare the medicinal ingredients in the Application to those available in the *Pharmacopoiea*, by opening the paper submission to the page on which the proposed medicine's ten medicinal ingredients are listed, and turns to the computer to open an electronic version of the *Pharmacopoeia*. For the next while, Pat goes back and forth between these two documents, comparing the names and sources of the medicinal ingredients in the Application with those in the Pharmacopoeia. Pat also ensures that the proper (scientific) names of the medicinal ingredients in the Application are correct, by consulting an electronic database. The correspondence of names and sources established, Pat turned to a comparison of the quantities of the medicinal ingredients in the Application, as compared to the Pharmacopoiea. (N.B. any mistakes in the numbers that follow are mine; I fudged the numbers when I was writing them down, so they would not be identifying).

9:07 a.m. Pat gets out a calculator. Then puts it down. She opens an excel sheet, and enters the quantities from the application in one column, and takes their sum (1135mg). In the second column, Pat divides each quantity in the first column by the sum (1135mg). Pat enters the quantity of each medicinal ingredient as provided in the Pharmacopoiea in the third column of the excel sheet, and takes its sum (8000mg). In the fourth column, she divides each of the pharmacopoeial quantities by their sum (8000mg) -- as illustrated in Figure 13-1.

Figure 13-1: Pat's table

Medicinal Ingredient No.	Application quantity, mg	[divided by 1135]	Pharmacopoeial quantity, mg	[divided by 8000]
1	400	0.35	2800	0.35
2	550	0.48	3920	0.49
3…	185	0.16	1280	0.16
Sum	1135		8000	

The ratios of the quantities matched.

9:09 a.m. "Now I'll compare the claims. If the claims compare, this will be a very simple case." She observes a further detail is required.

9:12 a.m. "Time to check the dose." Looks at the application, reads the pharmacopoeia. Enters 10g for pharmacopoeia in the working assessment report.

9:13 a.m. Flips through pages in the application, gets to the page with the non-medicinal ingredients, and checks the ratio.

9:16 a.m. Consults the *Pharmacopoeia* to find out whether dextrose and sugar are to be found in the preparation, and looks through the doses.

9:17 a.m. Changes the denominator in the table. Goes back to reading the *Pharmacopoeia*.

9:18 a.m. Flips to the specifications sheet in the Application (usually only consulted for quality assessment) and compares.

9:19 a.m. Edits assessment report to read “Composition and dose are the same. Claim is similar…. “ and adds in a note regarding the issue with the non-medicinal ingredients, pointing out that the pharmacopoeial dose with sugar is 10g per bag, with dextrose, sugar and ethanol then added to make granules. In the pharmacopoeial standard, therefore, the percentage of medicinal ingredient in the final product is 70%. This differs from the percentage of medicinal ingredient in the medicine proposed in the Product Licence Application, wherein the percentage of medicinal ingredients in the final product is 43%: the medicinal ingredients are 1135 mg plus non-medicinal ingredients dextrose 1g and sucrose 0.5g. [Scientists may consider the effects of what are frequently considered “non-medicinal ingredients” in the NHPD as a whole but that within a “traditional medical paradigm” are considered to have effects].

9:23 a.m. Sighs. Adds in another sentence to the assessment report: “Confirm with applicant that percentages equivalent. Flow chart required in quality IRN.”

Pat then proceeded to finish the assessment and the report.

As I hope the description of that half hour makes evident, the numbers (dose, ratios, and so on) were important in Pat’s comparative reasoning, but the calculation was configured as documentation to be used in comparison. Pat’s reasoning with numbers, like scientists’ reasoning with other textual standards, was also not strictly linear.

Scientists’ reasoning with number little different than reasoning with texts

Scientists' style of reasoning with number was similar to their style of reasoning with other textual evidentiary standards. Number was used as part of reasoning through taxonomy and comparison (the latter especially) in a non-mentalistic, non-linear, and embodied way, often involving interacting with excel tables, ferreting out information in a stash of calculating aids, or moving one's glance between the application and a standard. The reasoning was also similar in the sense that if they were at all unsure about the appropriateness of a calculation or number (comparison), they sought out the advice as an expert. As Darren explained: "You, like, specialize. You know what you know, what you need to know, to get your job done. That's why other people are there; they're there to help you do your stuff."

Scientists in the Directorate sought the opinion of internal statistics experts or other experts in Health Canada with whom they had acquaintance through personal networks, coursework, or got their colleagues who had such acquaintances to contact these experts. While the Clinical Trials Unit had employed a much-appreciated statistician on staff before the time of my fieldwork, it was widely recognized that there was not enough "real statistics" in the Directorate to maintain a statistician, because, among other things, the Directorate's scientists' questions often pertained to research design, not statistics *per se* because the applicants only very rarely supplied original, unpublished results from clinical trials with "raw" data.[17] When it came to statistical data, rather than a "centre of calculation" (cf. Latour 1993), the Directorate seemed more like a tangle of portals and stashes.

Scientists not strikingly different than "everyday folks"

Scientists' reasoning with number was not strikingly different than the reasoning by "everyday folks" with number as described by two social scientists whose work directed my attention during my fieldwork. Scientists are not less "everyday folks" than non-scientists; reasoning in a cubicle is no less "in setting" than reasoning in a supermarket.

Jean Lave and Helen Verran are two social scientists who have employed empirical methods, namely participant-observation combined with field experiments, to study "everyday" mathematics as part of "banal" and "material" routines of life. Both argue against the individualistic and mentalistic accounts of rational number use in cognitive science, developmental psychology, and philosophy of science, and instead focus on the performance and enactment of number in "everyday life." Neither author privileges "scientific" mathematics in her analysis, but explores the ways in which different forms of arithmetic do or do not overlap. The theoretical language they use to analyze their fieldwork is different, but both researchers emphasize the importance of counting and calculating as an *activity* inseparable from "setting" and/or social relations. Lave, for instance, emphasizes how, when looking at math "in action," the problem and the answer are often co-constituted, rather than proceeding in a linear arrangement as they are in school mathematics; it is from her I have taken much of the formulation used in my description of scientists' reasoning with number. Both Lave and Verran argue that the availability of materials often changes the process and results of mathematical

actions (e.g. Lave 1986), although Verran emphasizes the correlation between varied social experiences and varied arithmetic proficiency.[18] Where Lave's analyses tend to highlight the importance of incommensurability, those of Verran explicitly address the way in which multiple logics and numbers are used by a single reasoner. Because the work of these two scholars provided a model for scientists' "everyday" reasoning with number, I provide a detailed account of the work of each.

In the 1970s, Jean Lave conducted research among Vai and Gola apprentice tailors to investigate the arithmetic processes these tailors used. These tailors had varying experience as tailors and with education, both formal and apprenticeship. She and a colleague used observation and field experiments, with the latter including paper-based "testing" asking tailors, for instance, how many buttons would be required for five suits if each required five buttons, or how much change should be given to a customer. The experiments were designed to "diagnose" the calculating process used by the tailors via the types of errors systematically made. Lave and her colleague concluded that tailors tended to make errors where there were fewer "social costs" of mistakes, for example making magnitude of error mistakes in school-based arithmetic but not in the tailor shop. Although Lave and Reed observed many "coexisting arithmetic systems" used by the same tailor, different systems were rarely used for the same application. Rather, the systems were distributed across activities. For example, the system a tailor used in money exchange might be different from that he used in tailoring (Reed and Lave 1979).

This observation with respect to incommensurability is also present in some of Lave's later work in the US. She describes US American families' practice of having multiple "stashes" of money for different purposes (pocket-money, gifts, household expenses, etc.) as a way of embedding incommensurability into the setting, rather than, say, tallied in a ledger (Lave 1988).[19] Lave's emphasis on the way in which this incommensurability is managed by physical actions was something that I observed, at least in electronic stashes, if not physical stashes.

Lave is preoccupied with how "cognition" observed in everyday practice is distributed -- stretched over, not divided among -- mind, body, activity and culturally organized settings" (1988:1). Lave's emphasis is on the "person-acting-in-setting" (1986:99). Her studies of number are situated in specific "arenas," the "public and durable entity" such as a supermarket, in which the action takes place; the "setting" takes into account that the arena is experienced differently by various people (1986). (It is from her work that I believe I have drawn my focus on scientists' reasoning in their cubicles, although I have used the phrase "environmental form," drawing from Thévenot 1984, instead of "arena," because attention to "arenas" in the sociology of science has a more discursive than material emphasis). One of Lave's most cited discussions of the importance of "setting" in arithmetic is her study of the math done by US adults while shopping (Lave, Murtaugh and de la Rocha 1984) and while cooking according to Weight Watchers stipulations (Lave 1986, 1988). Both studies involved a combination of

observation and field experiments. She provides an explanation for why the 25 “expert” Californian shoppers scored 59% on a paper-based arithmetic test, but correctly solved 98% of analogous problems while shopping. (This is a difference in scores, that has been found in many studies of arithmetic in the marketplace). She argues that the difference is in part due to the way the shoppers used linear and place-holding arithmetic on the paper and pencil test, but used “dialectic,” or “gap-closing” arithmetic in the store. In the latter type of arithmetic, she argues, the problem and solution are generated simultaneously, in a kind of dialectical relationship. Thus, arithmetic in the supermarket was “activity in setting” (Lave, Murtaugh and de la Rocha 1984), in which the setting acted as a “calculating device,” structured a series of actions, and shaped how shoppers approached and constituted the “problem.” Arithmetic with numbers only came into play in shopper’s decisions when there were alternatives that were equally satisfying on other grounds, and “a choice on qualitative grounds appeared arbitrary” (Lave 1986:103). A vivid anecdote from her study of Weight Watchers should suffice to illustrate this “arithmetic in setting.” A participant in the Weight Watchers study was asked: if you needed to use 3/4 of the 2/3 cup Weight-Watchers allotment of cottage cheese, how much would you need? After musing about having taken calculus, the participant measured out 2/3 a cup of cottage cheese, dumped it onto a plate, patted it into a circle, cut it into quadrants and removed one quadrant: the remaining cottage cheese was the solution. (Paper-based methods might have also produced the same result, 1/2 cup). That anecdote nicely encapsulates Lave’s approach to cognition, arithmetic and number as situated activity.

Helen Verran uses a similar combination of research methods in her study of Yoruba and English systems of numbering, with the addition of historical research (2001). Her central analytical concerns in *Science and an African logic*, however, are quite different from those of Lave. As I described in Chapter 9, Verran emphasizes the way in which students managed – even played with – *differences* in numbering and generalizing logics, rather than documenting the way in which incommensurability was created. Specifically, she gives accounts of number, logic, and certainty "within an imaginary where worlds emerge in collective acting," in rituals re-enacted in physical contexts, in which only *embodied* certainty is relevant. She tells number *as* social relations, drawing from the work of Marilyn Strathern (1995), but possibly also indexing the work of Bruno Latour.[20]

While "determined to keep these generalizations as objects," Verran is "equally determined to abandon their status as *abstract* objects" (2001:157). This analytical approach many parallels to philosopher Isabelle Stengers' approach:

> Abstraction is not the product of an "abstract way of seeing things." It has nothing psychological or methodological about it. It is relative to the invention of an experimental practice that distinguishes it from one fiction among others while "creating" a fact that singularizes one class of phenomena among others. (2000:86)

This analytical move permits Stengers to analyze various facets of science without reproducing the hierarchical asymmetry between the "abstract" and the "experimental." Likewise, Verran makes a similar analytical move, in her description of number as *real*, but changing "the metaphors and narratives that lie

at the heart of stories about realness" (2001:35). She does this through changing the "framing" of the stories she tells about number from many previous ones. She attempts to do so in such a way that the "real" is "emergent" in the "gradually clotting and eventually routinized collective acting, and not only human acting" (37). Both Verran and Stengers emphasize the continuous nature of this process. For instance, Verran argues that the "objects/subjects [that are] outcomes of past collective going-on […] participate in remaking particular times and places as (re) generating worlds" (2001:94). Verran approaches number as inseparable from, or essentially *being*, routines and social relationships.

Number and the clinical trial

While Jean Lave and Helen Verran approach number as embedded in routines and social relationships, this is at odds with the rhetorical and ideological uses of number in vernacular representations of science and medicine. Statistics have a privileged place in evidence-based medicine, and other late-twentieth-century "transparency" phenomena more generally in Anglophone countries (Porter 1994), precisely because they are approached as entirely separate from, or even the antidote to, social relationships, interests, biases (Porter 1995, Daston 1992). The Canadian research community that is coeval with the NHPD is no exception;[21] openness to "innovation" in clinical trials, such as n-of-1 clinical trials, was proposed by the Directorate's officials as a means of obtaining these numbers in a

manner consistent with the individualized focus of various non-biomedical healing paradigms.[22]

Fieldwork in the Clinical Trials Unit

My fieldwork in the Directorate's Clinical Trials Unit was a last-ditch attempt to find scientists reasoning in the pre-market evaluation of medicines by transforming statistics. I did not work in the unit; my fieldwork consisted only of observing via cubicle visits, hanging out, interviewing, and the examining five full Clinical Trial Application files including the safety and efficacy assessment reports.[23] At the time of my observations, the Unit was a highly cohesive group of seven workers, many of whom lunched together daily, and a few socialized off work time.[24]

The Clinical Trials Unit constituted a different culture of evaluation than other units in the pre-market review of medicines at the NHPD, although the rote explanations of evaluation as described in Chapter 4 were the same (in terms of four levels, and as based on regulation).[25] The difference in approach was in part because of the partially different reasoning activities into which the scientists were interpellated. Not only were there fewer applications – only a hundred or so in the first three and a half years of operation – but there were fewer scientists involved and the Unit Head had been a member of the Unit for a few years and the scientist in the level above the Unit Head had also been present for a few years. Also, scientists in the Clinical Trials Unit would spend a month or more researching and writing a safety and efficacy assessment report that was the basis for recommending the

authorization of the clinical trial. Another difference was that scientists in the Clinical Trials Unit did not base their decision solely on what was included in the five-centimetre-thick file that constituted and application for authorization to conduct a clinical trial; they were expected to do research. In their safety and efficacy evaluations, the scientists would summarize the application, research the endpoint measures and relevant clinical guidelines, keeping many considerations in mind and "writing a little review article" in the words of one scientist. Scientists approached the work in different ways. One scientist would start by "trying to see what they want, what they're after;" another would read the documents in the file in a systematic order; yet another would act as a detective, examining the file "knowing there's something wrong," with the task being to find whatever was wrong. The final assessment reports, on the other hand, seemed to be uniform based on the sample I read, probably because the scientists consulted with each other on a regular basis, would review the reports of others, and all work was supervised by one unit head. Because of this – or so I would argue – there was no emphasis on standard operating procedures; there were no concerns with consistency because, I suspect, general sociability in a clear hierarchy was sufficient in this smaller and more closely knit unit, and furthermore there were simply fewer applications and near zero chance that an applicant would submit exactly the same application twice, undetected, as happened in the product licencing side.[26] These differences in evaluation activities meant that different sorts of attentions, interests were valued and sought compared to those sought in other assessment units; it had a different culture of evaluation.[27]

The puzzle, re-occuring in the Clinical Trials Unit

In the Unit, scientists' approaches to reasoning with statistics in the Clinical Trial Applications they were evaluating varied widely. According to Patti, some of the Unit's scientists "take forever and pick out everything," whereas she assumed the the applicant consulted a statistician who was more competent than herself, and so she "just check[s] the n value to make sure that the trial is big enough, has enough power… that takes two seconds." Despite this variety, all of the unit members (past and present) with whom I spoke had the same interpretation of one regulation – and interpretation with which I disagreed, and even found shocking when I first heard it. I am convinced, however, that had I been an employee in the unit, I might still have disagreed but I would have been interpellated into exactly the same interpretation and reasoning, because by virtue of the reasoning activities I would have been brought into the same *social* position as were the regulators in the unit. The next part of this chapter explains how and why.

The regulation[28]

The interpretation in question has to do with whether the evaluation of the statistical analysis proposed in clinical trial applications falls into the ambit of the scientists' work. I had assumed it would, because in the *Natural Health Products Regulations*, clause 67 states: for a clinical trial to be authorized, there needs to be reasonable grounds to believe that the objectives of the clinical trial will be met.

And as Louise, a member of the unit, stated, “part of the objective being met is [that] they have the right statistics.”

When I began interviewing the unit’s past and present scientists, however, saying that I wanted to look at how statistics were analyzed, right away they told me that I was going to be very disappointed. Their involvement with statistics, they clarified, was limited to the verification of sample size, which was only really important in phase three trials for which, they reported, they did not receive many applications. They characterized the majority of the Clinical Trial Applications received at the NHPD to be pilot studies. There were no expectations that pilot studies would necessarily meet the requirement of statistical significance produce *facts*, although evaluators generally hoped they would produce *findings*.[29] Even when scientists received a phase three trial, they explained they usually used the simplest methods available to verify that the sample size was not grossly inappropriate.[30] The statistical analysis proposed by the trial, they all stated, was something that they did not really have the authority to look at, because: “well, it does not affect the safety of the subjects;” “it is something that could be changed after the fact” [authorization]; “it’s not really in the regulations”; “once we tried but we didn’t get anywhere”; “they don’t listen to us anyways”; “they are the experts, what are we to say.” It seemed to me they jumped from justification to justification, although I got the sense that this explanation was seemed perfectly reasonable to them; these were not excuses, nor post-hoc rationales borne from buck-passing. I believe the rationales are unified and sensical when one looks at them as statements

indicating the ambit of scientists' efficacy – their authority – as they perceived it. The point of this analysis is not whose interpretation is "correct," but rather to explore what brought all the scientists to make the same conclusion, judgement. I do so by describing the messy intersection of dispositions, mantras, and social position into which the evaluators were interpellated by virtue of their work activities.

Authoritative dispositions

In the Clinical Trials Unit, most employees expressed the public servant disposition that "we're here to help." This disposition, a desire to be of help, was often read as a breach of etiquette on the part of the applicants, who had a different opinion on the social role of the regulators, and more precisely, the boundary beyond which regulators should not and could not comment. In the context of this disposition on the part of scientists, the unit members all articulated a key decisional nexus in their evaluation work. One the one hand, they repeated, "we need to ensure the safety of clinical trial participants," and on the other, "we can't make it too difficult," with "it" referring to authorization.

"We have to assure the safety of clinical trial participants" was a phrase expressing the fundamental purpose of the unit, and was frequently repeated by scientific staff as rationale and as guiding principle, in a way that made it a standard, a bar, typical of my imagined public health protection of the mid-twentieth century. (Indeed, to my surprise, I never heard the phrase "risk-benefit ratio" in the Clinical

Trial Unit, although I was listening for it).[31] In the evaluation process, scientists could and would require that the applicant change the protocol – to add extra safeguards or monitoring, or to change the proposed population to be represented in the study (participants with metabolic syndrome were of particular concern during the time of my fieldwork) – until the scientist felt that the safety of the clinical trial participants would be ensured.

The use of this mantra served its purpose to refocus scientists' attention on what mattered most in their evaluations. It was easy for scientists to get distracted in a regulatory environment where the applications submitted for clinical trials were rife with mistakes – spelling errors, discrepancies in how many weeks the trial would last, the objectives of the study changing from document to document.[32] To give an example of the type of applications the scientists were working with, I observed one assessor who was clearly frustrated and confused by discrepancies with implications for safety and informed consent within one application: was the study going to last 13 weeks as stated in the Investigator's Brochure, 18 weeks as stated in the Protocol, or 12 weeks as stated in the Informed Consent form?[33]

The corollary of this strong sense of purpose was that anything other than participants' safety was less important. It is therefore unsurprising in this context that the regulatory clause mentioning a reasonable chance that the study would meet its objectives was de-emphasized. For instance, one newer assessment officer noted that although most statistics in the clinical trial applications seemed to

be very basic, once she had assessed a trial proposing statistical techniques that her beyond her level of expertise. I asked what she had done, and she replied: “Because there were other people who […] considered that it did not affect the safety of patients, it was unnecessary to go further into analyzing” (Frieda). This was a common refrain.

The other valence of the decisional nexus, “we can’t make it too difficult,” I call a mantra because the phrase appeared to be used in assessment during moments of trying to decide what mattered in situations of uncertainty; it was used to refocus reasoning activities towards problems that fell within the ambit of the scientific regulator’s job. “We can’t make it too difficult” helped interpellate scientists into the correct dispositions for reasoning in the Unit. The mantra indexed the core value of research: “research is a good thing,” “you can’t be against research,” “we want to encourage research in Canada.” I was told that if an application for a clinical trial were to be refused, it was almost guaranteed that the applicant would call the Minister, and if “it’s perceived that research is being blocked, the politicians usually jump really high” (Alma). If regulatory scientists made the process “too difficult” by pointing out too many discrepancies in the application or asking for information not directly linked to the Unit’s main purpose as they conceived it, the Unit members told me that the applicant would complain to the assessor’s superiors, give up on the trial, or drop the Canadian arm of the trial (if it were an international trial) – all potential actions which went against the disposition of the unit members to help, to value research in Canada. So, they reasoned, “we can’t make it too difficult.”

This reasoning was inseparable from scientists' self-assessments of their authority as regulators, self-assessments that were in turn inseparable from the perpetual contestation of regulatory scientists' authority by applicants. The applicants for proposed clinical trials – at the time, about half from academia, and half from industry – complained regularly. These complaints did not pertain to the regulators' quality of work but rather their processes and ambit of authority. Regulators also recognized that most times, the clinical trial application had *already* been peer-reviewed by prestigious funding agencies such as CIHR, ethics boards, the applicants' academic peers; in many cases, the applicants from academia were world-recognized men experts. In challenging non-safety elements of proposed trial, the Unit's scientists, who were hired as applied biologists and not medical doctors, who were mostly in their thirties, and the majority of whom were women, would be challenging all those experts. The Unit's scientists responded to their position in this social web by defining their role to be to raise "red flags," but not to prescribe exactly what should be done, "especially on something like statistics because it is *merely* scientific opinion" (Louise.)

A formative experience for the Unit, that several scientists recounted, occurred when an applicant proposed to use a blatantly incorrect statistical analysis – there was no "variety of scientific opinion" in this case; it was wrong. The Unit asked a statistical expert from another branch of Health Canada to comment and this expert wrote a formal expert opinion explaining what exactly would need to be

done in the statistical analysis for the study's objectives to be met. The unit – helpfully – sent this expert opinion to the applicant. The applicant, in turn, completely ignored the expert comment. The trial was authorized with the incorrect statistical analysis in the application.

I asked one Unit scientist recounting this narrative, "But you couldn't just force it on them?" The scientist's reply underscores the inseparability of reasoning from the scientist's social position:

> Well, it was, well, ok, that is a very good question.
>
> We chose not to pursue it *ok* because at the end of the day there is no harm to subjects, and at the end of the day it doesn't really impact efficacy because like I said they'll have the data set, and they'll just decide to reanalyze it. In terms of our focus as regulators, efficacy and safety have been met *ok* so we're almost now crossing our boundaries.
>
> So that is what we struggle with. You want to do it all. You want to comment on everything – but you have to bring yourself back to what we are at the end of the day. You're a regulator. Safety and efficacy have been met, so you're done. So, ya. Like I said when we do raise the flag, they come back and they're hostile and don't change anything. Then we're like, okay, well at least we raised it. They know about our concerns and they chose not to address it. We did what we could at this point, right? So it's a struggle. It's a struggle.

There had been heated discussion within the Unit, and between the Units' scientists and applicants. This did not result in the applicant following the recommendations. Louise conjectured this was because:

> they see us as a regulator and not as a scientist. And they see that there is a fine line between the two and we should not be crossing it. And so I do what I can to apply the regulations so they realize that we're truly applying the regulations.

Back to the anthropological literature

What of these disappearing numbers? Anthropologists have been unable to get closer to medical statistics before. This is inapproachability is not in any "black box" or "forbidding" sense, but in the sense that as one approaches the numbers they are no longer there – in looking closely at a number, one slips to the other side of the looking glass.[34] This seems to have happened to many medical anthropologists (Lock 1998, Kohrman 2003, Adams 2005). Vincanne Adams, for instance, attributes the apparently baseless source of rates of maternal mortality in Tibet to a scientific epistemology that predates the apparatus to produce and track the numbers (Adams 2005).[35] Other reasons for the disappearance of the basis of numbers include estimation (Kohrman 2003, Mathews 2008), the proprietary nature of numbers (Lakoff 2005), cultures of secrecy or bureaucratic avoidance (Petryna 2002), and the distributed (Mol 2002) nature of number production, in either a figurative or geographic sense. Many of those reasons involve a conscious acknowledgement of something that existed, but for whatever reason could not be explicitly stated.

The inapproachability of clinical trial statistics in my fieldsite was of a different type. This is not because I was studying scientists, and the other anthropologists were not; I would argue that this was because the inapproachability of number has less to do with any qualities inherent in numbers themselves, but everything to do with the style of reasoning in which they were embedded. The scientists I studied reasoned in a very different thought collective than the ones, say, studied by

Vincanne Adams in Tibet (2005). The scientists I interviewed showed little restraint in stating their theoretical objections or calculations in interview and other exchanges with me, the observing anthropologist. They had tried reasoning, in their evaluation work, along those avenues; they had found the results of reasoning in that way, unreasonable. They were simply not in a position to wield calculations and statistics in clinical trials authoritatively, and because there was no reason for them to calculate for aesthetic reasons or pleasure, those calculations and statistics became unapproachable. What remained was to follow the only option, a pragmatic one. (Pragmatic, as in addressing practical rather than theoretical considerations). They worked to ensure the safety of clinical trial participants, and to not block research; this largely entailed that they did not comment on the statistical analysis proposed in a clinical trial application. Calculations pertaining to the statistics in clinical trials were not workable in the style of reasoning into which the scientists were interpellated, largely, I argue, because of the social position of (limited) authority they were placed by virtue of their reasoning activities.

I will return to the question of authority below, but there are also some larger considerations. That numbers such as p-values are that which is most important in a clinical trial, I would suspect, is a conviction that is (1) held more frequently in the periphery of biomedical thought collectives, to use Fleck's terminology, and also (2) culture-bound. Marcia Meldrum (1994) highlights the disjuncture between various actors' interpretation of trials results using the example of the large-scale testing of a polio vaccine in the early to mid 1950s; the trial, which was largely viewed in the

public eye as a success, was indicted by the lead investigator who stated that "[f] rom these data it is not possible to select a single value giving numerical expression…. to the effectiveness of vaccine as a total experience" (Francis et al. 1955:49-50 quoted in Meldrum 1994:162). There are numbers involved with competent randomized clinical trial reporting and analysis that no competent reasoner would deny. But to get to the numbers, at least for those closer to the centre, the vanguard, of the thought collective, so much else needs to be addressed before a discussion of number can occur. To dispel the idea that achieving statistical significance had always been the goal of randomized experimentation, and to explain the ambit of the randomized controlled trial internationally to discuss NHPD scientists (lack of) authority; all these projects are accomplished by a brief history of the randomized clinical trial.

Origins of the randomized clinical trial

The idea of the "randomized trial" was initiated in the realm of agricultural testing by R.A. Fisher, who envisaged experimentation as a *process* of trials. Measures of significance, for Fisher, were only interpretable in the context of replicated experiments (Gigerenzer et al. 1989). Fisher claimed randomization gives a valid estimate of error (Cochran 1976:18-19), without which it was difficult to draw conclusions from a trial. He emphasized randomization to the extent that he would not accept the epidemiological findings linking cancer and smoking, because he argued that only a randomized experiment could settle the question (Gigerenzer

1989:262). (Gigerenzer also notes that Fisher accepted money from tobacco corporations).

Although many subsequent authors in biomedicine claim to draw from Fisher, the purpose of randomization and p-values were very different for Fisher and for medical reformers in the mid-century (Marks 1997). For Fisher in his agricultural experiments, randomization was a *precondition* for interpretation, as it provided parameters on error and limited the effects of “objective” bias (i.e. fertility gradients in soil); the reduction of “objective” bias was not through randomization itself but through the replication of the randomized experiments. For later medical reformers, Marks argues, randomization reduced the effects of “subjective” bias, specifically the expectations of the clinician. Furthermore, while Fisher mentioned p-values, he did not provide a standard p-value for acceptance. For Fisher, p-values could only be interpreted as part of a long series of trials in the sciences, although he often used 5% because it was “convenient” (Cochran 1976). The idea that there is a threshold value to be used was developed by Egon S. Pearson (the son of Karl Pearson) and Jerzy Neyman as part of their introduction of hypothesis testing in statistics. This use of the threshold value is not necessarily tied to seeing an experiment as part of a series (Neyman 1976). For instance, Neyman also developed the idea of confidence intervals, now common in the reporting of randomized clinical trials, in the 1930s; these, likewise, do not require interpretation in terms of a series of experiments (Neyman 1976).

Although historians disagree on the precise moment of the intersection of clinical experimentation and quantification in European medicine, there is a consensus that the randomized clinical trial emerged in the 1940s. Historians give various reasons for the rise of the randomized clinical trial, including: the sway in public opinion with the advent of potent, industrially-produced antibiotics (Matthews 1995); the objectification of disease coproduced with bacteriology (Meldrum 1994);[36] the wartime conditions of scarcity (Marks 1997).[37] At any rate, it was first defined in the literature in 1946, and adopted by a government in the evaluation of medicines in 1970 (Meldrum 1994).

The randomized clinical trial became increasingly influential following the publication of the *Final report of the drug efficacy study to the Commissioner of Food and Drugs, Food and Drugs Administration* (FDA), when the US FDA published its requirements for the "substantial evidence" substantiating a manufacturer's claim of efficacy for new drugs. These US requirements effectively institutionalized the randomized clinical trial (Meldrum 1994, Marks 1997). Since the early 1990s, the UK, the EU, and Japan have created international standards for national government evaluation of drugs – through the International Council on Harmonization (ICH) – and these requirements are increasingly becoming global as other countries comply with the standards in the ICH.[38]

Anthropologists have asserted that the "international" requirements have a thoroughly US American base because the US American market for

pharmaceuticals dwarfs any other; the “international” requirements often entail the export of US institutions such as the research ethics board (Adams et al. 2005, Petryna 2005, 2009). Through these and other studies, readers learn that the RCT itself has been anything but static since the 1970s. Changes in what is perceived to be a suitable control (for histories of the placebo, see de Craen et al. 1999, Harrington 1997), the conceptualization of trial phases, new entities such as data monitoring committees (Keating and Cambrosio 2005), and formalized ethics procedures (Corrigan 2002, 2003, Adams et al. 2005, Fisher 2005a) have changed the RCT.[39] New configurations of trials jointly conducted in academia and industry, as well as changes in the pharmaceutical testing industry towards the increased use of contract-testing agencies in the late 1990s, affect who is included in the tests, and which results get disseminated (Petryna 2006, Fisher 2005b, 2006, 2008a, 2008b, 2009). New formalized ways of evaluating the reporting of RCT (Jadad et al. 1996), and of synthesizing results from many RCTs such as the systematic review and meta-analyses (Hunt 1997), have been co-produced with the evidence-based medicine movement in North America and Europe. Social scientists have examined the results of randomized clinical trials have become an integral part of the web of standardized information in evidence-based medicine (EBM) that – through protocols (e.g. Berg 1998, Dodier 1998), clinical guidelines (e.g., Weisz et al. 2007, Knaapen et al. 2010), and technology assessment – is intended to affect clinical practice and policy (Pawson 2002). (And EBM seems to at least be effective in policy, if only for “tranquility for the decision-maker”(Colson 1973) or “transparency” (Porter 1992a)[40]). The tracking of the international

distribution of clinical sites for RCT is proving to be a crucial anthropological project (Petryna 2006). Recently, anthropologists have detailed the distribution of risks associated with clinical trials – noting how they tend to burden those with the least socioeconomic status within national boundaries (Fisher 2005a, 2009), in the international hierarchies of medical traditions (Adams 2005), and through the global economy (Petryna 2006).

This international harmonization lends authority to regulatory scientists working in those domains, as I discuss below. This international harmonization, however, does not mean that "the rules" are the same in each country. Arthur Daemmrich argues that, in the late 1970s, a new law was passed in Germany that made the evaluation of the safety and efficacy of a drug inseparable from clinical trials like in the US; "unlike in America, however, the criterion that tests follow "knowledge and methods currently available to medical science" was used less to mandate government control over a rigid methodology of double-blinded, clinically controlled trials that to grant official recognition to the profession authority of [physicians]" (2003b:30-31). In the US, Daemmrich as well as sociologists point to an important shift in the 1990s wherein the role of the regulator shifted from protection of the vulnerable, to facilitating consumers' own risk-management.[41]

The privileged place of statistics is clearly culturally-embedded. Everywhere, reasoning – including reasoning with numbers in the randomized clinical trial – is inseparable from thought collectives and their particular social position. The

specific numbers in produced in a randomized clinical trial perhaps do not hold the same significance outside specific cultural arenas; or at least perhaps the anthropologist should not expect them to. Fleck highlights the importance of thought-styles in basic actions such as counting. In a telling example, he outlines how an earlier anatomist gave detailed descriptions and counts of many bones, muscles, veins etc. of the human body, yet how in 1937:

> such counting is impossible, since we often regard it as arbitrary whether three bones or four, for instance, can be separately identified in a given articulation. But thought styles exist in which the number, just like the name of the object described, is important not as a means of description but in its own right. Only a vestige of such number mysticism remains with Fontanus [the anatomist in question]. But in many thought styles such as the Indian thought style and that of the Chinese, such a system was elaborated until it formed a rich number cabala, in which numbers were accorded special signification and meaningful connections were established among them [Fleck 1979:139].

Fleck also argues that when thought styles are so divergent, common understanding is impossible. Even when counting is possible (such as with p-values), how these counts matter to the vanguard and periphery of a thought collective may differ.

International harmonization and authority

I presented an earlier version of my findings from my fieldwork in the Clinical Trials Unit at a conference with several Health Canada evaluators from other Directorates, as well as anthropologists who had done fieldwork in other parts of Health Canada. Their response was: “Oh it is so different at TPD, at BGTD,” the NHPD’s sister directorates in the Health Products and Food Branch.[42] On the one hand, I would argue that this difference may be related to what one is analyzing:

textual standards themselves, or textual standards in action. I am skeptical that work quotas, backlogs, concerns for fairness, and so on are less relevant among the style of reasoning at TPD, than NHPD. (I would also contend that TPD officials cannot really fairly comment on the comparison until they have permitted an anthropologist to do fieldwork among evaluators!)

On the other hand, there are important differences between the process of authorizing clinical trials at the NHPD and at TPD. For instance, because I was interested in the affective side of uncertainty in one's worklife, if I could slip the question into conversation or interview, I would ask evaluators whether they lost any sleep over their decisions. There were only a few at NHPD who said they did, and these almost all related to intrerpersonal matters such as staffing action, not evaluations. Scientific staff at the NHPD also frequently scoffed at the question. The evaluators at TPD who I asked not only did not scoff at the question but also detailed how they lost sleep or managed their work so that they did not lose sleep. There are a few possible reasons for this difference.[43] At TPD, there were more first-in-human studies, and, I would argue, for certain chemicals "ensuring the safety of clinical trial participants" might be more than evaluators could do at TPD, armed only with animal studies. There was also the issue of the products themselves; in some cases products proposed for clinical testing at the NHPD were foods (fish oil, yoghurt) in which human consumption was going to be ongoing, in large quantities, outside the confines of the clinical trial. Another reason, indicated by two evaluators at NHPD who consulted their colleagues

whenever they were unsure, was the certainty emerging with social consensus and support. But the difference in which I am interested is specifically the position of authority (or lack thereof) into which the assessors are interpellated. This does not, exactly have to do with changing moral economies and labour in calculation in general[44][45] and in the randomized controlled trial in particular (e.g. Meldrum 1994, Marks 1997),[46] although it does have something to do with labour markets. The authority of TPD reviewers, by virtue of training, position *and* international harmonization, was different.

Projected authority of TPD reviewers

The review units at TPD, according to an NHPD scientist, are very stable and have experienced staff:

> Because not only are they all [in higher-ranked positions than at the NHPD], they also get a medical bonus for doing clinical trial applications, so what's the motivation to leave? You know it is an interesting job, it's really well paid, they get a bonus.[47] So the other Health Canada directorates doing clinical trials they have very experienced, very well–qualified assessment units [in which] there's no turnover. So after years of years of doing [reviews of clinical trial applications] – and you can imagine how good these people are, I mean they're very skilled. They know the clients and everything else.

Among reviewers at TPD, there were medical officers – medical doctors with licence to practice in Canada – as well as medical doctors trained in other countries and hired as applied biologists. There were also many senior research scientists at Health Canada working as reviewers.[48] They had authority by virtue of experience and position. But to continue with words of the scientist quoted above, "I mean that's one thing: and then the processes are completely different."

The clearest determinant of the authority, was different processes – specifically, different social positions enabled by international harmonization. This was because, on the therapeutic product side, if a Clinical Trial Application were ever *rejected*, that rejection would need to be reported to any other national regulatory agencies in which the applicant was subsequently seeking permissions. This, I believe, gave the reviewers considerable authority. I was told that if a reviewer at TPD had serious concerns about an application, she or he would get on the phone with the applicant, explain that she or he had some serious concerns and that while she or he was sending written correspondence to the applicant detailing these concerns, if the applicant could not address the concerns in the allowable window of time (e.g. 48 hours), that the reviewer *strongly* suggested that the applicant voluntarily withdraw the application to have time to put the data package together and then make a separate application. (This way, such an unsuitable application was never technically rejected – if an applicant withdrew the application, it was as if the application never existed.[49]) This authority is inseparable from the position into which the TPD reviewers were interpellated by virtue of the activity being harmonized internationally. Conversely, the reviewers of clinical trial applications at the NHP, found they had to cite studies supporting their safety or other concerns, and even then, this did not always bring them into a sufficiently authoritative position to convince the applicant to take their concerns seriously.[50] The end result of the NHPD's style of reasoning was that, as Louise put it, "there isn't much started unless it's really off the wall." The numbers and statistics in the randomized clinical trial were, to some extent, no more than a "specific figuring of relationalities

in acts and expressing the embodied certainty of collective acting" (Verran 2001:275). Collective acting had been harmonized for clinical trials of synthesized or prescription drugs; collective acting was only possible on a much smaller scale for clinical trials of naturally-occurring medicinal ingredients.

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1 While anthropologists have long studied measurement, number, and arithmetic, with the exception of a few monographs dealing with the subject of "number"(e.g., Crump 1991) or "risk," most of the findings are written up in a few pages, or at most a chapter, in a monograph or article addressing some other subject.

The In the work of medical anthropologists, "measurement," "number," "statistics," and "arithmetic" are rarely keywords in databases or in indexes. There are few controversies specific to discussions of "number in medicine," as, until recently, there had been no focused exchange other than that pertaining to risk, especially the intersection of genetics and risk (e.g. Lock 1998, Kaufert 2000, Rapp 2000, Petryna 2002, Finkler 2003).

There are established research programmes in sister disciplines in the social studies of science addressing risk, statistics, probability, and the history of clinical trials, as well as related discussions of objectivity and standardization in medical science. One such programme is well-documented in the edited collection *The Probabilistic Revolution* (Krüger et al 1987a, b); a few other programmes are described in subsequent endnotes.

2 Formulation from Hallpike's conclusion that "ideas of number and measurement, like those of space, time, and causality, do not just emerge ready-made from the recesses of the mind, nor are they imposed by the categories of the culture; they depend for their development on the kinds of problems that have to be solved and the means available for their solution" (1979:253).

Contemporary with these more recent works in social anthropology was a larger shift in social studies such that "science" begun to be included in the ambit of what might be studied empirically, and what might be problematized (e.g. Latour and Woolgar 1979, Knorr-Cetina 1981; in medical anthropology, Young 1982). This shift is manifested in contemporary studies of the social history of mathematics (see MacKenzie 1978, Mehrtens 1980). For instance, in his formulation of the strong programme in the social studies of science, David Bloor decenters the notion of a culture-free scientific mathematics, asking the question: is there an alternative mathematics? (1991 [1979]) Bloor states that an "alternative mathematics" would be indexed by "systematic, stubborn, basic" errors (1991:109). Although he hints that "[a]n alternative mathematics might be embedded in a whole context of purposes and meanings which were utterly alien to our mathematics. Its point would perhaps seem to us to be barely intelligible" (108), this is not his emphasis. Drawing inspiration from philosophers such as Wittgenstein, who argued that there were many number worlds because there were many cultures, Bloor draws examples from the "number worlds" of Greek and Alexandrian mathematics to illustrate the variation found in mathematics that is attributable to "social causes" by examining differences in "style, meaning, association and standards of cogency" (Bloor 1991:129). As such, he hopes to rid mathematics of its "aura," and encourage studies of mathematics itself; a recent example of this would be a study of the mathematics involved in computing (MacKenzie 1998).

(3 continued from above) Likewise, Bruno Latour has since argued that it is the "logistics" of the numbers on paper that must be studied, rather than "the seemingly miraculous supplement of force gained by scientists thinking hard in their offices" (1987:237). For Latour, numbers are, on the one hand, nothing special in science, and are simply one of the many allies that may be marshaled in support of an argument in science (as politics). On the other hand, numbers, as "inscriptions" or "immutable and combinable mobiles," have a portability, a quite literal portability – they can be sent on paper etc. via longer distances than can, say, biological specimens, or even sentences in French – that enable the "mobilization of actors" on a scale that is different than other allies. A privileged location of research, for Latour, is where these mobile yet relatively stable materials (animals, numbers, plant specimens, maps, etc.) are brought together in one place, where they may be compared, combined, or otherwise manipulated; he calls these locations "centres of calculation." It is at these centres of calculation where iterative social relations converge in the process of inscribing numbers as summaries of other data, and then inscribing numbers as summaries of other numbers, etc. occurs. It is also at these centres of calculation where the higher order inscriptions can be traced back to the lower level ones. The two-way activities at these centres of calculation are what give modern science, which otherwise should be seen as a form of knowledge like any other, its power to "act at a distance." Thus, Latour argues, the distinction among forms of knowledge as "simply a question of scale" (1987:225).

4 Answers included: to compare units (vitamins), potency (homeopathics), concentration, standardization, percent label claim (quality), dilution (homeopathy), purity and acceptable limits (quality), crude dried equivalent (herbals). There were a handful of scientists who stated they did not have, or did not use, a calculator. (There were budget issues during my fieldwork, so some scientists had brought in calculators from home; others used the calculator application on the computer). Then of course there were the joking answers, although the jokes were simultaneously serious: one scientist just occasionally liked to push the buttons, and several scientists in tenuous appointments, to calculate work hours or verify pay.

5 For scientists making judgments based "on the totality of evidence," as Richard explained: "If you read enough articles, you get a sense of if it [the proposed medicine] works and is it safe; it takes more effort to be critical of just one study. So we look at the totality of evidence – you do not have to critically analyze the statistics in each trial."

6 This grouping is not meant to be generalizable to other situations; only as a pragmatic way of discussing the way in which scientists' reasoning in the pre-market evaluation of medicines involved number.

I mention this because Hallpike distinguishes between measurement, in which one is dealing with a part-whole relation that may involve series, and standardization, in which some object is used to mark distance, but is not "susceptible of seriation" (1979:249-252).

7 If I were to consider the features of the scientists' style of reasoning that could be considered *mathematical*, I could work with a wider list, including: algorithms (e.g., SOPs), geometry (floor plans), sets (need a complete set of documents for any application type), modeling (SOPs again, and using on file as an example for another), patterns, and so on.

8 I made many transcription errors regarding fax numbers. Except in one instance, I caught these myself, because I was so worried about sending "confidential business information" to the wrong person that I double- or triple-checked the digits. The same went for the product licence numbers (error once caught by the director general before the licence went out). These were the numbers that I was worried about, in the sense that the accidental substitution of a digit could have legal implications. These digits did not seem to worry my colleagues as much, perhaps because they were generally more attentive to detail or better with remembering sequences of digits.

9 The submission and file and licence numbers, because they were assigned sequentially from the beginning of the Directorate's activities, gave the scientists an idea of when the submission was originally made (which had implications for its likely "messiness"). Likewise, the date of the monograph and the number of information request notices already sent gave the scientist an idea of how complicated the assessment might be. Locations could be deduced from cubicle and phone and fax; organizational ken from position and rank numbers.

10 When scientists really did not know, but had to make a decision based on, say, animal data, scientists took the standard toxicological approach of adding uncertainty factors. This was not really interpreted as statistics, given Reiko's description of number use in a post-market area:

> Well, risk involves the probability of bad things happening. So I guess statistics is involved in that sense. But I don't think that they really use hard numbers. [pause]
> *Why do you think that is?*
> Because they usually don't have that information.

This type of situation did not happen in the premarket evaluation of medicines, where if there was no information a medicine could not be licenced; the situation would occur in the separate Health Hazard Evaluation Unit, that evaluated reported marketplace hazards.

11 Assessment-related electronic spreadsheet template calculators included: the additive tables for combination medicines; vitamin conversion factors; a spreadsheet for milk thistle. There were also many excel spreadsheet templates used to count the number of evaluations completed, to be discussed in the next chapter.

12 These collections of studies were varied and often shared. Another scientist kept a group of journal articles handy: one on samples size determination, another on "Clinical Trial Design Issues: At least 10 things you should look for in clinical trials." Attached with these was an e-mail that had circulated among scientists, a discussion in *Nature* on meta-analysis versus clinical trials for a diabetes drug (dated May 30, 2007). Included in this group of papers was also a piece in the *Medical Post* on "a systemic failure in research governance by Health Canada. Health Canada has delegated its responsibility to protect the rights and welfare of research participants to research ethics boards without establishing standards…" (March 20, 2007).

13 Staff in the Bureau of Clinical Trials and Health Sciences, when they did not have extensive background in statistics, were encouraged to take coursework on statistical analysis internal to Health Canada. A list of courses offered, dated from 2006, included: Introduction to Biostatistics & Epidemiology; ICH E-9: Statistical Principles for Clinical Trials; Analysis of Clinical Trial Data I (Continuous Data); Analysis of Clinical Trial Data II (Categorical Data); Critical Reading of the Medical Literature; Analysis of Time-to-Event Data; Meta-analysis of clinical trials; Non-Inferiority Trials; Safety Assessment in Clinical Trials. Staff tended to keep the handouts and other notes from any courses they attended stashed in their cubicle.

14 From an observation, of a homeopath, who was sitting in front of an application for a proposed medicine with potency of 30CH, and with a textual standard of evidence with the limit listed as 200D:

> Ah… I need to do a calculation. [Thinks].
>
> 30CH is 10^{30}. Nope. 10^{60}. OK [writes it down].
>
> 200D is 10^{200}. [writes it down, expression of frustration].
>
> Oh. [looking at powers]
>
> 60D is 30CH.

15 For instance, one applicant, determined to be able to make a claim that required a certain parthenolide component of the feverfew product (that the feverfew the company was working with did not have), began offering what I can only call creative mathematical operations, like saying: "well, we have two tablets in the daily dose, so we can double the parthenolide percentage claimed for our product."

16 According to the NHPD's *Product Licencing Guidance Document,* the "extraction ratio is always expressed as the quantity of crude material (fresh or dry) to extract, regardless of whether it is a liquid or a solid. For example, a tincture (liquid) ratio of 1:5 means that 1 g of crude dried material was used to prepare 5 mL of extract. In a solid extract, a ratio of 5:1 means that 5 g of crude dried material was used to prepare 1 g of extract" (Health Canada – NHPD 2006a). Sound simple? The document gives the example of 1g of Echinacea that is dissolved in 5mL of ethanol, making a tincture. The applicant should declare this, on the Product Licence application form, as:

> Quantity of *Echinacea purpurea* per dosage unit – 5mL
>
> Extract ratio – 1:5
>
> Quantity crude equivalent (dry) – 1g.
>
> And then one gets into mixtures from master tinctures into subsequent tinctures.

17 Because I had hoped to study statisticians, I asked a few scientists, in interview, whether they felt it would be useful to have a statistician on staff. Most responses, even though they were yes, (one was not), indicated to me that the only difference would be that there might be slightly more frequent consultations of an "expert" (statistician) :

> Yeah! I think it would be very helpful…. Just for the inexact questions. It may not be very common, but uh, when you need them, you need them [31]

> [long pause] Probably, yes. Yes. A statistician for sure. That's a good question because I always try to understand what is going on. So you know, it really is subjective to say whether I need or not more information, because you are limited by field – so you think that you can manage. But a statistician here, I would say yes. I was able to understand basic statistics […] but some have complicated [statistics for which] I don't have the training [40]

> There isn't enough work to keep a statistician. We would go to the statistician all the time, though, with questions. [48]

18 For a similar argument in the sciences regarding the use of solid or liquid fuel in missiles, see MacKenzie (1990:318-20).

19 Medical anthropologists have also observed the effort put into maintaining incommensurability in biomedical sciences – for example, in the effort to keep the "sacred" human life and its counts distinct from cost-benefit analyses (Rock 2004:286-7).

20 Bruno Latour's construal of the "social relationship" is different than Verran's, but it is still there. For instance, in his prescription of how science should be studied, Latour remarks that "[a]lthough it sounds counter-intuitive at first, the more technical and specialised a literature is, the more "social" it becomes, since the *number of associations* necessary to drive readers out and force them into accepting a claim as a fact increase." (1987:62). Of course, he has subsequently spent more than a decade eschewing use of the term "social" as redundant anywhere and everywhere.

21 In the Canadian research community that is coeval with the NHPD, there has been sustained and focused attention on measures used for complementary and alternative medicine (see, for instance, www.incamresearch.ca for a database of outcome measures for complementary and alternative medicine).

22 Openness to "innovation" in clinical trial design has been a frequent response by NHPD officials to the issue of "scientific" evidence being inappropriate for alternative or complementary medicines; the n-of-1 trial in particular, posited as a clinical trial well-suited for medicines tailored individually. When I asked around about n-of-1 trials among scientists inside the Directorate, however, I got variations on Dorrie's response: "all I know is that when industry starts getting all upset at a meeting because of a need for randomized clinical trials, [a manager] is always harping on the n-of-1 trials, saying but we'll accept n-of-1 trials." I believe most scientists would be genuinely delighted to see a file with an n-of-1 trial; that would, however, required that applicants submit them (cf. Kravitz 2008.)

23 I devoted a few weeks to fieldwork in the Clinical Trials Unit in September 2007. I shadowed two safety and efficacy assessment officers in their work, attended the unit meeting and unit luncheons, and interviewed all but one of the unit's workers. I had previously interviewed past employees of the unit, and been walked through the steps for the quality evaluation for clinical trials by a chemist in a related unit.

24 The Unit's labour situation was similar to the products assessment units, in that four of the assessment officers (Bi-03s) were "casual" or on contract, the unit head at the time had been acting for over a year. There were only two employees who "owned" their organizational box as of summer 2007, one of whom was part-time. Despite these high rates of tenuous appointments, the unit seemed relatively unaffected by or uninterested in the reorganization plans of upper management, and thus had less of the sense of impermanence during the time of my fieldwork than assessment units in the Bureau of Product Review and Assessment that I describe in Chapter 17.

25 The "levels" of work in the approval of a clinical trial application were the same as those for product licensing. Thus, the clinical trial applications passed through the hands of the filing clerks in the basement's mailroom, the data entry clerks and the unit's submission co-ordinator for screening (levels one and two). The complete applications were then moved up to the second floor, where the unit head assigned to them to assessment officers for the "L3" (level three) assessment which focused on the Investigator's Brochure, the Protocol, and the Informed Consent form. After correspondence with the applicants to clarify/correct that would be first approved by the unit head and then dispatched back through the submission coordinator, the assessment officer would recommend approval/not which would need to be signed off by the unit head and then the Director, level 4.

26 All evaluations of the safety and efficacy for clinical trials were signed off by a single unit head, and by a single Director. Nevertheless, a dedicated submission co-ordinator had prepared draft Standard Operating Procedures for the screening of the submissions (level 2) and for asking small clarifications of the applicants ('How to Issue a Clarifax' draft); and the unit head had prepared a list of 13 "New SOPs in progress," e.g., the ones that would need to be developed to codify the many tasks of the unit (internal draft document "Natural Health Products Regulations: Designated Authorities for Part 4 – Clinical Trials Involving Human Subjects, draft February 9, 2007). There was also a Draft Standard Operating Procedure for Co-ordinating Joint Review for Clinical Trial applications involving a Therapeutic Combination Product prepared by the Therapeutic Products Directorate. There were only about forty standard lines in the clinical trials tab, most applicable to the screening level.

27 Prior to my fieldwork, there had been substantial movement between the Clinical Trials Unit and other assessment units, as scientists self-assorted to their preferred work environment when the opportunity arose.

28 The need for a separate regulatory regime for clinical trials of natural health products, apart from pharmaceutical drugs, was not the impetus for the change in regulatory regime in the late 1990s. The clinical trial regulations were developed to be similar to those already in place (for drugs), and consistent with the balance of regulations for NHPs. There is very little in the resulting regulations that reads remarkably different than what one might expect of regulations for single chemical entity drugs.

The one major exception is the requirement that the research ethics board approving the trial has at least one member knowledgeable in complementary or alternative health care. This reflects the early NHPD stance in "strongly encourag[ing] that clinical trials be conducted with input of relevant practitioners" (Canada Gazette II 2003:1587). Although in the drafting stage, there had been some discussion of allowing licenced, non-M.D. health practitioners (the ability to be licenced varies province to province) to be the "qualified investigator" in the trials, it was determined that this would be inconsistent with the *Food and Drug Regulations* as well as international ICH guidelines in which the common understanding that the "qualified investigator" must be a medical doctor (Canada Gazette II 2003:1587; answer to question at Information sessions, November 27th, 2003)*.

Another important difference is that the phrase "if any" is included after many categories of information normally required for the investigator's brochure in a clinical trial application; e.g., pharmacological, pharmacokinetic, toxicological, carcinogenicity studies in animals are not always required, because the trials were not generally "first in [hu]man" trials.

There are many presumed differences with TPD's evaluation, both assumed and explicit. I describe the issue of authority in the main text. Another minor difference is that the placebo ingredients must be listed in the CTA to the NHPD, because, mentioned the staff at a public Information Session for Clinical Trials on June 21st, 2005, in a previous application there was a possibly active NHP in the placebo – undergirding the fact that the NHPD does not assume that NHPs, even "spent herbs," have no effect. Other sorts of endpoint measures may also be considered, although I am unclear whether TPD would also consider validated endpoint measures (e.g., I assume they accept well-accepted quality of life measures). At an information session for clinical trial applications, a participant voiced her annoyance at the use of the MD's paradigm, focused on cure, rather than, say, that of an ND who is talking about more than symptoms. The answer provided by NHPD officials was that they are "flexible," and will look at "more holistic end point such as quality of life measures."

*That an M.D. was required to be the qualified investigator was contested at many public information sessions provided by the NHPD. At one on Clinical Trial Applications on June 21st, 2005, a participant from Guelph University (which specializes in functional foods testing) asked why the qualified investigator must be an M.D., because, "they know nothing," a comment which was followed by applause by other participants. After the NHPD presenter replied that the principal investigator could be a naturopath or other practitioner, another participant from Guelph noted that there was a lack of M.D.s, and the M.D.s that there are don't want to participate in clinical trials of natural health products because of insurance issues. [Principal and qualified investigators need not be the same person, although they can be].

29 Allan Young discusses the way in which the numerical results of statistical techniques are interpreted in the process of hypothesis testing in psychiatric research. He observes that psychiatric research, because of its low status among the sciences, has an obligation to meet statistical norms to remain respectable. Nevertheless, Young notes, many results of laboratory studies in psychiatry do not meet the requirements for becoming *facts* – i.e., that they do not meet the standard level of statistical significance (usually $p < 0.05$). Nevertheless, he argues, the results do not necessarily become *discarded results* in psychiatric science. Rather, what he observes is that the results that "miss" statistical significance are often preserved as *findings*, and that in the literature of the biology of traumatic memory, it is these *findings* rather than *facts* that proliferate. This preservation of findings "has permitted psychiatric researchers and writers to buy time for their findings – time to work with them, time to mature them into facts – through connecting them (via research technologies) to fact-rich sciences, such as neuroendocrinology and molecular biology" (1995:272).

30 For instance Emma, when answering an interview question about the sorts of things she did when considering the statistics in trials, stated:

> And actually this is probably not directly answering your question, but I should note that, that was one of my biggest surprises in the unit, was the lack of emphasis on statistical data, considering what I knew of [from previous work.]
>
> *Did you ever approve a CT where you didn't think it was sufficiently powered?*
>
> Uh. [pause]. Well that's hard to say, because our assessment of power was not in my mind rigorous. Um. I don't know if that answers your question. Sort of like they gave you a calculation and it looks somewhat reasonable, so that's fine. Just leave it alone, ya.
>
> *When you were in a position like that, were you didn't agree with the scientific assessment or procedure, at least it sounds like you didn't, what did you do?*
>
> It was not just the sample size, it was not just one situation, it was just like a general comment, where, um, I though we should have more information to be able to assess it better, and that sort of thing. And basically I was told that we just trust that the clinicians have more expertise in that field. At least that was what I was told. So then I do it. So all I would do was take their numbers, make sure their math added up, and approve it. Um [laughing]. So I did mention it – not strongly, I mean I was not in a position to challenge them on it. Ya.
>
> *And is that something that you're comfortable with?*
>
> No. But I'm not uncomfortable enough to rock the boat, let's put it that way. If the whole directorate thinks its fine, then okay.

31 One interviewee suggested this was because, when one was considering authorizing a clinical trial, there was no extant or known "benefit;" the risk-benefit stuff, he suspected, would come in later when the applicant had completed the trial and wanted market authorization for the product (Darren).

32 A scientist recalling the first assessments conducted by the clinical trials unit remarked:

> It was interesting to see how the politics work too. We started sending out a little bit too much. At first we were correcting the spelling which … didn't last long. It was weird though because it was one of those things where like technically it was a legal document, you don't was any mistakes in there, but at the same time, you know they [applicants] get a little testy when we start doing that.

This is, according to another interviewee, a very different situation than posed by applications received at TPD, the sister directorate in the pre-market evaluation of drugs. Whereas at NHPD, scientists were sensitive to the fact that some applicants were graduate students writing on behalf of their professors, I was told that TPD was a different kettle of fish: "no, you guys are trying to make money." At TPD, I was told, spelling is rarely a problem, but "you get the impression that people are trying to hide things […] out in the open, they're very sneaky about it [….] in a 200,000 page document."

33 Naavah explained:

> At the NHPD you really have to be detail-oriented with the files, because they [the applicants] are not professional. And it is not their fault. I mean a lot of the time these professors got their grad students to write up the reports for the government and the grad students don't know because they've never written an investigator's brochure before. So you'll get something gthat says you have 50 people in this study. And you have another part that says 55. And then you'll get something that says it is a parallel study and then it's a crossover study. You know, well, what is it? And how long is the study doing got be because here you have 24 weeks and here 50…

34 Of course, an important note in any anthropological investigation of quantification in health and medicine in general is what is left out (the study of knowledge-non-transfer is also topical in science studies at the moment e.g. Schiebinger 2004). For instance, even traditional measures such as maternal mortality may be omitted in studies because of insufficient participants to provide a "good power calculation" (Adams 2005). The remark that elements get left out of statistics is nothing new, of course – R.A. Fisher employed the term "statistic" to denote a number that represented some group of data, and was interested in measuring the information lost when using these statistics (Hacking 1992a: 49). Indeed, it might be best for the anthropologist not to approach statistics as reductionistic but rather as the creation of a new entity, no more or less complicated with other types of description (cf. Strathern 2004a). However, this issue of erasures and reduction is not quite the same problem as the disappearing trick that statistics may perform.

35 One anthropologist, for instance, began her quest for rates of maternal and infant mortality in Tibet thinking that all that was required was locating the appropriate bureaucracy. Upon approaching the TAR Health Bureau in Lhasa, she was given an average, but told that specific figures for the areas she was studying would have to be found in the Municipal Health Office. She was then directed to the county-level hospitals, but

> [at] the county-level hospitals we found that numbers were everywhere but were nowhere consistent. Each person at each office seemed to have conflicting information or no information at all about the numbers we were trying to collect – that is, until evidence of official government statistics entered the conversation. As if handed down from on high, these numbers were magically brought into the discussion by the Health Bureau physician who had been assigned to work with us. With this information available, all agreed that those government numbers must be correct …. [a] process [that] repeated itself all the way down to the level of the household. [Adams 2005:80]

36 Marcia Meldrum, in *"Departures from the Design": The Randomized Clinical Trial in Historical Context, 1946-1970* discusses the *pragmatic* and variable practice of those involved in randomized controlled trials (Meldrum 1994). In her dissertation, she traces the RCT "in practice" through three historical case examples, arguing that the RCT is a complex technology that is a social exercise in problem solving. She notes that the network and infrastructure of "lay organizations" such as the National Foundation for Infantile Paralysis and the Planned Parenthood foundation were crucial to involving sufficient numbers of subjects in the trials of two of her examples. She also describes how controlled trials may also increase the legitimacy and authority of interventions in the medical literature, even if they do not answer the original question set by the participants. Furthermore, the particular nature of each intervention changes the way in which the trial may be conducted, and/or what it is not possible to test. For instance, very simple and/or "household" methods were not tested in a study of contraceptives, because "[i]t was difficult to establish medical control over their introduction and use" in an RCT; products were easier to have medical control over than other methods (Meldrum 1994:201).

37 Harry Marks discusses the *negotiation* (and persuasion and politics) involved in the project of therapeutic reform in the United States (Marks 1997, especially page 240). *The progress of experiment: science and therapeutic reform in the United States, 1900-1990* (1997) also contrasts the "well-controlled experiment" of the first half of the 20th century, with the idealized controlled trial after World War II (Marks 2000). In the first half of the century, he argues, therapeutic reformers focussed on institutional reforms, standardizing the ways in which data was collected in "cooperative investigations." Physicians, however, were not compliant in following the protocol of these investigations. Marks argued that the reformers then shifted their focus to methodology, and ultimately the role of the policing ended largely in the hands of statisticians by the 1960s. Harry Marks's study of the randomized clinical trial construes the popularity of the randomized clinical trial as a result of the *mistrust* of physicians and of the pharmaceutical industry (2000).

38 The setting of international procedures for obtaining national measures occurs in many domains, including for the international classification of diseases (Bowker and Starr 1999), the measurement of science, including "basic science" (Godin 2003).

39 These phases are an idealized model of how the clinical trials of a new drug should proceed. First there are tests of human pharmacology, including of toxicity (Phase I). This is followed by exploratory studies of the efficacy of the compounds on a small number of people (Phase II). The large, randomized clinical trials are most often those of Phase III, in which a hypothesis is tested. The first three phases, since 1970, have for the most part been required by regulatory agencies *before* marketing approval is given. Phase IV clinical trials are "post-marketing" trials. Peter Keating and Alberto Cambrosio emphasize that the terminology has changed over time, giving the example of earlier US cancer trials (2005). Furthermore, in the General Considerations for Clinical Trials Guidance Document E8 of the ICH, a nosology organized on the purposes of the trials seems to be preferred to the phases.

40 Two scientists in the clinical trial unit also attributed the fact that their assessment work did not keep them up at night, because they were "evidence-based" decision makers.

41 One particular change in the RCT in the US has drawn the sustained attention of sociologists. While patients involved in clinical trials in the 1950s did not necessarily even know that they were involved in a trial, abuses of certain subjects and groups (e.g., prison populations, black men as in the Tuskegee Syphilis Study) began to be denounced in mainstream medical journals in the late 1960s and early 1970s. Thus, many of the "ethics" involved with the trials in the next decade involved the protection of potential and actual participants (for US FDA: Marks 1997: 237 footnote 27). In the early 1990s, "desperate patients" with cancer (Löwy 2000) and AIDS (Epstein 1997) lobbied governments to effect changes in the RCT. In the words of one author, "exceptional practices" were normalized (Löwy 2000:62); most but not all authors attribute this shift at least in part to the work of AIDS activists (Dodier and Barbot 2000, Epstein 1997, cf. Löwy 2000:72). Analyses have now shifted to pay attention to how the systematic exclusion of women, the elderly, and certain ethnic groups because of "lessened" or "altered" metabolism of drugs in the phase I trials may lead to an increase in adverse events these groups experience in later trials (Corrigan 2002b). The lobbying efforts essentially changed the general attitude towards the role of government in trials. It has led towards an emphasis on the *inclusion* of marginalized groups in clinical trials – on patients needing participation – rather than the previous protection of disadvantaged groups – on patients needing protection (see Epstein 2004 for a review). Furthermore, the shift involved changes in methodological design and conduct of trials, but also affecting what could be known about the efficacy of these drugs (Epstein 1997).

42 The comparison between NHPD and TPD was not infrequent, for many reasons. The first was simply genealogical; the NHPD was responsible for evaluating products that had been previously evaluated by TPD. There was also a close connection pertaining to clinical trials in particular. If medicines were new, but naturally-occuring, any clinical trial thereof had to be authorized by the NHPD. Nevertheless, if the recommended conditions of use were going to be best monitored by a physician – if the company, subsequent to the successful completion of the trial, wanted to get prescription-only status for the medicine – it would be TPD that would need to issue the market authorization, not the NHPD. (Because, by regulatory definition, "natural health products" were not on Schedule F, the prescription-only drug list). A third and important reason for the frequent comparison was that large companies would often use the comparison as leverage for changing processes in a way that benefited them. For instance, a few larger companies were interested in having the 30-day assessment limit encorporated into the *Natural Health Products Regulations*. Fourth, the NHPD and TPD were in the same Health Products and Foods Branch, competing for the same budgets, their performance commensurable at the level of the ADM: "There's a rivalry, because, you know, we're dealing with similar products and it is sort of like who's performing best. And if the other directorate is getting a lot of negative press, it takes the heat off whoever isn't getting the negative press" at that moment (Alma).

43 Beyond the fact that the NHPD scientists had known of me for a year, whereas the TPD scientists were people I had just met, chatting with at breaks at conferences or consultations.

44 Lorraine Daston describes the changing moral economies of calculation in the 18th and 19th centuries in France and England. Rational philosophers in the eighteenth century "conceived of intelligence and even moral sentiment to be in their essence forms of calculation" and thus far removed from "the realms of menial labor, of the automatic and the habitual" (Daston 1994:185). In the early part of the 19th century, however, calculation became associated with repetitive physical labour, and was derided as a very low mental faculty. This change was in part gendered. "Hence it comes as no surprise that women, once scorned for their vivid imaginations and mental restlessness, ultimately staffed the *bureaux de calculs* that did the plodding work of compiling the tables and reducing the data for major astronomical and statistical projects until the end of World War II" (Daston 1994:186). [In related histories of statistics there are many brief mentions of women "computers" (Agar 2003:63), "calculators" (Marks 1997), and "assemblers" (MacKenzie 1990:405-406). Aihwa Ong has written of the gendered production and consumption of electronics; she focusses on how the extremely detailed and repetitive work by (female) factory workers in Malaysia is managed by both workers and managers through gendered cultural scripts (1987a, b).]

As science expanded in the middle of the 19th century, it required more workers – and that cheap labour was often less educated and skilled labour, although Daston notes the exception of the female family of the scientist. This coincides with the "mechanization" of laboratory and mathematical labour, in which authors such as Charles Babbage suggested that the "mechanical" labour can – and perhaps is best – performed by the less skilled. The eighteenth century norm of the aristocratic, skilled, genius observer was changed to one of the interchangeable, unskilled, mediocre observer (1992:611). Furthermore, calculation garnered an "unsavoury moral connotation" of amorality and selfishness (1994:199).

(45 continued from above)

By the middle of the 19th century, however, the Victorian emphasis on the control of attention, and of the will, made calculation somewhat of a duty with a positive valence (200). The "elimination of fancy" was effected through a routinized skepticism towards judgements (Porter 1994:55).

Not all moral economies of scientific quantification aim for accuracy, although those involving precision measurement usually do, and involve an ethos of self-discipline, of exactitude, of painstaking attention to minute detail, of integrity of the individual (Daston 1995:8-12). In other moral economies of quantification in science, precision, communicability, and impartiality are virtues, there is often a high level of sociability but little tolerant of deviation.

The moral economies of calculation are quite clearly culturally embedded. Daston gives an example of the different interpretations of the ideal social organization of the "calculators," as people, in France and Britain. She begins by describing the calculation of ten thousand sine values (to 25 decimal places) in the terms of the new metric system after the French Revolution. Engineer Gaspard Riche de Prony directed a few "excellent mathematicians" (writing formulae). These "excellent mathematicians" in turn directed approximately 8 "calculators" (determining the numbers needed to use the formulae in computation), who in turn directed 80 "individuals" to do the millions of additions and subtractions required. Prony had been inspired to use this pyramid-shaped division of labour from Adam Smith's description in *The Wealth of Nations*. Nevertheless, Prony described his use of "manufacturing" methods for the creation of these tables in terms of the social organization and state-sponsorship of the pre-Revolutionary French luxury trade. In this luxury trade, Daston argues, "[a]rtisans engaged in such finely divided labor […] became less, not more mechanical" (1994:196). Thus, Prony conceived the tables as unique, made under "extraordinary circumstances," ones unlikely to reoccur (198). Daston argues that Prony's use of "manufacturing" was misinterpreted by Charles Babbage in England, who understood "manufacturing" in terms of the "mechanical" work in Manchester mills, and so thought that perhaps the calculations could be done by machines themselves. For Babbage, economy was tied to this manufacturing; for Prony, the term "economical" connoted the opposite of "manufacturing." Nevertheless, Daston argues, Prony's tables were pivotal because, in bringing together these people from such different classes, it "pushed calculation away from intelligence and towards work" (190), changing, as noted above, the moral economy of calculation.

46 I am unaware of any truly labour-oriented study of statistics (although an article by the Government Statisticians' collective in 1979 can perhaps now be considered "history"); this is not especially surprising as this type of labour falls between that addressed by the literature on professionalization, and that of the working class. A possible model could be the study of laboratory workers in the maritimes through the middle of the twentieth century by historian Peter Twohig in *Labour in the Laboratory* (2005); this work addresses not only the funding and organizational structures, but also the professional and unprofessional workers. He describes how the labour market and cultural norms truly gendered the labour force in the laboratory.

Harry Marks, in his history of the randomized controlled trial (1997), footnotes labour-related facts such as; the existence of a central statistical unit in the National Institues of Health (111), the involvement of primarily women in the calculation of earlier trial results (136), that for the price of a clinician one could in 1960 hire two experienced statisticians (152), and the resistance of physicians to "merely act as technicians" without having autonomy of the direction of the experiment (109).

47 TPD reviewers who were hired as applied biologists (BIs, not medical officers or MOFs) were also ranked a position higher than NHPD reviewers (BI-04s rather than BI-03s), which made an approximate difference of $10,000 in annual salary, and also received another approximately $10,000 yearly as some form of risk or clinical bonus. Therefore, several scientists in the NHPD's Clinical Trials Unit noted that the unit was a training ground for TPD, as, when the scientist was sufficiently trained, TPD might poach, e.g offer the scientist an "offer they could not refuse:" a position doing similar evaluation over at TPD, paying $20,000 more annually.

48 Amidst grumbles that this maneouvre could not be separated from the introduction of cost-recovery measures tied to the introduction of a time limit for the evaluation of clinical trial applications, thirty days, in the regulatory regime. Several of these senior scientists had been given a letter of offer for a reviewer position, attached to their notices of termination when Health Protection Branch management closed the Bureau of Drug Research in the late 1990s. These grumbles, which I have not verified, circulated with rumors, that management needed to staff credible "scientific authority" quickly and therefore closed the laboratories in the Bureau of Drug Research; perhaps the events were simply coincidence.

49 One interviewee explained:

> And the reason why they get compliance with that [withdrawal], is, in the ICH guidelines, or I think it's the declaration of Helsinki, it says … they have to disclose if they have ever had this clinical trial rejected. And then, whoever you're applying to, so let's say Health Canada rejects a clinical trial application, and they decide, screw Health Canada, I'm going to the [US] FDA. So they apply to the FDA. Well, if they're actually not going to break the law, they have to say, by the way, Health Canada previously rejected this application. Then the FDA will say to them, why did they reject this. Because they want to know why they rejected it, because if there is a safety concern that another country has already pointed out, in other words, they're not going to take the chance of assessing it and missing something that another country has already identified. So they want to know why, and then they'll make that decision, well, you know, Health Canada is being unreasonable, or, you know what, we don't like it either. So it puts a real negative spin on any clinical trial application if it's been previously rejected. But if they withdraw it, they don't ever have to say anything. Like, they don't have to say we were asked to withdraw. Withdrawing a submission basically it means it never existed.

[50] One scientist in the clinical trials unit who was convinced that five subjects was insufficient for a trial with six crossovers – something verging on the ridiculous when one considers the inadequate washout periods proposed, likely borne out of a particular company's attention to costs rather than useable statistics – had to hunt down a publication stating that three crossovers requires six subjects minimum, to provide a published reference to lend authority to her assessment that the current design did not meet regulatory requirements.

Chapter 14
Numbers of management

Management's reckonings

"It is all about the numbers," stated several assessment officers in interviews. The numbers to which they were referring were not *in* the product licence applications. The numbers in question were *of* the product licence applications. The numbers in question included the "number of gadgets," to use the language of one manager (Ommy), that these scientists were required to produce weekly. More commonly referred to as "productivity quotas," and also as "performance standards," these numbers were clear and omnipresent: management expected safety and efficacy assessment officers to produce 7.5 assessment reports (SEARs) each week, and quality assessment officers, 35 assessment reports (QARs) weekly.[1] This chapter asks whether quotas affected scientists assessments, and if so, how.

These productivity numbers are of a different sort of number than the statistics and measures that I discussed in the previous section. These productivity numbers, or quotas, were tools of management, used to reckon the Directorate's position in the sea of product licence applications, or to use the language of upper management, the swamp that is the backlog. Scientific staff generally provided a consistent explanation for the implementation of quotas:

> I could see the utility of performance standards, and I understand that they are important for … uh, the ADM [Assistant Deputy Minister], for example, we're in a backlog situation, and the ADM needs to be able to say to stakeholders, "We will be out of a backlog situation by X." It's important to industry, *et cetera, et cetera*, and so […] that person needs to know what

> can we realistically achieve on a weekly basis or a daily basis." (Sharon, unit head)

There was very little ambiguity regarding what the performance quotas were for: managerial control. One could always tell when the Directorate's upper management was about to meet with its Assistant Deputy Minister, industry associations, or Management Advisory Committee[2] because units were encouraged to work especially hard to "get the numbers [of licences] up" or to "clean up the numbers" within the next week or fortnight, so the numbers would look good for the meeting.

Productivity quotas have many similarities to other numbers of control studied by social scientists, whether those numbers are in national censuses (e.g., Appadurai 1996) or of genes (e.g., Holmberg 2005). The general finding of this social science literature is encapsulated by Holmberg's observation (2005): that *numbers* themselves "play a quite contingent role," whereas *numbering*, while "plastic," reconfigures the entities in question (see also Hacking 1991, 1982). For example, when speaking of censuses, Ian Hacking also concluded that although many – perhaps even most – state interventions in the realms of biopolitics fail, they do effect changes in the categorization and thus experiences of people (Hacking 1982:280).[3] Take the example of quantification in the nineteenth century Indian census, as discussed by Arjun Appadurai (1996). Appadurai observes that the "unmanageable flow of information" resulting from the collection of caste-information led to the heuristic of numerical majorities, an "apparently innocuous bureaucratic principle" that has shaped politics in India to the present day (128).[4] I

would argue that likewise, the production numbers make the tens of thousands of product licence applications received at the Directorate manageable, but in so doing, have also created the heuristic of the backlog, an “apparently innocuous bureaucratic principle” that has and will continue to shape federal health protection in Canada for many years to come.

As numbers of control, the Directorate’s productivity quotas were inseparable from a whole system of tracking both files and staff. The Directorate had originally created one tracking database, NHPSAS, for this purpose. Nevertheless NHPSAS soon proved insufficient for the required control of files and assessment officers, and a series of additional and replacement databases joined its ranks. (At one point during my time at the Directorate, I had to track my work on each of ‘my’ files in at least four databases). Staff tweaked the databases to churn out weekly tables, pie charts, and numbers for management, some of which were forwarded to all scientific staff. This Dilbert[5]-style proliferation may have been especially apparent the year of my fieldwork, because, as one manager explained to me, 2006 was “really the first year of maintaining the statistics of staff to understand the flow of files and identify weakness in the chain [of work]” (Amélie). Mid-way through my fieldwork, all levels of biologists slowly came to the conclusion: “It is definitely numbers that the DG [Director General] wants, and pretty pictures too. That is what we need to show.” Productivity quotas were just one number among many in this complex system of tracking and control, but they were the important numbers in

the workdays of many assessment officers, and so I focus on productivity quotas in my analysis.

Management introduced individual productivity quotas in the spring of 2006, although the full impact of the quotas was not felt until the fall of 2006, when a database co-ordinator created a weekly report listing each assessment officer's productivity, a report that was circulated to the Bureau's two Managers who had the power to hire and fire. Individual productivity quotas were not novel in the Health Products and Food Branch in 2006, although they were new to the Natural Health Products Directorate's (NHPD's) assessment officers.[6] Quotas, often in the form of X evaluations per unit time (usually per month or per week), were also very present in the minds of at least some other, senior evaluators in the Branch, if their remarks to me were any indication.[7] As one experienced government worker noted, prior to the time of my fieldwork, assessments officers at the NHPD had the "limited luxury" of not having to work under performance standards (Kimberly).[8] "Limited luxury" or not, productivity quotas were contentious at the NHPD among its scientific staff for two main reasons, which I discuss in turn. In so doing, this chapter will also give the reader a sense of the impact of quotas on assessment officers and their everyday work.

Temporary workers and threat of job loss

The most important reason for the contentiousness of quotas in the Directorate, was that many assessment officers – specifically those without permanent appointments – felt they would lose their jobs if they did not meet the weekly quota. This perceived consequence is probably related to the Directorate's staffing situation during the time of my fieldwork in 2006-2007. Although I will discuss the extent of the tenuous appointments in Chapter 17, for now it should suffice to say that a large number of the Directorate's assessment officers were not even considered employees of Health Canada, because they were hired via sequential short-term contracts. Many of these temporary staff

> felt like, if they don't get it [their quota] done it is going to cost them the job. And in a way [in a certain case] I think it did. So it is really kind of sad. (Ariella, 'permanent' assessment officer).

To some temporary hires, the quotas felt like "punishment, basically, if you don't do it you're going to get fired"[9] (Madison, temporary assessment officer).[10] This was a significant threat for workers – many of whom had moved themselves and their families to Ottawa on the promise of a permanent job.

Of course, temporary assessment officers had different reactions to performance standards. There were temporary workers who easily met their weekly quota. But even one "overperforming" temporary worker, however, felt that the quotas were "like the carrot on a string without the carrot. The only carrot is to get your contract renewed" (Evan, temporary assessment officer). For many temporary staff with whom I spoke, however, the quotas were a source of intense stress. Temporary workers developed nonstandard tactics to keep their weekly numbers up. These

tactics included maintaining banks of easy files in their cubicles in case they should need to bring their numbers up at the end of the week, staying late or working overtime, and avoiding any responsibilities unrelated to files.[11] (In this context, a file is a Product Licence Application). Tactics also included building up a bank of completed files that had not yet been entered as 'complete' in the tracking database, so that the tracking could be completed during a week in which the worker would not otherwise meet the quota. The following excerpt from an interview discussion with two temporary staff, Madison and Moira, summarizes the impact of performance standards on many temporary workers with whom I spoke:

> *… And is there anything else that is the bane of your day?*
>
> Madison: Quotas. Productivity. I don't like it. It stresses me out. You end up/ Well I end up creating a small bank of files just in case there's a blip in a week, [for instance if] there's a surprise meeting I have to go to, that is going to rob my time. There are some files that are adversely affected by it. But then there's the stress of keeping the bank. [laughs] Because if your bank gets down to none, you've got to go create the bank again.
>
> Moira: You've got to do your files *and* fill up the bank.
>
> *What is the number of files you're supposed to do a week?*
>
> Madison: I think they're 7.5 a week. But that is for the average person. And we all know that permanent and indeterminate people produce less than people who are casual or agency [my 'temporary']. So if you want to maintain/ My mentality is that if you want to maintain your agency or casual, you better be at the high end, because you're already competing against people who are performing well, none of them are permanent. So you have to be the best of the non-permanent people. And to do that, you have to/ There's a lot of stress, because the longer you're there, the more responsibilities I'm given, that aren't tracked weekly. If I were training people and going to meetings and taking the minutes and doing stuff like that, it would show a lower number. But at the end of the day, the people who look at the stats just look at the stats. So I don't want to be considered capable of doing other things [responsibilities].

Do you really feel if you don't meet the quotas, your job would be at risk?

Madison: Undoubtedly. Because they question people.

Moira: I think if it happened consistently. If it happens once – that happens to all of us. For instance, holidays. A file that has 10 binders associated with it.

Madison: And some people frequently do overtime. But with overtime comes more productivity expectations. So you'd better not be doing any overtime, if you're only getting 8 files [done weekly]….

So it would be fair to say that the way you approach your work is really shaped by these quotas?

Madison: Yup.

Moira: Yes.

Madison: I see meetings as lost time; I feel like I'm being robbed, I just find it stressful…. I just don't want to get involved.

Moira: I feel like I'm juggling big files, and working overtime because of files.

Madison: I have to group by MI [medicinal ingredient] to make it go faster.

Moira: I have to break up the French files, because they take longer. To have a bit of a buffer.

Madison: I told my unit head I definitely don't mind doing great big files with binders, but … I don't get the expectation thing time-wise. If there were no productivity standards associated with it, then it wouldn't be a problem at all. But now the expectations are the same even if you get swamped with nasty files. Nasty time-sucking leech files.

Some temporary workers felt they had to track their time in a quite detailed manner, to show how they had been working on other projects at the explicit request of management, in case management should subsequently challenge their productivity numbers.

Furthermore, because the hiring boom at the Directorate coincided with the emphasis on productivity quotas, productivity quotas were essentially placed on inexperienced or new assessment officers because management often did not specify a clear "training" period during which new workers were not expected to meet the quota. Gwendolyn, a temporary worker in the process of being trained, explained that she found it difficult to learn because of the quotas: "I'm nervous I will not get enough files done, so I can not learn as much as I would like because of the stress." She was also in a unit with files containing a lot of "glitches" as well as full-on "issues," the latter requiring meetings and working groups ("projects") to try and overcome systemic issues with the unit's files, but:

> If I run into a problem… that takes a couple of hours and I have to not take lunch. So I can't enjoy as much. In the back of my mind, when I'm doing another project, is: will it show in TWS [an employee tracking database, that focuses on file completion]. Especially when people are not getting their contracts renewed. As much as I can like it and believe in it, it is not valued (Gwendolyn).

Lower management generally acknowledged these serious limitations of the quota system: as one unit head noted, certain contract staff were "working sincerely," but that "will not *count*" (Megha). Previously in the interview with Gwendolyn, I had asked her whether the threat of job loss had ever been made explicit – or if the pressure was perhaps self-imposed. She had responded by naming three temporary assessment officers whose contracts had recently not been renewed.

Effects on permanent workers

The effect of the quotas on permanent employees was less marked. I asked Dorrie, a permanent employee, what would happen if she did not make her 7.5 files a week:

> Well, if I were on a 3-month contract I wouldn't get renewed. But because I'm indeterminate [permanent]/ Well I asked that, but there was no answer. Nobody really said. I asked "what is this productivity thing," I thought it was 8 files. And then I was told that it depends on any number of factors. There are mitigating circumstances. Ya, I've asked, and I'm not sure what the answer was, other than don't panic. You can be shifted around, I suppose, and that, I think is what happens.

Although Dorrie stated that she was very conscious of the quotas "sort of hanging over my head: got-to-get-it-done! You've got-to-get-it-done-faster!", for her, this was not a negative thing. She felt it was important "to do a good job, but put limits on it." When I observed another permanent assessment officer doing assessment, at the end of the day she joked that I should not record how many files she'd assessed that day, because she'd worked very hard that day and on files only, and if management found out how many she did "they'd make us do that every day." Other permanent employees commented that they "sometimes do not enjoy the work as much as [they] used to, because more time is about files and numbers, numbers, numbers" (Megha). For Zahra, another permanent employee, performance standards took "the fun out of" assessments. She explained that in the weeks she made her quota, she received "a blind cc e-mail from management saying *Congratulations. You made your quota!*," which she "didn't find very effective." When she did not meet the quotas, she feared "a nasty e-mail from her unit head." This made her strategize with her files, by maintaining banks of easier files to balance out the more difficult files, just like the temporary workers did.[12]

One permanent assessment officer I observed did not take all the files she had assessed to her unit head; she explained to me that she'd already met her quota that week, so she was saving the "extra" assessments to hand in the following week in case she got a difficult file. Several permanent employees resented having to do "the same boring stuff everyday"; those who had been working on other projects[13] especially resented being told that they were no longer able to participate in those working groups pertaining to systemic or inter-directorate issues.

But, as I have mentioned, not all employees found performance standards unpleasant. Two employees in addition to Dorrie explained that the standards gave themselves something with which to measure their performance, "because as someone who is a good AO [assessment officer], I feel like I have something to gauge myself with [….] We don't see the production reports, but I am confident that I would be up there with the other good AOs" (Kayte, permanent assessment officer). These employees, who tended to personally experience successes and failures of the NHP programme according to the measures of management, also felt performance standards would hold the "slackers"[14] accountable. Of course, still other employees totally disagreed with the implementation of performance quotas, saying the quotas were detrimental to morale given that everyone was working hard, and furthermore, the quotas made no sense for difficult files.

Difficult files and numbers

The issue of “difficult files” was tied in to a second reason for the contentiousness of performance standards at the Directorate. Variability in files was why most of lower management with whom I spoke was neither wholly for nor against performance standards. While they felt that performance standards were necessary in some form because they “measure people’s activity,” they were not necessarily proud of the standards, and often disagreed with the way the standards had been implemented or communicated. They quibbled that the standards did not take into account the quality of writing in the assessment reports, and, most often, they found the current numbers unreasonable.

The numbers in the actual quotas – 7.5 SEARs weekly, and 35 QARs weekly – are probably as meaningless to the non-specialist reader as they are meaningful to specialist readers. The quotas imply an assessment officer should produce a Safety and Efficacy Assessment Report (SEAR) every 3 or 4 hours, or at least one Quality Assessment Report (QAR) per hour.[15] The actual numbers in the quotas were conjured by upper management and consultants. I do not use the word conjured lightly: by most accounts, the numbers were based on wishful thinking: the “outputs for AOs all in relationship with the amount of work to be done” (Amélie). The magic number of “7.5 files” per week was calculated by modifying the actual rate of assessment in 2005-2006 by what management wanted to see, which according to one manager, was a cleared backlog by 2010 (Ommy). This is consistent with the reckoning in a discussion paper on “BPRA Production Standards”:

> Given that there are about 20 working days per month, the required monthly production is 1,200 licences. Since there are about 40 officers, this translates into 30 licences per officer per month (or 1.5 per working day, or 1 every 5 hours).[16]

The quotas were thus part of upper management's reckoning of the NHPD's place in the sea of files; "find[ing] an average that can be counted on" was key to this reckoning (Amélie, manager).

Of course, the quibble was whether the 7.5 or 35 quota was reasonable. The answer by various levels of scientists was never straight-forward, always highly qualified. A few experienced assessment officers explained that for the file with a single ingredient, not very complex, and competently documented, three to four hours was a reasonable amount of time for an *experienced* assessment officer to complete a Safety and Efficacy Assessment Report (SEAR) with the proper documentation and argumentation:

> Because I can get a file, and I can review the file in, say, an hour, I know whether that file is supported, or not. And I also know what, if it isn't supported, what it would take to get it licenced, and I can pretty much guess, you know, I'd say about 85% of the time I'd be accurate, whether that is something that is possible or not. But the test is can you put that into a report that is short, concise, and that you can give to anyone else to read and they'd come to a similar conclusion (Ebo).

For experienced assessment officers with straight-forward files, the quotas could be reasonable – but this did not reflect the situation at the Directorate. Nearly all *experienced* assessment officers on the safety and efficacy side were acting in a supervisory capacity as unit heads. Also, many files were not straight-forward. Interviewees generally emphasized the variability in files. Malik, who assessed the quality of the proposed medicines, explained that once it took him over a day to

assess one file, because it that had over 100 ingredients – but another time, he reviewed 20 files in one day, because they all had a single vitamin as the medicinal ingredient. A manager noted that some assessment officers were completing 15-18 assessments a week; he explained to me that therefore it was not possible to say that the 7.5 quota was too high, “but sure, if a file like this one [pointing to file on desk] has 8 binders you can’t ask the AO [assessment officer] to do it in half a day” (Ommy). Because of this variability in files, two Managers told me they never looked at the weekly reports to assess the performance of an assessment officer, only the monthly reports. This did not appear to have been generally communicated to, or at least believed by, assessment officers, however. Assessment officers worried about their weekly numbers and repeatedly stated that the variability of files made the system particularly unfair to the temporary workers in the units that assessed more difficult files.[17]

Impact on scientific assessments

To summarize, the quotas were contentious among scientific staff largely for two reasons: one, the harshness of the perceived consequences of not meeting the quotas on the many temporary workers; and two, the inappropriateness of the actual quota – specifically 7.5 SEARs weekly – given the variability in files. These issues are, one could argue, fixable while maintaining the quota system. It is conceivable that upper management could have circumvented the contentiousness by permanently hiring the temporary workers and working with the assessment

officers to develop mutually agreeable quotas taking into account file difficulty. These issues do not challenge the idea of quotas per se.

Can one say whether quotas, whether reasonable or not, affected the Directorate's assessments of product licence applications? And if so, how?

When I asked interviewees whether performance standards changed the way they approached their work, several employees who had been working at the Directorate for several years explained the introduction of the quota system had been tied to changes in several work-related processes. They pointed out that the Safety and Efficacy Assessment Report (SEAR) template had changed to become more concise, and standard operating procedures had been documented with administrative modifications. (For example, by 2006, the AO only examined the label text when it looked likely the application was licensable, rather than noting deficiencies in the first examination of the application.) In one internal training session, an assessment officer presented tips for increasing productivity, opining:

> Productivity is directly related to how fast evidence can be separated into 1 of 2 categories:
> 1. Able to support the recommended use or purpose (this includes evidence that could support a modified recommended dose)
> 2. Unable to support the recommended use or purpose no matter what.[18]

This distinction, tips for discerning relevant evidence, was both scientifically-sound; it must also be noted how it framed this judgement in terms of productivity, the presentation's topic. Scientific staff invariably presented these changes to work-

related processes in a very positive light, as part of the Directorate's commitment to increasing efficiency while not sacrificing safety or efficacy.'

But there are also the rather amorphous issues of the depth and quality of the assessments. Several employees who had been working at the Directorate for at least a couple of years emphasized the positive impact of performance standards on setting limits on assessment. "You need to say stop at one point," concluded Carolyn, a permanent assessment officer, when comparing the current processes with those from 2004, when Safety and Efficacy Assessment Reports (SEARs) might have been peer reviewed three times. She, like all other long-term staff I interviewed, argued that in 2004 scientific staff had used a "fine-tooth comb" in the assessment, a comb with teeth so fine that it was not appropriate.

Some, but not all, managers thought the quality of some assessment reports were adversely affected by the introduction of the quota system. This had direct repercussions on the managers, because it increased their workload. Unit heads and Managers had to sign off on the assessment reports, and when the reports were of poorer quality, sometimes several rounds of changes (back-and-forth between manager and assessment officer) were required before management would sign off. But a few managers noted that the pressure of productivity quotas on their staff made them, as managers, reign in any of their superfluous perfectionist tendencies:

> because when my perfectionist side wants to send it [the assessment report] back [to the assessment officer], my other side says there would be no

> difference to the [report's] conclusions, and it would just take time. So yes, I definitely take performance numbers into account because I worry about effecting penalties for people for things that are perfectionist (Abigail).

Nevertheless, even when managers felt that quotas adversely affected the quality of assessments, they did "not think [the Directorate] is making the *wrong* decisions, though" (Megha).

I suspect that nearly all the Directorate's scientific staff would agree with Megha: even if they felt the quotas changed the quality of the assessment reports, they felt that the teeth on the comb were not so wide that "wrong" decisions were often made. At the same time, I left the Directorate with the most definite conviction that temporary staff – and even possibly permanent staff – saw fewer potential safety 'issues' requiring substantial investigation because of the quota system. One manager remarked that although assessment officers were hitting their quotas, they had to be asked more often: "Have you looked into this? Have you looked into that?" But for Gwendolyn, a temporary assessment officer described above, ending up with an issue in a file could mean not taking lunch, working overtime, and possibly not completing her quota, which, to her, held the threat of job loss. And as I will explain in Chapter 17, most unit heads in product licence assessment were themselves in tenuous appointments, with some believing they would lose their supervisory role if their units were not productive (i.e., churning out assessment reports at a sufficient rate). While I do not believe, even for a moment, that assessment officers or unit heads *consciously* avoided seeing issues, there were

clear, structural pressures that encouraged them to value file completion, rather than investigations into possible side effects.

Indeed, I would argue that for the majority of assessment officers, whether permanent employees or temporary hires, the productivity quotas oriented the officer's *affective dispositions* to files, albeit subtly, and to the type of work they valued and enjoyed. Take, for instance, the responses of two permanent assessment officers to my question whether there were any types of files they were happy to see:

> I really liked getting the batch [of similar files] to assess. Because in the beginning, yes, it was a lot of work, but then, you could kind of see that all that hard work led to decision [licence or refusal]. And then getting those [files] was – they were easy in the sense that – and I was happy to do it because I know that it would help my performance standards – but I was also happy to get them because … you could see the fruits of your labour, for all the work involved in deciding claims and risks statements and all that, you could see that all that more dreary, harder [stuff], and meetings back and forth finally paid off. And now we're able to assess files quickly and most of them would get an NPN [a licence to be marketed]. So I knew that would be good for the Directorate to get more licences out. Sometimes I am also happy to get files that I know are very easily going to be refused. (Kayte).

> I dread getting files with 5 binders, because I know I won't get many numbers. It is always in the back of my mind, the numbers, and I have so many things to do; however I take the time if I need it (Carolyn).

Quickly completable files, in many interviews, were often described as files highly anticipated by the officer.[19] Even for permanent assessment officers who liked investigating scientific issues in-depth, productivity quotas were never far from mind. Take the example of Richard, who, in an interview, professed a profound ambivalence towards productivity quotas, finding them motivating but also

stressful. Later in the interview, he stated his preference for more complex scientific issues and analysis than was possible in the assessment of many files. He outlined possible approaches to files:

> One way is to spend days or a week to see if the claim is supported, but the problem with that is, it is time-consuming and management might not like it because your numbers will be low. You're not clearing as many files. So in terms of my own interest, it is sort of at opposite ends of the desired efficiency demanded by management.

When I asked Richard, as a permanent assessment officer, whether he would feel comfortable taking a week or several weeks to assess a file, he replied:

> Mmmmm. One way/ Although management only looks at numbers. There is one/ Although they just look at numbers, they do say you can qualify any discrepancies between what they want, like say you have more complex files. You just have to justify why you're taking time. I do not mind doing it, but I'd have to get management approval if it takes that long.

I have argued that the weekly quotas, especially in the context of high rates of tenuous employment, affected scientific staff's assessment of product licence applications. I believe that having quotas lessened the chance that scientific staff noticed potential "issues," unforeseen, possible risks or actual dangers to health. This was not because staff *consciously* disregarded any potential threat. In this system, research into potential risks to health was not explicitly, systematically valued. File completion, via the quota system, was explicitly valued. This subtly shaped scientists' affect by directing their attention in particular ways, effectively training the scientific staff to be less likely to notice possible "issues" in the first place.

Productivity quotas and their efficacies

There was also a third, more fundamental, reason for the contentiousness of quotas. This came in the form of a challenge to upper management that I only saw surface once during my fieldwork. The challenge came during an all-staff meeting of the Directorate in the summer of 2007, a meeting in which upper management repeated the themes of: “You cannot manage something without measuring it,” and “If you do not track, you do not know.” During the question and answer period, a temporary assessment officer asked upper management the question: “Have quotas improved performance?” Upper management was not able to provide a yes or no answer. Management’s response was rather multi-pronged. The first part of the response stated that the question was difficult to answer quantitatively, because so many procedural changes in assessment happened simultaneously. Certainly, continued the answer, “numbers” have not decreased since the introduction of quotas. The response then continued along a different track, beginning with the statement that competition brings out the best in people, as is clear in the private sector. Management’s rationale invoked Olympic swimmers, noting that no-one ever records a world record in practice, because it is only when the swimmers are in competition against other elite swimmers that they push themselves that much farther.[20] While this rationale seemed to be self-evident and convincing for the speaker, and perhaps some others, it was not entirely compelling for the assessment officers. Over lunch the following day, sarcastic comments flourished.

I mention this third challenge for two reasons. First, the efficacy of this particular system of tracking and control, is unclear. Despite a system of tracking and control – in which individual quotas played their part – upper management could not say whether the quotas improved performance, and thus it remains speculative whether introducing quotas helped achieve their ostensible purpose, to reduce the backlog. Despite this lack of efficacy – a lack that is generally consistent with social scientists' discussions of other numbers of control – the fact of numbering, in the introduction of quotas, has reshaped these scientists' work in quite possibly lasting ways.

To take but three examples: I asked one temporary worker a standard interview question, whether the NHPD's mandate to 'respect philosophical and cultural diversity' came into play in her work, and if so how. My question was followed by a very long silence; her response then came:

> I'm not sure that I think philosophical diversity is necessarily a good thing. I think that they'd [management would] be happier if there wasn't any philosophical diversity and everyone just conformed and agreed on everything. Because debates cause lost productivity time!!! [laughs] *Does it come into play in any other way?* No.

Likewise, take, for instance, the way in which Olivia organized her day. When I shadowed Olivia, a permanent assessment officer, she recounted how she had started her day, which is how she started her work day everyday. She would arrive, check her e-mail, then *open her daily electronic worklog spreadsheet*, triage files, *open NHPD Approach* and so on. I should emphasize that, as professional staff, assessment officers are, for the most part, able to arrange their workdays and the

way in which they complete their work tasks in any way they see fit. Olivia had chosen to structure her day through the use of a personally created worklog in conjunction with the required, regular tracking databases. The worklog she had created was a spreadsheet documenting the time she spent on each task daily – with the days grouped into the weeks counted by an official tracking database (TWS) – and when decisions had been reached on files and issues. I asked Olivia when she had created this daily worklog. She answered that she had created the worklog in response to the performance statistics, to keep track of her time spent in meetings and other responsibilities that she had been given. Now, she explained, she simply likes completing the worklog to be clear for herself, even if she writes something not important into the worklog: "I like seeing the numbers." Anthropologist readers will not need the parallels with Foucault's *techniques of the self* spelled out. While not all assessment officers chose to structure their days with a personal worklog commensurable with performance numbers, several scientists I observed spent considerable time "doing the tracking" of files and work in several electronic documents: the weekly tracking of files in one database, the breakdown of the scientists' daily activities in another, and, of course, identifying and communicating glitches in one of the newer tracking databases (TWS).

Third, the reckoning associated with quotas was making its way into the Directorate's "good review practices." In an internal training session in April 2007, it was declared that Good Review Practices, already established by a sister directorate (TPD), were the "ultimate goal of any organization." The presenter,

however, noted that of course “there are inconsistencies, that is to be expected: We’re not machines.” The time management scheme in Figure 14-1 was suggested, allowing 200 minutes (3.3 hours) per file, “an attainable target” :

Figure 14-1: Time management for assessment officers

Screen	5%	~10 minutes
Assess	60%	~120 minutes
Document	20%	~40 minutes
Standard Lines	10%	~ 20 minutes
Proof Reading	5%	~10 minutes

In general, productivity quotas were assimilated into – and shaped – assessment officers’ everyday work.

Although earlier in the chapter I described how productivity quotas affected scientists’ approach to the evaluation of product licence applications, there is an even more fundamental point to be made. Productivity quotas were notable in the sense that they created and normalized The Backlog in the everyday work of assessment officers. Thus, were the assessment officer to ask a social scientist, rather than management, “Have quotas improved performance?” I, like management, would probably not have provided a yes or no answer. Instead, I would have answered, thinking of the historical work of Michel Foucault and Ian Hacking, that quotas effected performance. Not affected, but effected. I would not, however, expect this answer, with or without more detailed analogies, to be self-

evident to anyone unfamiliar with the work of these scholars. This contrasts with the answer provided by the Directorate's upper management at the all-staff meeting; which, among other differences, upper management obviously felt should be compelling and self-evident to all.

The fact that a rationale provided can seem highly compelling even to the point of self-evidence to management, while rather irrelevant to at least some scientific staff, is arguably related to what was framed as a cultural disconnect among staff: of "MBA culture" versus "science culture." This is the subject of the next chapter.

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1 Some units had slightly different quotas. At one point, the weekly productivity quota in the Homeopathic Unit was 10 assessments of quality, efficacy and safety ("AAHMs"). I was also told that for trans-DIN files and other previously marketed products the weekly quota was "like 40 or something ridiculous"; but all assessment officers working on those files were "permanent" so the quota, as I will explain below, held less sway and, possibly because of its unattainability, was generally laughable.

2 The Management Advisory Committee, MAC, was a committee of industry representatives who met once or twice yearly with upper NHPD management. Although industry members were not supposed to use the meetings to lobby management, some employees grumbled that much lobbying indeed occurred in the meetings.

3 As Ian Hacking mentions, direct exercise of power through counts is the exception to the rule – although there are important and notable exceptions – whereas the classifications used in the counting effectively 'make up' people, in that a category "changes the space of possibilities for personhood" (1986:229). For a recent ethnographic example, see Petryna 2002. For instance, Hacking argues that the homosexual and the person with multiple personality did not exist as thinkable and decipherable types of people before the nineteenth century (1986), as before, these were "absolute, unthinkable and undecipherable nothingness" (232). In addition, he argues that classifications of humans have a looping effect, in that the humans and categories are co-produced, because humans change their behaviour according to the way in which they are classified. The refrain of the literature in science studies could be, s/he who sets the measurements often sets the terms of debate or experience (Bowker & Star1999, cf. Godin 2002: 13).

4 Appadurai (1996) distinguishes between the justificatory and disciplinary roles of numbers in this system. He argues that the former was important in arguments mobilized by members of the bureaucracy and also served the rhetorical purpose of making the bodies manageable rather than errant beings involved with sati, possession rites, and bodily manipulation. The latter shaped a bureaucracy in which numbers play a central role in "bureaucratic practices and style."

5 Dilbert is a popular comic strip that satirizes management and office workers in US American white-collar, cubicle-bound office places. Themes include various management fads, dysfunctional interpersonal dynamics, and advice for cubicle-dwellers.

6 The Therapeutic Products Programme's "Strategic Framework" from 1997 contains a defense of these performance standards, rationalizing why one of the "critical success factors" of the programme's role to ensure drugs available in Canada are safe, effective and of high quality requires performance standards. Notably, the framework's ten "guiding principles" include eight principles pertaining to management (e.g., 1. Conducting our business in accordance with the principles and practices of quality management" [emphasis in original]) and only two that can be construed to relate to science-based assessment (e.g., "5. Conducting and promoting risk/benefit assessment and management"). Health Canada. Therapeutic Products Directorate. May 1997. "Strategic Framework for the Therapeutic Products Programme, 1997-2000". [Thanks to AM]

7 I also discovered that in at least one other Directorate, however, the exact number of evaluations per unit time (the quota number) was considered highly confidential corporate information. I am fortunate that the Director of the Bureau of Product Review and Assessment at the NHPD, from whom I got permission to use such numbers in my research, interpreted the need to be "transparent" to extend to the NHPD's performance standards and standard operating procedures.

8 Many “performance standards” were not at the level of individual assessment officer, but were at the level of the Directorate, and consisted of an absolute number of days to come to a decision, rather than a rate of evaluations. For instance, for the type of product licence application I largely evaluated at the NHPD – applications attesting to the compendium of monographs – there was a limit of 60 “NHPD days” for the NHPD to issue a licence or refusal for the application. (“NHPD days” are the calendar days since the receipt of the application, minus any time the application has spent back with the applicant so she can provide additional required information.) That particular performance standard was included in the *Natural Health Products Regulations,* and so it was generally understood to be non-negotiable. Other similar performance standards were simply internal promises or goals. When a type 1 issue (riskiest type of issue for a product on the market) arose, the Health Risk Assessment Unit had to complete their Health Hazard Evaluation of the issue within 24-48 hours; this performance standard had been declared unilaterally by upper management without specific basis in regulations. Other units had ‘targets’, that were ideals that were not really expected to be met. For instance, the clinical trial unit had a target to review any application to conduct a clinical trial within 30 ‘NHPD’ days. The pressure for the establishment of this target was tied to comparisons with a sister Directorate, the Therapeutic Products Directorate, where regulations stipulate that Health Canada must object within 30 days of the receipt of an application. At the NHPD the 30 days was a target rather than a requirement, not only because there was no regulatory requirement, but also because of the Directorate’s different processes (requiring the signatures of three levels of biologists) and product types (e.g., getting applications for products containing 50 medicinal ingredients in the investigational arm). Furthermore, to meet the target, the Clinical Trial Unit would “have to be a lot more ruthless” – e.g., take the strategy of the Therapeutic Products Directorate and essentially ‘strongly encourage’ applicants to withdraw problematic applications before the 30-day mark – rather than helping applicants to meet the requirements of the *Natural Health Products Regulations*. (Supposedly, at TPD, if the evaluator thinks the application will not be approved, he or she calls up the sponsor, explains why, and the company *withdraws* the application. The withdrawal happens because if the trial is officially *refused* by Health Canada, the trial sponsor must report the refusal, according to ICH rules, if s/he applies to any other regulatory body in the future. When a sponsor withdraws the application, “it’s like the application never existed” (Almas). I was told the 30-day requirement for TPD emerged in 2001 so Health Canada could remain “competitive” with the United States’ Food and Drug Administration). These types of performance standards – the maximum- number-of-days-for-Health Canada’s decision on an application – did not bring up many issues discussed in this chapter’s discussion of “management reckonings.”

9 Technically speaking, management did not fire temporary workers, to my knowledge, but simply did not renew the temporary worker’s contract or find another way to rehire the temporary worker.

10 There was ambivalence towards the use of “carrots” in the form of bonuses rather than reprimands, however. Take as an example this conversation:

> Madison: So, [NHPD] should work on a reward system. TPD [the Therapeutic Product Directorate] does that. Where everybody gets paid a salary and then there is a bonus for performance. So people love to perform for that.
> Moira: Ya but then you get people who are doing shitty work just to get their bonus/
> Madison: but that’s why they need better standards!
> Moira: Ya, if they can nail down what the standards are that you have to adhere to, then I think that would work. But otherwise that doesn’t help either.

11 The spreadsheet that managers received weekly, and that listed the productivity of each and every assessment officer, did not list the number of hours each assessment officer worked.

12 “Harder files” were variously deemed files that: were received in 2004 or 2005, before industry learned how to fill out the forms properly; where the claim is really vague, hard to prove, or where there is lots of evidence (up to 8 binders worth);

13 I was told that the ideal at Health Canada was for 80% of an employee’s time to be devoted to activities directly within one’s job description, and the balance could be used for associated projects etc.

14 So I do not give the wrong impression, I should note that among assessment officers, I did not come across any “slackers”; from what I heard and observed, assessment officers were all very diligent, although they were diligent about things so different (e.g., making quotas, researching safety issues, ensuring clear communications with industry) that it is possible their colleagues did not recognize their diligence and work.

15 Calculated taking into account that at least one day of a worker’s 37.5-hour workweek cannot be used for work because of statutory holidays, vacation days, sick days, and meetings (and that is probably an overly conservative estimate – likely much more time is unavailable for assessment). Quotas were not officially presented in hourly terms at the NHPD.

16 Internal document dated November 8, 2005.

17 The problem of variability was framed as part of the files; only one assessment officer, Namir, noted that the quotas were unfair because “people are coming with so many different backgrounds and their approach is different.”

18 From presentation slide taken from presentation entitled “Speeding up the PLA Process: Suggestions for Increasing Productivity,” made May 4, 2007, as part of the AO Information Series.

19 Although this anticipation cannot be entirely attributable to mandatory performance standards. For instance, although I was not officially subject to weekly quotas, in my fieldnotes I would regularly begin my days’ recording with something to the effect of: “I did 5 recommendations and 3 IRNs to get rid of files.” At least one assessment officer in my unit kept track of how many licences she had recommended, a number that made her feel proud of her work.

20 No one pointed out that “records” by definition are only made in official competitions, because otherwise an excellent time is merely recorded as a personal best.

"So it has to be remedied because there can not be a backlog"

> Health Products and Foods Branch management, at a 2007 employee consultation on the Branch's Strategic Plan

Chapter 15
The Backlog

The swamp

At an NHPD all-staff meeting in the summer of 2007, NHPD upper management spoke of leadership. The analogy used was "leadership in the swamp." The swamp could be anything, explained the speaker – the backlog, international collaboration, and so on – but the speaker wanted to focus on the backlog because, the speaker stated, it affected everyone in the large room: all NHPD staff. The speaker explained:

> You have to drain the swamp, your ultimate goal. But you can't just do that, because you're getting attacked by alligators. So you have to stop draining the swamp to fight off the alligators. So you have to do a bit of both as you go along.

Mission impossible

One can imagine a bureaucratic version of mission impossible: the assignment, should you choose to accept it, is to evaluate applications for 40 thousand products, give or take several thousand, for safety, efficacy and quality within six years. Your conditions: no funding is guaranteed for more than a year, you have as few as eight scientific staff members assessing the products, and you have to develop all the processes, filing systems, databases, and so on. Your sister

bureaucracies, who could be assisting you, ignore, resent or belittle you. You need to seem reasonable to slick big firms who have mastered the arts of sneakiness and likely speak to your superiors, one-person companies packaging plants on the farm and who are without computer and whose fax machine is that of their local public library, and the small but amply vocal libertarian-infused lobby that would like to see you disappear entirely, and who will try and use anything and everything against you.

This was the mission set for the NHPD to accomplish. At the time of my fieldwork, this mission impossible had been shaped into the NHPD's "backlog" problem.

The Backlog – the product licence applications received at the directorate, but that were not yet licenced or refused – was, in retrospect, not a surprise. Many senior staff expressed the opinion that it was widely recognized that it was neither possible nor expected that, within six years, a new organization could evaluate the 30 thousand products already (but quasi- or fully illegally) on the Canadian market and not previously approved by the Therapeutic Products Directorate (TPD; roughly 10 thousand products had been licenced by TPD):

> I guess most recognize that this is not a possible thing to do, however that part of it was needed in order for the regulations to come into place.
>
> Essentially, without making that commitment, perhaps [the NHPD] would have never been a directorate. Because I guess the Health Minister at the time … needed some definite timeline …
>
> If you were to tell someone you're going to regulate the industry over the course of 25 years, I don't think that would be respected ... (Minkah)

NHPD as backlog

> We knew right from the start, we would have a backlog, but that hasn't changed the fact that we are under enormous pressure to clear the backlog as quickly as possible. (Robin Marles)

Backlogs are unthinkable in the management of Canadian health product regulation.[1] At a presentation of the "Blueprint for change," held for Branch employees at Health Canada's Banting theatre in October 2006, Branch management extolled the virtues of other directorates: TPD managed to clear its backlog, meet performance targets for drug reviews in 2003; and BGTD eliminated their backlog six months early. It was then noted that "well, it is not really NHPDs fault," because "as of day one" the new Directorate "had over 40,000 products in backlog." That last statistic led immediately into the Review of the NHP program. While the speaker mentioned the review would include the scope of the definition of natural health products, and that the Review had been scheduled years previously, one could not but get the impression that the backlog was a sign, a measure, of the Directorate's impossibility.

Scientists used the measure in their everyday talk, remarking jealously of another Unit, that their lack of backlog is "a feather in the cap" of that section (Violet), or stating: "we're doing [assessing] applications from 2004-2005, and now it is 2007 – that is two or three years for an application. I find it unacceptable from a business perspective." (Marie). Management circulated e-mails congratulating various units

or scientists on reducing the backlog in such and such a way, presumably as motivational endeavour.

The backlog appeared to be very important to management, as it was "not a good news story, and takes away from the good news story that the directorate exists in the first place and that products have appropriate oversight" (Amélie), or, as another manager, Jack, grumbled:

> all the news is about our backlog. [Interviewee uses another voice to represent that news:] 'Sure, you've got all that done, but what about the 20,000 other licences [in backlog.]'[2]

Manipulable, measurable with the tools of managerialism

The backlog was something that was manipulable, in the sense that it moved (conceptually) through the levels of NHPD's processing. For instance, the April 18, 2006 Bureau newsletter had this report on the backlog:

> Last Monday we were joined by [our ADM], as [the Director General] acknowledged many of our accomplishments in reducing the backlog. At level 1, the backlog has been eliminated and all new submissions are acknowledged within 3 days. Level 2 has screened and classified all 8000 submissions that were in Queue at the start of this initiative [….] It is anticipated that there will be over 5000 submissions at Level 3 within the next several weeks.

Detailed documents were drawn up, listing the exact number of minutes to be spent on each step of processing and assessing applications of different types. For instance, a presentation deck entitled "Backlog Action Plan: Statistics" dated March 6, 2007 stated that "To obtain a steady state of submissions and not increase the backlog, a rate of 24.9 decisions per day is required." In my third week of work at

the NHPD in September 2006, I attended a meeting on the Level 3 Standard Operating Procedures, at which we were informed that, according to the ADM at the time, the backlog had to be cleared by the end of that fiscal year (ie. by 31 March 2007). From excerpts of the minutes of management meetings in the Bureau of Product Review and Assessment, one can see the calculations spelled out:

> February 15: Currently there are 26 people doing assessment. There are 1.2 applications a day per assessor being done. We should now have a target for 2 a day….
>
> February 22: [A manager] met with the ADM and although we have increased our decisions from 4 a day to 24 a day we have been asked to give an exact date on when the backlog will be cleared. A firm date needs to be provided to the ADM. [Management] needs to provide a proposal plan, based on this conversation. [A manager] mentioned that NHPD currently has 200 employees, 26 of those are doing product assessment and are getting out exactly 1.2 assessments per assessor per day. S/he states that by [his or her] calculations 56 assessors should be working on assessments.
>
> Reminder that the backlog is priority!!!!
>
> [A manager] would like everyone to be working on the backlog.

An internal policy document stated that a "formal evaluation of the licence submission review process highlights the need to multiply the best productivity ratios five-fold to make significant progress in addressing the backlog." Even though the numbers in the backlog were so high, and upper management seemed to release ever-changing deadlines that seemed, well, wishful, to put it politely, there were very few of us who openly stated that "it's almost, like, a joke, I find" (Marie), or such an impossible task that it be perhaps best ignored. The backlog was actually quite difficult to ignore, much to my annoyance. Although I

never agreed with this particular way of making proposed medicines “backlog,” whose sole purpose was to be processed, because I kept fieldnotes I cannot hide from the way in which I was readily recording daily events in precisely those terms. Not only was I speaking in terms of the overall backlog:

> I did the two non-traditionals [assessments] today [even when not priority] because I figured the submission numbers are so low it would be my contribution to the backlog

but also I was configuring my assessment work – that on my very own desk, that I was ostensibly free to organize as I wished – in terms of backlogs, and to imagine my productivity in terms of file completion:

> Was supremely inefficient. I suppose I sent 3 IRNs and did 6 RCs, but did not get backlog cleared up.

It took only six months for me to begin reasoning in terms of the backlog, despite my lack of inclination towards such reasoning. (My attitude towards the backlog could be characterized perhaps as a rather vicious antipathy).

Backlog crescendo

Employees with exposure to management noted that the pressure had been present since at least 2004 when the *Natural Health Products Regulations* came into force; recalling that management and the eight assessment officers at the time asked “right away, OK how do we clear the backlog, what do we do.” Meeting minutes also indicate the backlog drew the attention of the Bureau of Product Review and Assessment from the start. In a draft presentation to NHPD’s [industry-based] Management Advisory Committee, upper management presents a detailed analysis of the backlog per level (e.g., 895 at level 1; 3767 at level 2; and 188 at

level 3), the throughput per level, and how the managers have “Optimized the Routing of Review Streams.” The purpose for a May 4, 2005 meeting, as stated in the meeting minutes – “To brainstorm ways for BPRA to issue 10,000 licences a year” – was particularly telling.

Nevertheless, employees outside of management did not seem to remember the backlog being an issue much before the time of my fieldwork. Several also attributed the backlog to things other than an original mission impossible: to the NHPD being understaffed, to the regulations coming into force too quickly to be well-thought out, or to the wide ambit of the regulations in the sense that many products were unintentionally caught by the definition of “natural health product” like toothpastes, deodorants, even possibly oxygen gas.

Two employees suggested that “the backlog” became an issue of concern to assessment officers as well in October 2005, because a consultant came in to do a report, with management communicating the grim news, with one scientist recalling:

> and I remember the backlog becom[ing] very clear, and you know, [that] the NHPD could shut down and all that stuff if the backlog was not cleared.

A manager said that it made sense that assessment officers were not aware of “the backlog” prior to this point, because there was “just the mountain of huge things that needed to be done and scientific decisions needed to be number one driver – you can’t establish standard operating procedures if you do not have the science figured out yet” (Amélie).

Assessment officers reported increased attention again in the spring of 2006, and growing even stronger just before I began my fieldwork in the summer of 2006. This was also a time when two upper managers overseeing scientists did not themselves have any background in science; so, as Amélie pointed out, it perhaps is unsurprising they focused on "process re-engineering" that came from the perspective of a "business rather than scientific model."

Backlog is everybody's business

During the time of my fieldwork, management pushed backlog reduction as that to which every employee should be contributing. Several in management had clear expectations that "everyone has to take part and fix this machine."

Submission status reports consisting of tables and pie charts were circulated regularly to all scientific staff via e-mail. At the beginning of my fieldwork in August 2006, there had been 15,280 product submissions made at the NHPD – at that time, nearly 2,000 proposed medicines had been licenced, and 3,700 been refused or withdrawn.[3] That still left nearly 10,000 product submissions in backlog. At the end of my fieldwork, the backlog had grown by several thousand. A total of 22,229 product applications had been received by mid August 2007, with 3,815 products licenced, and 5,375 refused or withdrawn.[4]

Various initiatives were pursued, using different perspectives to get applications out of “the backlog.” For instance, when one unit started to “triage” of Product Licence Applications received in 2006-2007, they took the decision to focus on the halted files, because they thought a full third of the files left were halted (e.g., waiting on a decision to be made by upper management on an Issue). Those initiatives continued, but they were never enough. [5]

Many managers clearly felt under pressure, with one evincing uncharacteristic and utter forgetfulness when missing a meeting with me:

> I’m sorry about that, a priority just came up. I’m under a lot of pressure. It’s the backlog. We’re having to make sure that everyone who could possibly be doing assessment is doing assessment.

Units that were not typically reviewing Product Licence Applications were temporarily reassigned. My unit as well as a few others started doing batches of non-compendial assessment “as our contribution to the backlog [reduction].” The “backlog” seemed to be used as a justification for threatening organizational change based on “non-productivity,” e.g., not churning out “deliverables.” In the middle of my fieldwork, the unit that developed monographs was supposedly given the ultimatum that if it was “not productive,” its assessment officers would be pulled from the unit and given Product Licence Applications to assess. Although a special project was initiated to produce monographs based on previously published monographs from other sources – because “Numbers are good, even if simple” – it was simply not possible to publish rigorous standards within a few weeks.

At meetings towards the end of my fieldwork, we were told that there were many backlog reduction measures coming through the pipeline, because there either needed to be “drastic measures,” or the NHPD needed to get more funding. As I was leaving, assessment officers who were working on regulatory research or monograph development in the Bureau of Clinical Trials and Health Sciences were permanently reassigned by upper management to the Bureau of Product Review and Assessment to assign individual files rather than develop and maintain the Directorate’s monographs, “to help with the backlog.” Because of the backlog, scientific staff in some (but not all) assessment units complained they were refused many requests which, according to the collective agreement (the scientists were unionized) and expectations of professional work, should not have been refused: vacation leave, permission to take French examinations when they were ready, permission to participate in long-standing scientific working groups requiring a grand total of two hours monthly, and so on. The pressure evidently continued, as in my last week of work it was apparent that most managers were all working on a report for the new ADM, who had requested a backlog report.

Applicants and the backlog

Interestingly, though, it is not clear that a quick reduction of the backlog was of importance to anyone outside upper management. Amélie noted that

> it is important for business that industry will have a predictable regulatory system. It is more important that the system is predictable than fast. [Mimicking industry:] ‘I don’t care how long it takes, but tell me when I will know the decision [to licence or refuse an application] so I know how to invest my money, position, and launch date’ [….] Predictability is not important for us, but for them.

That said, there were several types of “personal care products” that were considered natural health products (sunscreens, toothpastes, and deodorants), with the applications made by large companies putting out new lines of sunscreen, say, in line with current sunscreen trends and for them the length of licensing time was an issue. Several companies, very concerned about not doing anything “illegal,” were also concerned about the time required for licencing because they did not want to put a product on the market before they actually received a licence; representatives from other companies professed to me that they were actively exploited the “loophole” created by regulation without enforcement until the backlog was cleared.

Backlog Busting Progress Meters tackle “the elephant in the room”

A couple of months before my departure from my fieldsite, there was a large staff meeting (rare occurrences) to introduce the Backlog Busting Progress Meters. These metrics were human-sized images of thermometers, indicating number of submissions complete out of the number originally received (the backlog) from 2004 and 2005, and adorned the wall space near the elevator entrances.[6] I suppose the idea was so that employees would remain focused on the goal, feel a sense of pride in accomplishment as the mercury rose, and so on.

To me, these represented the most important measure of the pre-market evaluation of medicines at NHPD at the time of my fieldwork: the backlog. This was a particular sort of measure – its mere existence, was damning. By its existence, the

backlog damned the organization to tenuousness because, by managerial regulatory standards, the existence of a backlog meant the NHPD could not exist. Even when the thermometers were not in sight, the backlog was always present; when not explicit or visualized, the backlog remained "the elephant in the room." That same manager, Amélie, continued:

> I can't imagine this place without a backlog, but we're making it more organized, and better, with better use of resources that have faster better whatever –
>
> but this would have happened anyways. I think that in the absence of a backlog, we would have made it better, and cleaner.

I should note that prior to interviewing her I had believed Amélie to be one of the proponents of the backlog approach. I now suspect she was interpellated into the style of reasoning in which the backlog was incontournable in the same way in which I was: through reasoning activity. Like with the evaluation of homeopathy (chapter 9), "belief" was really not at issue.

The exact metrics chosen in this era of accountability matter; they encapsulate "miniaturized representations" "of the world" (Strathern 2006 in Nowotny 2007: 483), creating the ambit of the problem for which they are the solution (Nowotny 2007 drawing from Power 1997). For this and other reasons, most ethnographies of state-provided biomedicine include a discussion of statistics (e.g., Petryna 2002, Rapp 1999, Young 1995; see also Lock 2002, Rabinow 1999).[7] In any case, the numbers produced by state apparati are perhaps most clearly social relations when one considers the role of classification in the counting necessary for these state-

istics. Of course, one cannot just choose any metric (see also Desrosières 2010), and who exactly is choosing is never clear, and perhaps not determinable (cf. Hacking 1992b). Nevertheless, that the backlog of applications became the central metric, rather than, say, percentage of medicine samples conforming to their quality specifications, is and was disappointing to some. As a manager, Youssef, told me quite ruefully: “I am a specialist in the backlog now. I could do a PhD on the backlog.”

Again, this metric was neither specific to the time of my fieldwork, nor to natural health products, nor to the regulation of products in Canada (cf. Daemmrich 2000).[8] It is unremarkable in the cubicle-bound style of reasoning in public health protection late twentieth, and early twenty-first, centuries.

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1 Readers familiar with drug regulation internationally will also be thinking about cost-recovery. The NHPD did not have cost recovery, and in its current state, there did not seem to be any chance of moving in that direction. Although I heard a handful of remarks about cost-recovery being a source of the pressure to get rid of the backlog, most of the interviewees with whom I discussed the issue dismissed it out of hand. Even employees who thought that cost recovery was a good idea in principle argued that you had to have sufficient staff, which was not the case at the NHPD. In the evaluation of processes at the NHPD, however, I did notice at least one document dated June 22, 2007 that calculated the number of total staff hours that could be spent on any product licence application based on assuming total cost recovery presuming that the cost for filing an application would be on average one thousand dollars (Document “BPRA Current Versus New Processes – Applications and Backlogs”).

2 An example of a news article during my fieldwork was CBC online’s “Health Canada faces backlog of herbal claims,” last updated Wednesday November 1, 2006 (Http://www.cbc.health/story/2006/11/01/herbal-remedies.html, accessed May 16, 2007). The article explains that many companies are illegally making claims that are not yet approved, but figure they can profit before ‘Ottawa gets around to interpreting whether or not it is a valid claim.’ Similar articles were running in the French-language press, such as *Le Devoir*’s “Les produits de santé naturels contreviennent aux règles d’étiquetage” (November 17, 2006 p. A3).

3 According to the Submission Status Summary table for August 31, 2006.

4 According to the Submission Status Summary table for August 16, 2007.

5 Even post-fieldwork, new initiatives are continually introduced to address the backlog. For instance, an update from one of the industry lobby groups, the Nonprescription Drug Manufacturers Association of Canada (NDMAC), in its Quarterly report from 2008's fourth quarter, reported:

> The Natural Health Products Directorate (NHPD) conducted a brief pilot project for a new process entitled 'Early IRNs'. The goal of the new process was to identify submissions in the backlog that have one of seven major deficiencies and to provide feedback to sponsors earlier so that deficiencies can be fixed prior to reviewer assessment. With the participation of NDMAC's member companies, NHPD proudly announced the success of the pilot project and the new process was implemented in December (e-newsletter received January 27th, 2009).

6 The backlog became multiple to become manageable. In mid June 2007, decisions had been reached for just over sixty percent of 9,400 product licence applications received in 2004 and 2005; from June 15, 2007 2004/2005 Product Submission Status Repor).

7 Nicolas Rose has argued that numbers representing people (statistics, for example) are sometimes understood as more real than ephemeral and shifting people themselves (1996:106, see also Lock 1998). Many entities of biomedicine – organ shortage (Lock 2002), unmet need (Dixon-Mueller and Germain 1992), basic science (Godin 2003) – are unimaginable without numbers representing people, their bodies, their activities.

8 In an article published August 24th, 2009 in the *Law Times News*, John Harvey writes "Health Canada backlog haunts natural product industry." (Accessed online 10/15/2009); similar mentions and accounts of NHPD's backlog are found on CBC online, e.g. in October 5, 2009 article "Labelling deadline may keep natural health products off shelves" with the subtitle "Hundreds of natural health products could disappear from store shelves next spring because of a Health Canada backlog in approving licences, warns the Canadian Health Food Association." The industry groups mentioned in these two articles (Consumer Health Product Canada, formerly NDMAC; and the Canadian Health Food Association) have little in common besides being lobby groups, and, of course, their concern with the backlog.

Chapter 16
"Science culture" vs. "MBA culture"

> Question: Which would you rather manage?
> a.Product submissions
> b.Adverse event reports
> c.Ideas or concepts
>
> Answer: Product submissions, because they are countable and the numbers are meaningful.
>
> (Question and answer presented by a facilitator from the Office of Science and Risk Management, at an internal workshop on science in the Health Products and Food Branch in 2007).

The above question, presented with one correct answer, seemed unproblematic to the presenter. The above question, presented with *one* correct *preference* as an answer, left me flabbergast. But there was another reason for the audience, myself included, to be confused. The question and answer was used as a framing comment in a workshop on science in the Health Products and Food Branch. Or so I had thought.

I was not yet properly enculturated, and so the question and answer seemed "like a free flight of fancy" to me, to use Fleck's words (1979:141). It was not. It was part of a style of reasoning replete with its own tools, instruments, material culture, temporality – the reasoning of another thought collective. I was not truly interpellated into this thought collective, although like billions of other humans around the globe, I am likely at the periphery of the collective. I doubt I will ever be interpellated into that thought collective, with concomitant dispositions, preferences, because I do intend to reason as a manager. Nevertheless, as I will

argue below, like the billions of other reasoners on this planet I am unsure whether I will have a choice.

Managerialism

Managerialism, as a mass noun, can be defined as the "belief in or reliance on the use of professional managers in administering or planning an activity" (Oxford Dictionary Online).[1] Managerialism is by definition generic. The tools of professional managers are designed to be applicable to anything that can be figured as "activity" – a project, a government bureaucracy, a small business. This definition implies that managerialism is anything professional managers do.

My use of the term is more specific. It is specific in ways slightly different than managerialism's operationalization by other social scientists – for instance as the use of output measures in public administration, aka the New Public Management (Cutler 2005), or the ethos or refrain that "only that which can be measured can be managed" (Leslie 2010). These more specific operationalizations do not contradict my specific use of the term, although perhaps specific is not the right word because it is also broader than simply "anything professional managers do." Managerialism, the way I use the term, is a cosmology.

By managerialism, I mean the generic shaping of human endeavour according to the generic form of The Project. Projects are associated with Goals set by the

Vision of Leaders (professional managers). Irrespective of content, subject, or purpose, using the generic form of The Project As Means To Goal Attainment, human endeavour may be measured by managers using tools such as Tracking Databases and a variety of their outputs such as pie charts. Human activities are worthy only insofar as they contribute to the goal attainment: completed, measured, evaluated Projects. The corollary to this cosmology is that people are best temporarily appointed to positions or outsourced, because with Progress, new Visions are required (and thus new projects), entailing different human endeavour. Participants must be active, and above all, flexible.

Managerialism, in this more specific sense in which I am using it, could be defined as: the belief in or reliance on the tools of project management and the visions of leaders, as the best way to formulate and shape any human endeavour.[2] Managerialism is the reliance on professional managers, yes, but because many workers interact with managerial tools and are making themselves into managers in the Foucaultian sense it is more apt to focus on the tools and techniques that are part and parcel of professional management, but may be taken up by others.[3] Managerialism embedded activity-shaping routines, ideologies, and material culture into the workdays of the scientists I studied, through very mundane technologies such as the database, the backlog and its tracking, and performance quotas.

Managerialism not administration

As long as there has been bureaucracy, there have been managers. Nevertheless, managers are necessary, but insufficient, precursors to managerialism. Managerialism is relatively new in Canadian public health protection. It is difficult to pinpoint a precise date, but if I had to pick one, it would be 1982. In 1981, National Health & Welfare had an Administration Branch. In 1982, National Health & Welfare had a Management Practices Branch, rather than an Administration Branch. By 1984, this was the Corporate Management Branch, and by 1985, the annual reports from which I gleaned this information stop being a useful source of information of organizational structures and instead developed a new photo-heavy format that begins with The Vision (the mandate) and continues with other trappings of managerialism.

There are other indications that 1982 is at least in the right ballpark. Based on my prior archival research, managerialism did not exist in the NHPD's precursors in the National Health and Welfare prior to the 1970s. I say this with some certainty, because in the 1970s there were few or no professional managers in the food and drug divisions; the chiefs, directors, and so on were scientists or doctors who had risen through the ranks of the public service. These directors tended to remain in the same branch for years, often in the same position until retirement. This changed in the 1980s and 1990s.[4] This is unlike today where there seems to be an expectation that managers move onwards and upwards, and executives change *department* (not section) two, three, or four times a decade. I am also confident that 1982 is a reasonable approximate date, because I have yet to see any

evidence of the tools and entities so central in the managerial style of reasoning: backlogs, fickle strategic goals, and so on in records from the 1970s.

To give more precise figures for the Canadian Public Service more broadly, thanks to Dwivedi & Gow (1999): appointees to the positions of deputy and assistant deputy ministers by the 1980s were rotated from their position after 2.7 years; a decade or more previously they had, on average, six years in any given position. Dwivedi and Gow (1999) date this change as occuring in the Canadian public service more widely between the late 1960s to the 1980s. Among deputy and assistant deputy ministers, Dwivedi and Gow also note the decline in the percentage of those with technical expertise (e.g., academic or legal qualifications) in favour of management experience. The percentage of appointees with no more than a bachelor's degree increased from 18% in 1967, to 31% in 1987 (Dwivedi and Gow 1999:135).[5]

1982 was also the year of publication of the influential *In Search of Excellence* was (Peters and Waterman). According to Joe Moran (2008), this was the first management text on the *New York Times* bestseller list. This popular work called for the eclipse of bureaucracy as epitomized by Weberian rationality in favour of focus on customers' needs and the productivity of competition (Inwood 2009). In Canada (as well as in Australia and the UK), political scientists refer to the 1980s as the advent of the New Public Management – in contrast to the public administration through the earlier twentieth century – and tie the New Public

Management to the general governance approaches of Margaret Thatcher in the UK, Ronald Reagan in the US, and Brian Mulroney in Canada.[6] The New Public Management is “a set of techniques, practices and organizational structures that have been applied in public sector services in a systematic way, broadly over the last quarter of a century,” including a focus on *outputs* that can be reckoned with *performance indicators* (Cutler 2005:126).[7] In Canada, Inwood argues, the New Public Management model was in evidence in the Program Review and PS2000 statement (Inwood 2009:312). Several writers link the New Public Management to the development of specific measures: the introduction of programme budgets (Dwivedi and Gow 1999:127), and even more specifically the focus on measures of outputs and performance measures (Dunleavy and Hood 1994). While the *administration* of monies given for a program has long occurred in bureaucracies, the new feature of NPM, the *management* of monies – including the focus on *outputs* was not; previous costing of the public services involved inputs only (Cutler 2005). Inwood (2009), states that the New Public Management also involved a reduction in state bureaucracy, concomitant with an increase in privatization, decentralization, deregulation, contracting out, downsizing and other cost-cutting measures in staffing.

It seems that the managerialism of which I am speaking is related to the New Public Management; in both cases managerialism involves measuring (costing) progress, although I place more emphasis on the worlding with projects. Nevertheless, I will continue to speak of managerialism and not public

management for three reasons: (1) It is concise, (2) I am unclear as to its relation to industrial management applied to scientific endeavor before the 1980s, and, most importantly, (3) there is substantial evidence from other social scientists that the cosmology, the style of reasoning of which I am speaking does not appear to be restricted to the civil service.

Cosmologies of managerialism

Blueprints for Renewal.[8] Strategic Plans.[9] Roadmaps. Operational Planning. Business Plans. At least one of each was developed between fall of 2006 and April 1st, 2007, during my fieldwork. Many involved the development of Visions, Missions, Mandates, Issues, Strategies, and of course had to be assessed with pre-planned Performance Evaluation. The development of these strategies were entirely generic, in the sense that the schema and framework could be applied in everything from a tire-recycling business, a non-profit sexual assault centre, IBM, a tiny bed and breakfast, and, in this case, a federal department of health whose activities are set out in Canadian law. Figures 16-1 and 16-2 provide presentations slides depicting these generic strategies (reproduced without permission from the HPFB Employee Consultations On Strategic Plan Framework, January 25 – February 2, 2007).[10]

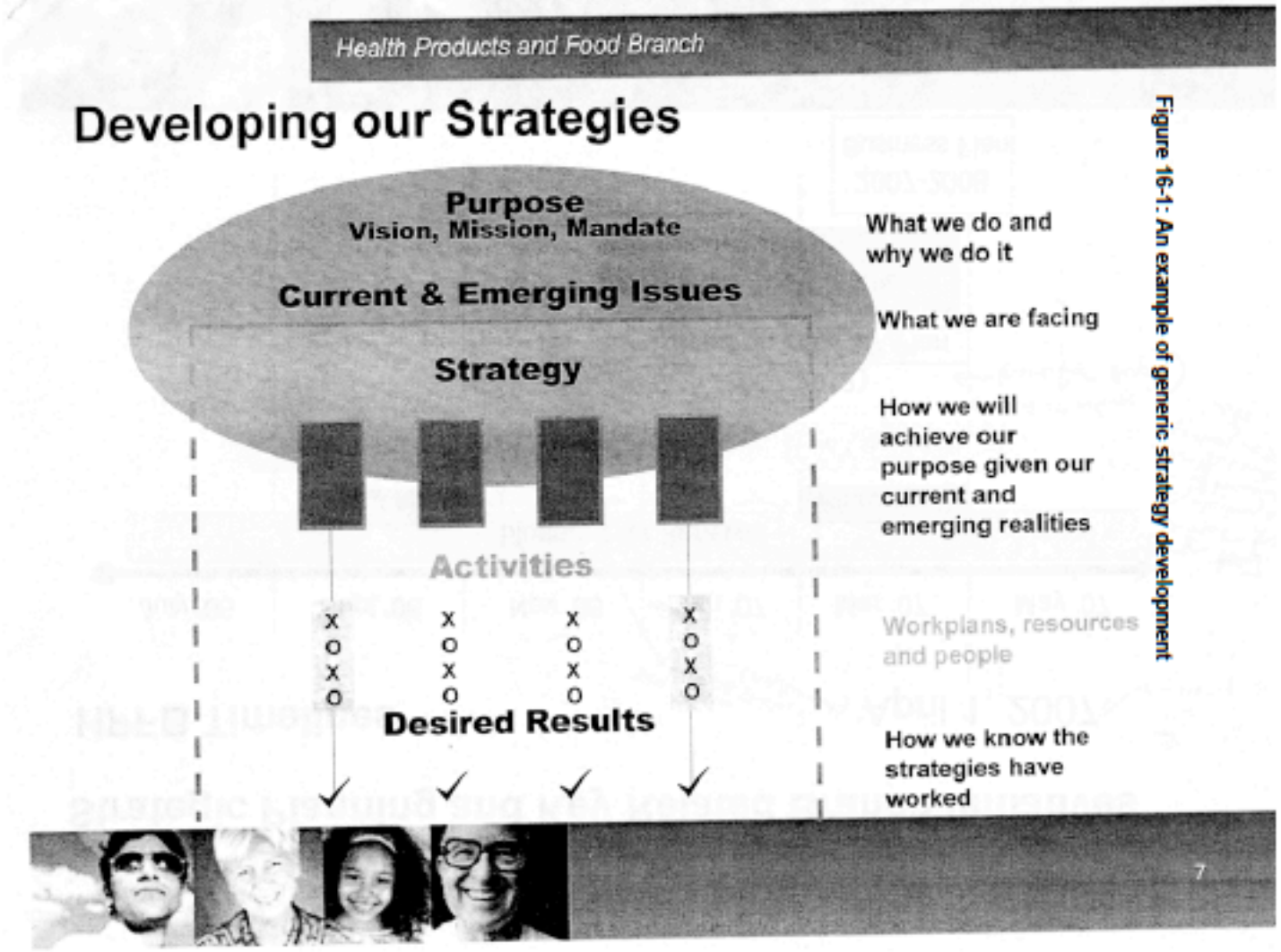

Figure 16-1: An example of generic strategy development

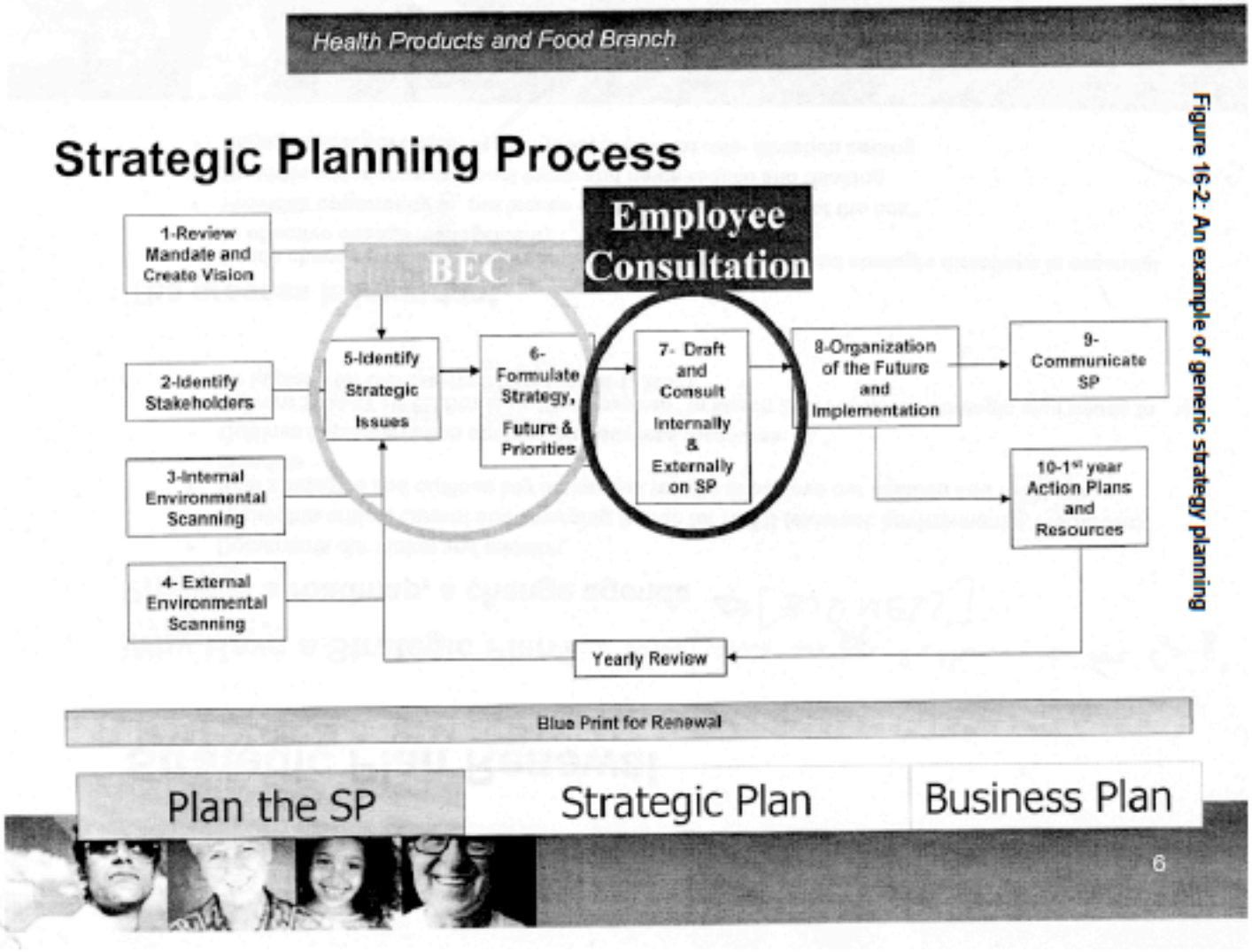

Figure 16-2: An example of generic strategy planning

It was in upper management's interest to be bold and have "active and dynamic verbage," be *client-centred*, as well as include some "safe strategies," ones that could likely be met at the end of five years.[11] They all required consultation.[12]

"Our long term vision" as the Health Protection and Food Branch, I learned at a meeting in the fall of 2006, was in electronic presentation deck format:

> Vision:
> Health Canada will be an internationally-recognized regulatory leader, with an adaptable and sustainable regulatory system and capacity.
>
> We will:
> - Enable timely access to safe, effective and high quality health products and food
> - Sustain and improve efficiency; maintain safety standards
> - Remain transparent and open
> - Contribute to better alignment of regulatory and reimbursement decision-making
> - Strengthen oversight through a product lifecycle approach."[13]

The first bullet point is unique in mentioning "health products and food." With only two substitutions (underlined), I can produce a plausible long-term vision for Industry Canada:

> Vision:
> <u>Industry Canada</u> will be an internationally-recognized regulatory leader, with an adaptable and sustainable regulatory system and capacity.
>
> We will:
> - Enable timely access to <u>innovations</u>
> - Sustain and improve efficiency; maintain safety standards
> - Remain transparent and open
> - Contribute to better alignment of regulatory and reimbursement decision-making
> - Strengthen oversight through a product lifecycle approach.

This independence of content is what I mean by *generic*. These generic Visions, were developed according to generic Plan, sectioned off into discrete generic Projects. I was often at a loss at how to provide constructive commentary at these consultations; because, really, what where they saying? For instance, did the specific “regulatory challenge” mean?

> An outdated regulatory toolkit that is increasingly limited and inflexible in responding to today’s health products and food environment and is falling behind international best practices.”(Health Canada 2007: 8).

Was this saying that there would be an increase in the dollar limit on penalties that could be imposed on a company found guilty of contravening the Food and Drug Act, because that limit was set in the 1950s? Or was management considering the precautionary principle to be part of the outdated regulatory toolkit, because the US did not ascribe to the principle? Either way, why did “they” not just say so?

Marilyn Strathern (2006), in an article entitled “Bullet Proofing,” considers whether these sorts of managerial statements, often written in bullet point form, are simply not meant to be analyzed for meaning. While I could make neither heads nor tails of such statements, and sometimes lapsed into thinking the whole process was some sort of cloak-and-dagger political maneouvering, I believe that there were many upper managers who did find meaning in these statements. I say this because when I made my contributions to “consultations,” I invariably stated that I could not provide meaningful feedback because I could not discern whether the proposed changes, visions, plans were going to increase public health protection and safety standards, or lessen them. Based on the responding managers’

reactions, which was not defensive, but rather one of explaining what they meant (but in equally obscure, generic terms to my mind and that never seemed to really answer my question) I got the impression that these statements really *did* mean something to at least some managers.

> OUR VISION
> *WHAT WE WANT:*
> - To be a trusted and respected scientific regulatory authority in Canada and internationally, playing a vital role in protecting and promoting the health and safety of Canadians.

That draft vision was circulated as part of the package for the Employee Consultation on the Strategic Plan Framework in early 2007.[14] Something irritated me about this statement. (And here I mean something beyond the standard irritation at the need for long-established institutions with clear legal mandates to busy themselves with trendy short-term public relations statements in bulleted format, cf. Strathern 2006). Once at the consultation, and in my usual inarticulate style, I tried explaining that I felt this statement seemed to put the cart before the horse, because it was only by actually protecting and promoting the health of Canadians that the Branch would become a trusted scientific authority internationally; one should not hope to be a trusted scientific authority without doing good science. I was surprised at the comments that then emerged from other, more senior employees attending the consultation: “University researchers will start challenging us”; “I don’t think management really understands how little actual science goes on here”; “What we do isn’t really science, although we like to say it is. We ensure researchers are doing their job in evaluation; we don’t do

science itself." A facilitator explained that the draft text had been developed at a recent retreat for upper management ("BEC [Branch Executive Committee] retreat").[15] It was only during this barrage of exchange that I realized that probably some of management had absolutely no clue what their underlings actually did, because these managers had neither science background nor much experience at Health Canada. The process of developing a strategic plan renewal, I learned, while important for many reasons, also served to engage the "executive team in their most important role – direction setting."

Who sets direction in a science-based regulatory agency

When I was looking for relevant documents pertaining to the development of the standards of evidence on the NHPD's shared drive, I came across the following incomplete draft mission statement from 2004, which I found telling: "A nationally based, flexible organization that has the capacity to fulfil [sic] its mandate and priorities in a changing environment," with the first and only bullet point: "improved management tools and systems."

During the course of my participant-observation, I made several faux pas with respect to management at the NHPD. Many faux pas were inevitable, part of my becoming properly socialized. One I truly regret. I made a statement with only the best intentions, but I realize now, it might have been the ultimate insult. The statement was made in the context of one of my indirect managers soliciting written feedback on her performance. I thought she was doing a great job, so I gave her

what (to me) was the highest of complements – stating that any issues we evaluators had in assessment seemed to be promptly dealt with by higher management, and otherwise I barely heard from her. As I continued to explain, an excellent manager facilitated the work of their underling scientists; so when everything was running smoothly and issues facing the scientists were resolved as quickly as possible by upper management, this was the sign of an excellent manager. Unfortunately, I now realize that what I meant with only the best intentions – I really thought this manager was doing an excellent job – might actually have been the ultimate insult. Apparently, managers need to be *active*, and as one becomes an executive one must pay attention to "their most important role – direction setting." Clearly, this is completely at odds with my belief of what upper management's most important role is, in a *regulatory agency* with legislated roles in public health protection: ensuring that the scientists and other regulatory staff have sufficient resources to do their work, and clearing any hurdles to the regulatory staff's work. My very outdated assumption was that management supported professionals, worrying about the necessary politicking and general operations so the professionals could do their work. I believe, that much of the rhetoric in the branch can be read as just the opposite: that professionals are expected to work to support management. This is the definition of managerialism.

Back to the workshop on science in the Health Products and Food Branch

Had I been a more astute observer when I attended the science workshop that I mentioned at the start of the chapter, I would have paid more attention to the

context of the workshop: held to develop a science *strategic plan* for the Health Product and Food Branch, a science plan that would complement the overall strategic plan for the Branch (that was the focus of the workshop described in the last paragraph). Although the science-specific workshop was open to all Health Product and Food Branch employees – of which there were at least a thousand, I believe, although estimates varied – there were fewer than a dozen of us sitting at tables arranged into a large semi-circle in the so-called "paradigm room" lost in a maze of hallways at Holland Cross, a building across the street from Health Canada's main campus at Tunney's Pasture. Although the attendees were clearly not a representative sample of Branch employees, the dynamics of the group – including substantial divisions of opinion and perspectives between scientific staff and managers – were indicative of levels of misunderstanding in the organization in general, if my year of fieldwork was representative.

I think it would be fair to say that most participants, who were laboratory-based scientists who had been working at Health Canada for years, claimed that basic science, at Health Canada, was akin to a "dirty word." One participant explained that if one defends one's laboratory work as "applied" science, they (management, politicians) say industry should be doing it. If one defends one's laboratory's work as "basic" science, they say academia should do the work. Another participant said that a new word was required, and a representative from the Office of Science and Risk Management countered that we already had it: "regulatory laboratories with independent capacity."

At a certain point in the workshop, after several rounds of volleys, I decided to state that there seemed to be two solitudes in the Branch: science culture, and MBA culture. To my surprise, several other attendees (mostly long-term laboratory scientists in the Branch) readily took up this language, with a representative from the Office of Science and Risk Management later complexifying the situation by adding a third category, versus “public administration culture.”

Clearly no employee at that workshop the Paradigm Room could claim to be exclusively one of: regulator, scientist, health practitioner, manager, administrator. As a public servant, each person in that room acted, during the workday, as a blend of at least two. And yet there were, to put it mildly, cosmological misunderstandings. My personal favorite was when one laboratory scientist recommended: “management should not make basic science a dirty word.” A representative from the Office of Science and Risk Management transcribed this recommendation as: “the importance of interdisciplinary teams.” (Although, judging by the exasperated facial expressions of scientists around the table, no one seemed to agree with this rephrasing, but for this individual it seemed to be a direct transcription.) There was also the perpetual issue of credibility, which clearly meant very different things to scientists and managers. In science culture, a scientist reasoned, people do not talk about the “organization’s credibility” – “individuals are who build credibility,” by developing research or reference expertise. In MBA culture, as I discovered, Health Canada’s “brand” credibility was on the table.

These discrepancies were the source of tensions. One statement in the strategic plan, attempted to have it both ways, by emphasizing that science was central to the brand: “As a science-based organization, excellence in science is the cornerstone of our credibility and our ability to accomplish our mission.”[16] But the tension persisted because, at the end of the day, scientists and managers could not entirely go their separate ways. Scientists needed managers to get the money so they could do their work in health protection; managers needed scientists for a credible brand. What was important to one, was not necessarily important to the other (cf Strathern 2001).

Standardizing along business lines

I had been introduced to this tension during previous “science” oriented events, but at those previous events I had just dismissed management’s statements as, to put it charitably using the words of Fleck, “free flights of fancy.” To take an example from during the 2006 Health Canada Science Forum, when I attended a panel on “ethics” out of curiosity. The panel speakers included an upper manager from a science-heavy branch, as well as a senior scientist. The upper manager, who had a background in political science and had been appointed to Health Canada from Industry Canada, spoke first. The senior scientist’s statement that followed, included the remark that a central challenge in the regulatory sciences was how to get senior staff who are not scientists to “understand better the technical stuff.” As the panel discussion continued, the upper manager was at some points quite

clearly speaking another language, for instance asserting that “Health Canada has a very strong brand.”

This attention to the Health Canada brand was possibly a government-wide (managerial) endeavor, given the memo announcing the launch of “new Visual Identity at Health Canada”:[17]

> To help build Canadians’ trust and understanding of Health Canada as the national reference in health matters, I am pleased to announce the launch of the Department’s new visual identity for Health Canada publications, Web sites and presentations.
>
> As part of the visual identity, we have included our new brand promise: *Health Canada – your health and safety … our priority*. The brand promise tells Canadians who we are and what we do, and reflects our mission. Along with the brand promise, a new descriptor is being launched that will help you explain more clearly to Canadians our Department’s role.
> (Memo circulated 2007-07-23).

Professionalism, with a tinge of cynicism, was affective disposition scientists were interpellated by virtue of social position in the bureaucratic hierarchy

But these presentations were not of interest to many scientists at the NHPD. For one Branch-wide presentation by management, the Director General circulated an e-mail giving blanket permission for the approximately two hundred staff members of the NHPD to attend the presentation at the main Health Canada campus, a 20 minute drive, or 40 minute bus ride away from the NHPD. I counted a total of 16 people from the NHPD attending, including at least four in upper management. When heading back, one scientist summarized the taken-home message from the presentation, as she heard it:

> What I took from that is that it doesn't really affect us. Or at least we'll have jobs for the next while.

Although scientists monitored "what the truth is, according to management," they did so only to monitor what could possibly impact their work. The most well-adjusted public servants, at least as I picked them out among the scientific staff, appeared to have learned to roll with the lingo: "As long as they are paying me, I'll do what they say." One assessment officer who made that statement to me, had scientific as well as practitioner training and was perfectly comfortable stating her scientific opinion; she let the other stuff "roll off"; in fact, she liked changes, remarking "I'm never bored here. There is always something new going on." Many of these well-adjusted scientists also had a well-developed (wicked) sense of humor. This attitude of professionalism, tinged with cynicism, appears to be a well-established attitude into which professionals between the technical and the higher levels are interpellated, as a collective of Whitehall statisticians observed thirty years ago (Government Statisticians' Collective 1979).[18] This ability to let things "roll off" was not an ability that I mastered within twelve months; I, as well as other potentially less well-adjusted scientists, continued to resolutely point to non-sequitors (from the perspective of "science culture" in government).

The truth according to management: regulator culture is the problem

Of course, truth is always relative to the thought collective. While for some regulatory scientists (including myself), "my" culture may have been "science culture," with the "other," "MBA culture," there was plenty of culture-blame to throw

around. At a Branch-wide presentation on the Strategic Plan, upper management commented on, among many other things, “regulator culture.” One of the internal issues regarding transparency and openness, it was explained, is that “there is sort of a culture, regulators tend to be inward-looking and conservative” (cf Chapter 6). This upper manager hedged that he thought this was “natural for regulators,” especially given the omnipresence of litigation, what with 300 lawsuits involving the Branch ongoing.

Two solitudes, as experienced by scientists at the NHPD

Scientific staff at the NHPD often expressed disappointment, and sometimes anger, regarding the actions of upper management, but in most cases they did not *blame* upper management for its choices. This is perhaps not surprising coming from a group of public servants, whose daily activities are circumscribed by the work description of their position. And as I will explain in Chapter 17, this lack of “push back” is also partially attributable to the high rates of tenuous employment in the Directorate. It may also have been for other reasons, including possibly the belief that the two solitudes were insurmountable. As one acting unit head explained her situation:

> Right now, I’m struggling with which career path to choose from, because there are really two: you have science, or you have management. And the minute you go into management you’re pulling yourself away from the science. As you go higher, you’re really are pulling yourself away. I think that many people one step above from unit head – you’re going even further, and at the Director level, well.

In any event, staff at the NHPD generally felt that what was important to lower level scientific staff was not necessarily important, or even known, to upper management. For instance, one long term employee told me how deeply disappointed she felt when, “in the early days” of the NHPD, scientific staff were told to get monographs up in a week, which resulted in some very problematic flaws in the monographs published by the NHPD. She stated that she still feels disappointed, nearly five years later. But she was very quick to point out that she feels ignorant in knowing what upper management feels in terms of pressure from higher management within Health Canada, and industry, when it comes to producing decisions and monographs quickly.

> But the reality is that it takes longer, even though at the senior level, it must be hard to see what the technical pace is. Because of this gap, everyone has to come up with compromises. (Emmanuel)

An instance of FiSH™-y managerialism

It is not that management was not trying hard, in some cases, to work towards “organizational excellence.” It is just that sometimes this induced culture clash, culture-shock, the whole works. Managerialism has many tools for the development of correct disposition – occasionally FiSH™-y ones.

At an NHPD-all-staff in the summer of 2007, its upper management spoke of leadership (in the swamp, see Chapter 15), priorities according to the strategic plan, and changes to the upper levels of the NHPD’s organizational chart. I learned:

Leadership is not something that comes with a position – that is old school. Leadership is something everyone must do from where they sit. Authority is different from leadership. Old school, authority, is when you tell people what to do and they do it. That does not happen anymore. Or maybe it does, but, the speaker hoped, not at the NHPD.[19]

The interactive component of the all-staff began with a staff mixer in which one had to meet others with the same fish species on one's nametag (quite enjoyable, as one got to meet one's colleagues that were usually squirreled away in their cubicles) and self-assorting to tables grouped by fish species. We were treated to a motivational speech by upper management, on the desired work environment. The speech introduced the FiSH philosophy,™ which was expounded by a (presumably purchased) streamed online video promulgating four imperatives:

1. Choose your attitude
2. Make their [the customer's] day
3. Be there
4. Have fun. (Play).

(I have no doubt that the two minute trailer of this video will be illuminating for the reader. The video, featuring a nearly all-male staff animating dead fish and throwing them about in a US American market stall, can be accessed at: http://www.crmlearning.com/fish-video). After the video screening, staff were directed to split up into small groups to brainstorm concrete ways in which we could put the video's FiSH philosophy into action, in our workplace. Some ideas shared in these small groups were along the lines of the video; other interventions were a little more cynical, as a colleague joked: "I really like the idea of 'choose your attitude' – let's shred all the crappy files!" But when each group shared some ideas with the

entire staff, responses included things like: looking one's colleague in the eye, visiting one's colleagues' cubicles rather than e-mailing, and asking how people are doing. (Which, in my experience, is what happened anyways).

Upper management's reflections concluded: "We are the youngest directorate by the way. It is good to be first in something." This youth ("young and young at heart") and relative inexperience in the public service was tied to flexibility and eagerness for change. "If this were the private sector – " the speaker started, but then stated, "but it isn't." Nevertheless, that should not prevent the Directorate to be different, to have a different "culture" than the other Directorates in the Branch.

Managerialism is everybody's business

I have defined managerialism as the cosmology in which the visions of leaders and the tools of project management are the best and only way to formulate and proceed with any human endeavour. In this chapter I have described the Visions and dynamics of their formation in the Health Products and Foods Branch, as seen by a scientist at the extreme periphery of the managerial thought collective. In the previous two chapters I detailed the ways in which the tools (performance measures) and imaginaries (of The Backlog) were brought into scientists' reasoning in public health protection, independent of scientists' belief in, or opinion of, managerialism and its tools.

This phenomenon, is clearly limited to neither the Health Product and Food Branch nor the even the federal public service. In a recent article, Myles Leslie (2010) draws from thirteen interviews with managers, scientists, and technicians working in three forensic DNA laboratories in Canada. In these laboratories, the work has been reconfigured in the past decades so the "scientists" work in suits, "mostly on the phone, in seminary rooms, and occasionally in court," and that have become "first and foremost case managers" (Leslie 2010:294, footnote omitted). Leslie defines managerialism slightly differently than I do, emphasizing process and risk management:

> Managerialism is a way of thinking about organizational activity that emphasizes control through precisely quantified surveillance and focuses on tangible internal processes rather than more nebulous external outcomes (2010:285).

Leslie focuses on the "core managerialist tenet": "If you can't measure it, you can't manage it." Leslie does not point to any particular advocate for the managerial approach to quality assurance in forensic DNA laboratories. He argues that it was a solution compatible with the new style of public management to the problem of "legal deconstructionism" brought to the fore by the trial for O.J. Simpson:

> The QA [Quality Assurance] solution to legal deconstruction might just as well have taken on a more clinical professional form, setting up loose networks of experts to quality assure one another's work through informal contact or the most general and cursory of inspections. Instead, reaching for the option preferred by its new public sector masters [in New Public Management, NPM], forensic biology sought to assure the quality of its work through the precise application of management principles and a focus on process (286, citations omitted).

The interview quotations included in the article belie a similar mindset as in my fieldwork, however, including mention of process reeingineering, but most importantly, the managers' focus on backlogs. This involves a reconceptualization of work. Just as at the NHPD, one of the labs set up a "high volume" processing stream rendering decisions within 30 days, for cases of robbery that are not usually challenged in court; this lab was lauded. "Managerialist approaches do not simply require scientists to audit their own work. Rather they must also think beyond science and into process," explains Leslie (2010:289).

One of the DNA laboratory technicians interviewed by Leslie offered an interpretation of the impact on quality assurance on the workday very similar to the interpretation offered by Binta of her work in comparative assessment (cf. end Chapter 6):

> I wouldn't call it a burden. Everyone knows it's important. At times you can probably feel bogged down from it …. We all know it's important. We all know you have to do it. It's like vacuuming, you know? No one likes vacuuming but you know you have to do it. It's just part of life (cited in Leslie 2010:294-295).

Leslie argues that technicians, scientists, and managers experienced and interpreted quality assurance differently; as necessary drudgery, as vague and unquantifiable activity, and as success. From this variety of reported experience, we can rule out any overriding determining role of innate personality; mapping scientists' uniform reasoning onto an ethos –positing a characteristic spirit of

managerialism as manifested in scientists' attitudes and aspirations (taken from *OED Online* definition) – is also neither accurate nor useful.[20]

The phenomenon of managerialism, I suspect, is neither limited to science nor to Canada. Many students in graduate programs now have their approach to research and writing subtly or unsubtly shaped by upper university administration's concern with graduate students meeting their performance standards ("finishing times") so the administration can meet its productivity quotas. For this reason, senior academics (e.g., Brenneis 2004:581) note the importance of studying managerialist language and practices because of its influence; for instance Waters argues that:

> there is a causal connection between the corporatist demand for increased productivity and the draining of all publications of any significance other than a number. The humanities are in a crisis now because many of the presuppositions about what counts – which is, not to be too cute about it, counting – are absolutely inimical to the humanities. When books cease being complex media and become rather objects to quantify, then it follows that all over media that the humanities study lose value…
>
> One reason we in the academic world might get confused about our duty (as I see it) to make judgements is that we might believe that because of the very hierarchical world we inhabit in the academy, no one really expects us or wants us to exercise our judgement even in cases like tenure decisions that seem to call upon us to judge (Waters 2004: 6, 33)

With a few wording substitutions, Lindsay Waters' concerns in *Enemies of Promise: Publishing, Perishing, and the Eclipse of Scholarship* could apply as easily to the judgements of scientists in public health protection, as they apply to scholars in the humanities.

Based on fieldwork as a research assistant in the Immigration Services Branch of the South African Department of Home Affairs (DHA), anthropologist Colin Hoag (2010) describes many factors at work in the officials' reasoning and judgements. Many differences in institutional context notwithstanding, several factors are identical to the situation at the NHPD. The officials needed to meet quotas, and while they were not in computer-equipped cubicles, "one of the few functioning computers was connected to the Movement Control System (the primary database with which officials interact in their day-to-day activities)" (2010:8). Factors such as high levels of temporary or acting staff and staffing turnover, and high rates of database crashing, may seem spurious, but when combined with other factors clearly only some styles of reasoning are feasible:

> According to [entry-level immigration] officials, [upper] managers have not the vaguest idea of how things work on the ground, disseminating rules and regulations that are totally out of touch with "reality." They know that many of the people in management positions have no history working at Home Affairs (much less at the ground level) but rather have bounced around from one government department to another and therefore lack the nuanced understanding required to manage the DHA's complex responsibilities ….
>
> [The entry-level officials] are instructed during training and through the course of their work to "apply their minds" – to evaluate each case on its own merits "like a judge." This is impossible, however, if they also accede to the simultaneous pressures to interview, research, and write asylum decisions on as many as nine applications per day (i.e., with fewer than 45 minutes per application. (2010:13)

Many of us at the periphery, consider these counts, tools, and framings to be peripheral to our "actual" reasoning. But are they really? If we are to follow the insights of Fleck (1979), that reasoning is inseparable from materially and socially-

embedded activities: as human endeavor and activity is increasingly shaped by managerialism, does it not follow that cognition (as result of a collective, social activity) is increasingly shaped by managerialism? If so, Fleck sets out the next task:

> It is one of the most important tasks in comparative epistemology to find out how conceptions and hazy ideas pass from one thought style to another, how they emerge as spontaneously generated pre-ideas, and how they are preserved as enduring, rigid structures [Gebilde] owing to a kind of harmony of illusions. It is only by such comparison and investigation of the relevant interrelations that we can begin to understand our own era. (1979:28)

Arguably, this new way of seeing and managing the world in terms of generic "activities" is yielding one of today's more common forms, and an important proto-idea circulating among many thought collectives today, to use Fleck's terminology. I suspect what passes from one thought style to another are the measures, the quotas; but even more: the database.

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[1] http://oxforddictionaries.com/definition/managerialism

2 "What is project management?" asked the Qs and As for Sponsors, (Internal document, undated, entitled Project Management in the Review Process). "Project management is a systematic approach to carrying out a specific body of work within an established timeframe. It includes identification and planning of resources, tools and tasks available and required to complete the work."

3 An internal posting was for a Regulatory Information Officer (SG-SRE04) to conduct, analyze and report on another directorate's drug submission performance, as well as preparing reports, doing quality control checks on tracking database entries, and identifying performance issues (Reference # 0607-001202, through the Health Canada Assignment Program). The only thing remotely related to 'science' that I could discern was one assignment tasks, to "conduct environmental scan to determine trends in drug development as it relates to specific therapeutic areas and possible impact" on the Directorate's workload.

4 In the proceedings of the Parliamentary Standing Committee on Health from the late 1990s, there are several testimonies from scientists previously employed in the Health Protection Branch speaking on precisely this issue of managerialism (here defined as anything that professional mangers do). I include here an excerpt from April 26, 1998, in which an elected member of representing a party considered very right wing, asking a question of the former head of a pre-market evaluation division who left her position because of problems she perceived in the branch:

> Mr. Grant Hill (Macleod, Reform Party of Canada): … We have heard that one of the problems with the HPB [Health Protection Branch, which was transformed into the Health Products and Food Branch as well as another in about 2000] is that the scientific capability is still good and yet the administrative capability has been overtaken by, if I might call them, in quotation marks, “business types”. We did actually hear that in years gone by.... The name of Dr. Morrison came up as the leader of the HPB, as having a scientific background and the ability to assess and correct the HPB in a much better way. Do you concur that the department is skewed in that way?
>
> Dr. Michèle Brill-Edwards: I not only concur; if you're at all interested as a committee, I can demonstrate to you nearly a decade's evidence of the systematic disappearance of medical and scientific expertise from the branch, facilitating this whole policy of deregulation. The outcome is exactly as you've put it: that what we are running now is a business and not a health hazard management group, because the people at the upper levels don't understand or have familiarity with the Food and Drugs Act as it marries with medicine and science, and there's no intention to have that capability in the department.
>
> A committee of consumer watchdogs over blood regulation met with the department last summer and were appalled to realize that there are no blood specialists in the bureau of biologics. There is no doctor who is a specialist in transfusion medicine helping after the blood scandal. That's appalling. The department didn't think that was appalling at all; they justified it and said, “What do you want? If we had a specialist like that, what would you want? Would you expect them to be the director?”
>
> So you see the competition now between the so-called managers, who don't have the expertise to do their jobs properly, versus the threat of bringing on board qualified people who would then have a reasonable say in the wise decision making of the department.

5 The eclipse of professional judgement, and rise of managerial judgement, has also been discussed by Wistow (1992) in his discussion of UK public health policy.

6 See also the table comparing the language used in the UK, US, Canadian, French, and Japanese government reports or programs from the 1980s and 1990s in Dwivedi & Gow (1999:128-129).

7 The New Public Management is also not the same as industrial management, applied to science. This long predates the supposed advent of the “New Public Management” in certain British-inspired public services in the 1980s (cf Thévenot 1984, Shapin 2008).

8 The Blueprint for Renewal was longer-term, without a specific timeframe, and outlining bigger initiatives; the Strategic Plan had a specific timeframe and was a planning document, outlining "the actual deliverables that should result from Blueprint initiatives" (from slide 24 of presentation by Branch upper management at an HPFB all-staff meeting, entitled "The Future of HPFB. 2007-2012 Strategic Plan" on May 29, 2007.) BUT "The Strategic Plan offers the broad, strategic direction for the Branch […] while the Blueprint outlines specific strategic policy initiatives on the regulatory/ policy side" ("Questions and Answers – Strategic Plan 2007-2012" page posted on HPFB Intranet, via Home > Key Initiatives > Strategic Planning, accessed May 24th, 2007.)

9 Still confused, after the last endnote? The Strategic plan "is a key tool to strategically position [HPFB] for the future," articulating "mandate, vision, and values" as well as objectives and actions to meet those objectives (from October 2006 presentation). Whereas, the Blueprint for renewal emphasized regulatory changes.

The Blueprint for Renewal used to be the "comprehensive review", something that makes infinitely more sense, but is administrative (e.g., with associations of inaction), rather than managerial.

10 I was advised by a Health Canada access to information specialist that "if it is published, it is public" and "published" includes internal power point presentations; thus the slide is reproduced in accordance with this rule.

11 The google.ca web descriptor for Health Canada's website (accessed October 2, 2009) proclaims the Health Canada website to be "a client-centered point of access to one of the Government of Canada's collection of health related resources…."

12 Of most salience, in my mind, was the so-called A-base review. This is important because it is in line with that useful adage for any researcher: "Follow the money." From what I understand, the "A-base" is the amount of money given to a department every year to pursue its activities; this amount is negotiated by ministers with other ministers, aiming to get increased money from the fixed pie of the tax-base. A stable organization, one would think, would have a stable "A-base." Such was not the case, for instance, for the Natural Health Products Directorate, which had, I was told, absolutely no A-base funding, and therefore every year there was a scramble to find the money to cover the Directorate's operating costs and which, of course, did not make the Directorate popular among other Directorates who likely perceived the NHPD as a "giant cash sponge." I do not remember a consultation on the A-base review, however. (There is a chance I had insufficiently honed my bureaucrat sensibilities, though, to notice such a consultation announcement in my first months of fieldwork.)

13 Slide 7, entitled "our long term vision," in presentation entitled "HPFB in 2010 and Beyond. [presented at the] 4th Canadian DIA [Drug Industry Association] Annual Meeting, by Omer Boudreau, Director General of the Therapeutic Products Directorate." Presented internally to HPFB staff November 2006.

14 Draft Framework for the HPFB Strategic Plan 2007-2012, circulated January 29, 2007 as part of package for the Employee Consultation on the Strategic Plan Framework January 30, 2007.

15 The final, published version of "Our Vision" in the Strategic Plan did indeed include the inversion: "To play a vital role in protecting and promoting the health and safety of all Canadians by excelling as a trusted scientific and regulatory authority for health products and food in Canada and internationally."

16 Health Canada. Health Products and Foods Branch. 2007. Health Products and Food Branch 2007-2012 Strategic Plan: 2.

17 The last paragraph of the memo was: “The Marketing and Consultation Directorate developed the new visual identity after extensive consultations with both the public and employees. It adheres to all federal government policies, including the Federal Identity Program and Communications Policy of the Government of Canada.”

18 The Government Statisticians Collective, from the UK, was making an observation about the tendencies towards certain attitudes, or dispositions, up and down the hierarchy in technical areas in Whitehall. They simplified the hierarchy into three levels.

The first, policy makers, a category including ministers, mandarins, and administrators, had the common attitude to work of “cynicism.” At the NHPD the equivalent would probably be upper management, of which I did not have much contact other than as a witness to their presentations to scientific staff.

The second level, the technicians (computer programmers), had the common attitude to work of professionalism. Between the first and second layers the Collective included an intermediate level, the statisticians. I believe most scientific staff would fall into the technical or intermediate later.

The attitude to work of the third layer, the clerical officers, card-punchers, and so on, was characterized by the Collective as naivety or indifference. At the NHPD, the equivalent would likely be the non-scientific staff whom I only interviewed or observed to contextualize scientists’ work.

The Collective writes:

> The ‘attitudes’ of different layers of staff to their work [in the hierarchy], whilst being simplified representations, are nevertheless worth recording on this understanding. Administrators are not all cynical – some really believe in ‘serving the state’, or even ‘reforming society’; while cynicism may be found among routine employees, as well as naïve commitment or indifference to their work. Powerful influences, however, do tend to structure attitudes in the directions shown. For example, the higher placed people are in the hierarchy, the more information they have about the real rationale for policies (often so different from those publicized), and the more useful cynicism is in adapting to this information.
>
> By ‘professionalism’ is meant the ethos by which professional workers try to maintain a certain independence, and standards of competence, accuracy and integrity, within their own narrow technical sphere, while carefully abstaining from questioning, or taking responsibility for, the ends to which their skills are used. Statisticians, working in closer contact with administrators than most other professional staff, retain only an attenuated professional ethos, and partly come to share the attitudes of administrators. (1979:137-138)

19 A discussion of domination and authority relative to Weber’s work on professionals in the bureaucracy – in the sociological literature – is provided by Clifford Nass (1986).

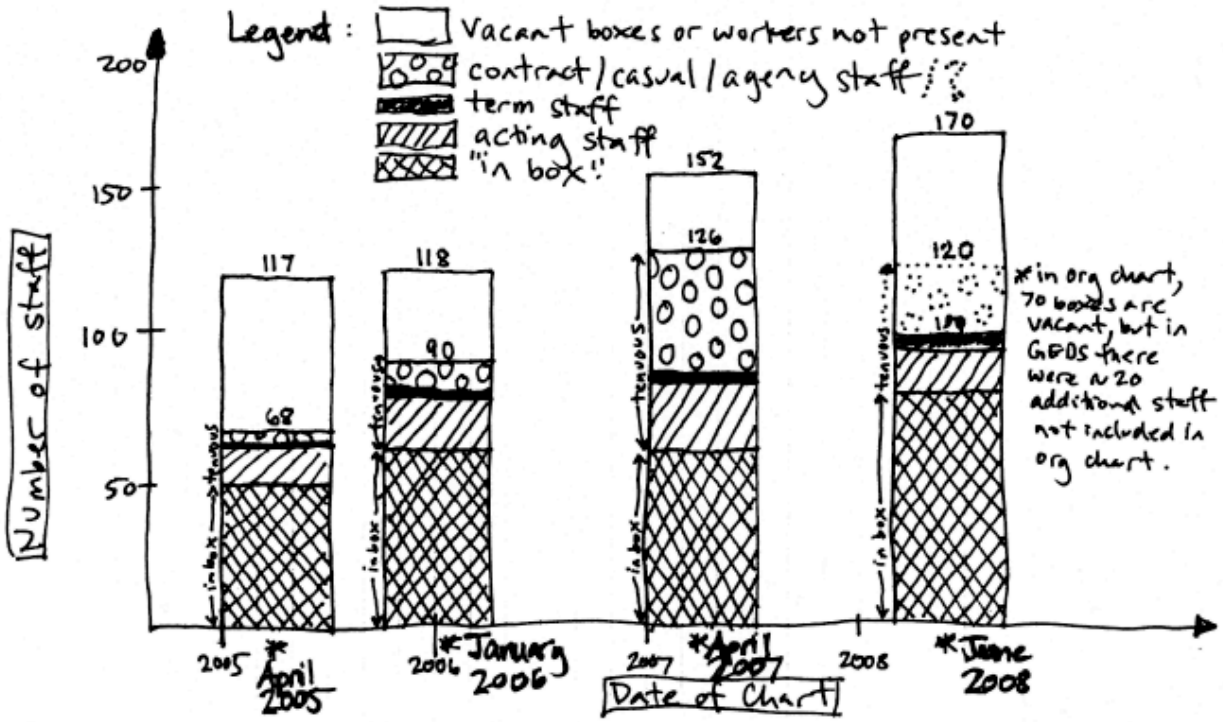
20 While I could perhaps argue that yes, I found a characteristic spirit of managerialism manifest in attitudes (we have to be flexible!) and aspirations (file completion, backlog reduction), this seems to miss the point entirely, and is therefore incorrect. ‘Ethos’, given its association with ‘spirit’, seems to internalize or miasmize; when my observations lead me to externalize, materially and vocally. Scientists ‘bought-in’ to the rhetoric, tools, and trappings of managerialism to different extents, if opinions expressed in interviews were an accurate indicator. There were genuine advocates, who used the measures of managerialism to evaluate themselves in comparison with their peers. There were absolute cynics. Either way, scientists used the rhetoric and tools of managerialism while reasoning. In my work as a scientific regulator, I know that my own reasoning with the mantra *We have to be flexible!*, did not result from an internal managerialist spirit.

Part VI. Peopled standards

Chapter 17
Staffing matters
The high rate of temporary and tenuous employment among scientists

Staffing was a particularly salient – and sensitive – issue at the Natural Health Products Directorate during my participant observation in 2006-2007.[1] Rates of precarious and tenuous *employment* in the Directorate were high among scientific staff. The reason why I have been using the term "staff" rather than "employee" to speak of the scientists in the Directorate is because a significant number of scientists were not technically considered employees. At one point in my fieldwork, a staffing specialist ventured that forty percent of the scientific staff at the NHPD was hired via temporary employment agencies on contracts of a few months length; this implies that forty percent of NHPD's scientific staff was not considered employed by Health Canada. Lower management believed those rates were even higher among assessment officers, telling me that nearly three quarters of their assessment officers were not considered "employees" in September 2007. I use the modifier *tenuous* to indicate the precariousness of obtaining sequential and multiple contracts via hiring agencies. I use "tenuous," rather than precarious, because the concern over the renewal of contracts happened seasonally, rather than daily. Compounding the sense of temporariness, many full employees, while not in tenuous *employment*, were in tenuous *appointments*. In April 2007, nearly thirty percent of all permanently-hired scientist-employees at the NHPD were "temporarily" acting in supervisory positions (see Figure17-1).[2]

Figure 17-1: Number and Type of Staff in Scientific (SG-SRE; BJ; CH) Positions in the NHPD Organizational Chart, 2005–2008



According to my calculations, during the time of my fieldwork, over half (51%) of the NHPD's *entire* scientific staff was "temporarily" staffed in or appointed to a position (see April 2007 in Figure 17-1).[3]

Staff turnover was also an issue. An audit of NHPD staffing, conducted just after my departure from the field, identified up to fifty percent turnover in some assessment units (Elliot and Plante 2008:14 in Health Canada – ATI A-2008-00193). The sense of flux was such that, for some staff, a relatively stable workforce at the NHPD – a workforce of approximately two hundred at the time of my research – became simply inconceivable.[4] When one of my colleagues stated at a social event that she was losing sleep trying to figure out how the NHPD's backlog could be cleared by 2009, another colleague looked around the large table of NHPD scientific staff, shrugged her shoulders and instructed the stressed colleague not to worry "because none of us will be here [at the NHPD] anyways." While most of the scientists who sat around that table are indeed still at the NHPD at the time of writing (2009), I doubt any one of them would have comfortably predicted, in 2006, that that would be the case.

This high rate of temporary, and often tenuous, appointment combined with a sense of institutional flux is noteworthy for the anthropologist for several reasons. First, it was an important topic of discussion among scientific staff themselves – a good enough reason for anthropological investigation. Second, I argue this high rate of tenuous appointment had an impact on the assessments done by scientific

staff, because half of the scientific staff depended on the good graces of their immediate supervisor (and of other forces in the NHPD and Health Canada) for the extension of their appointment every few months. This dependence, according to my observations, encouraged obsequiousness. I will address this first and second point in turn.

Methodological caveats

But first, the conditions of my fieldwork require that I make two important caveats. The first caveat is to note the timing of my fieldwork: August 2006 to September 2007. A few managers in the Bureau of Regulatory Assessment were concerned that I specify the timing of my fieldwork in my research reports, because, they felt, that time period was anomalous due to the NHPD taking "exceptional measures" to reduce its backlog. I agree that this timing is important to specify, because during my period of participant observation, levels of temporary staffing were higher than before and after my fieldwork, at least according to formal documentation. Specifically, in the organizational chart from April 2007, 51% of scientific staff had temporary appointments (i.e., were casual, agency, term or acting), versus approximately thirty percent just over a year before and after (see Figure 17-1).[5]

The second caveat is that this chapter is not meant to convey a sense of bleakness regarding the NHPD work environment. Not only can I attest I was a very content employee at the NHPD, in my confidential interviews with scientific staff, a common, unprompted refrain was "the NHPD is such a great place to work."[6] But,

as the reader will likely infer, the actions and attitudes of direct and indirect supervisors strongly shaped staff's experiences at the NHPD, and these attitudes varied widely across the directorate. There were 24 positions for management in the two bureaus involved in scientific assessment, including: 17 unit heads, 5 Managers, and 2 directors. There was also substantial turnover in upper management at the time. Nevertheless, because the emphasis in this dissertation is on systemic issues indexed by gossip like the labour situation and the particular meaning of fairness, and I do not comment on issues particular to micropolitics. This is not to say that, like in any organization, micropolitics were not important to those in management. Early in my fieldwork, when I explained my research focus to two employees in management, I specified that my focus was not on micropolitics, and that "anyways, it [micropolitics] does not seem to be a problem here."

management 1	[*noticeably raised eyebrows, uncharacteristic*]
management 2	[*long pause*] I'm glad you feel that way.
Jennifer	Well, anyways, I haven't noticed it, and I will continue to remain willfully ignorant.
management 2	[*laughing*] Willfully ignorant!
management 1	Ignorance is bliss.[7]

Finally, a caveat regarding interpretation: if a few sections in this chapter and the next read like a primer "How to get around hiring rules in the Canadian Public Service," I should underscore that, during my fieldwork, the NHPD was a new Directorate with many new managers who, as far as I could tell, were entirely unsupported by Health Canada's Corporate Human Resources and other peers. Furthermore, NHPD's in-house Human Resources was staffed primarily by non-

employees (agency and casual staff, as will be explained below), and so these staff had limited access to training and "institutional memory."

Social knowledge is key

My suspicion is that any ethnographic account of the Canadian Public Service that did not discuss staffing matters could perhaps be compared to a version of E.E. Evans-Pritchard's *The Nuer* (1969) that made no mention of cattle. Let me begin by describing the general importance of staffing matters to the NHPD's scientific staff, even for those in indeterminate employment or appointments.

For these staff, the importance of keeping up to date with the positions, roles, responsibilities, and movement of others in the NHPD and public service cannot be over-emphasized. Scientists frequently consulted with others for their expertise, and it was often difficult to do one's own scientific work without ken of others in the organization (cf. Chapter 7). As historian Steven Shapin points out in *The Scientific Life: A Moral History of a Late Modern Vocation*, "knowledge of things still depends upon knowledge of people" (2008:xvii); perhaps nowhere is this truer than in the public service. As public servant scientist pointed out in an employee consultation on HPFB's science priorities, one should not underestimate the "importance of being able to go out for coffee with someone who is up-to-date." Even for non-scientific issues like knowing the proper administrative procedure, one had to find

“the guardian” or go-to person for any given procedural document before giving much credence to a document not known “personally,” because of these documents’ tendencies to go obsolete.[8] Up-to-date knowledge of Health Canada’s social organization was also crucial should a scientist be unsatisfied with his or her work environment and want to transfer to a preferred environment. A subset of employees, who worked pro-actively on their careers, were amazingly adept at cultivating and staying current with their social networks, and put their social and organizational knowledge to use in obtaining desired assignments and promotions.[9] This skill was encouraged at events such as Health Canada’s orientation for new employees, where a facilitator explained “it’s all about networking.” One employee explained “the more you move around, the more people know who you are, and the better things are.” Even employees who did not appear to be especially driven by career aspirations, when asked about the history of the NHPD, provided me with a surprising amount of unsolicited detail regarding job competitions, acting appointments, and other such “organizational knowledge” that had occurred many years previously.

Much of this information was circulated informally. There were, however, a few formal ways to find out another employee’s position or to track movement in the public service. Staff regularly consulted an internal database available on Health Canada’s intranet for other employees’ position titles and contact information.[10] The career-minded employees often arranged to receive e-mailed alerts of job competitions and notifications pertinent to their job classification from a service

(Publiservice) available to public servants.[11] The ultimate, formal key to organizational knowledge within the NHPD, however, was its organizational chart, or, as it was known at the NHPD, the "org chart."[12] On my first day of work, my supervisor had walked me over to this irreplaceable bundle, of about 12 papers stapled together, that was thumb-tacked to the notice board in the kitchen of each floor in the Directorate. My supervisor pointed to my box – then titled "Vacant 14," but later titled HFHNE-914– and explained how the org chart told me what Bureau I was in and who her supervisor's supervisor was. This tool was crucial for my daily social interaction until I could remember the names of my many colleagues, and until I learned to keep track of my ever-changing indirect supervisors through chitchats.[13] A few months into my work, the org charts disappeared from the kitchen bulletin boards.[14] After that point, the org charts were distributed only to management, who were instructed to keep them in locked cabinets, out of sight from other staff. Although certain managers regularly updated their employees on staffing changes in the Directorate, other managers did not regularly share this information. Informal means such as gossip and chitchats – locally referred to as "the NHPD rumor mill" – were thus the primary means of following the entry and movement of others in the Directorate, as well as detecting the possibility of widespread organizational change. I will return to this gossip below, but first, a description of the scientific positions in the NHPD's organizational chart, because this chart is as important as kinship diagrams in British ethnographies, or, perhaps more appropriately, as the family lines provided in the first pages of multi-generational Russian novels. I have included a non-standard overview of the

multipage organizational chart from April 2007 (not formalized) as Figure 17-2; the details are less important than the pyramidal hierarchical structure. (The boxes are "boxes" I refer to below, the circles are abbreviations of many boxes.)

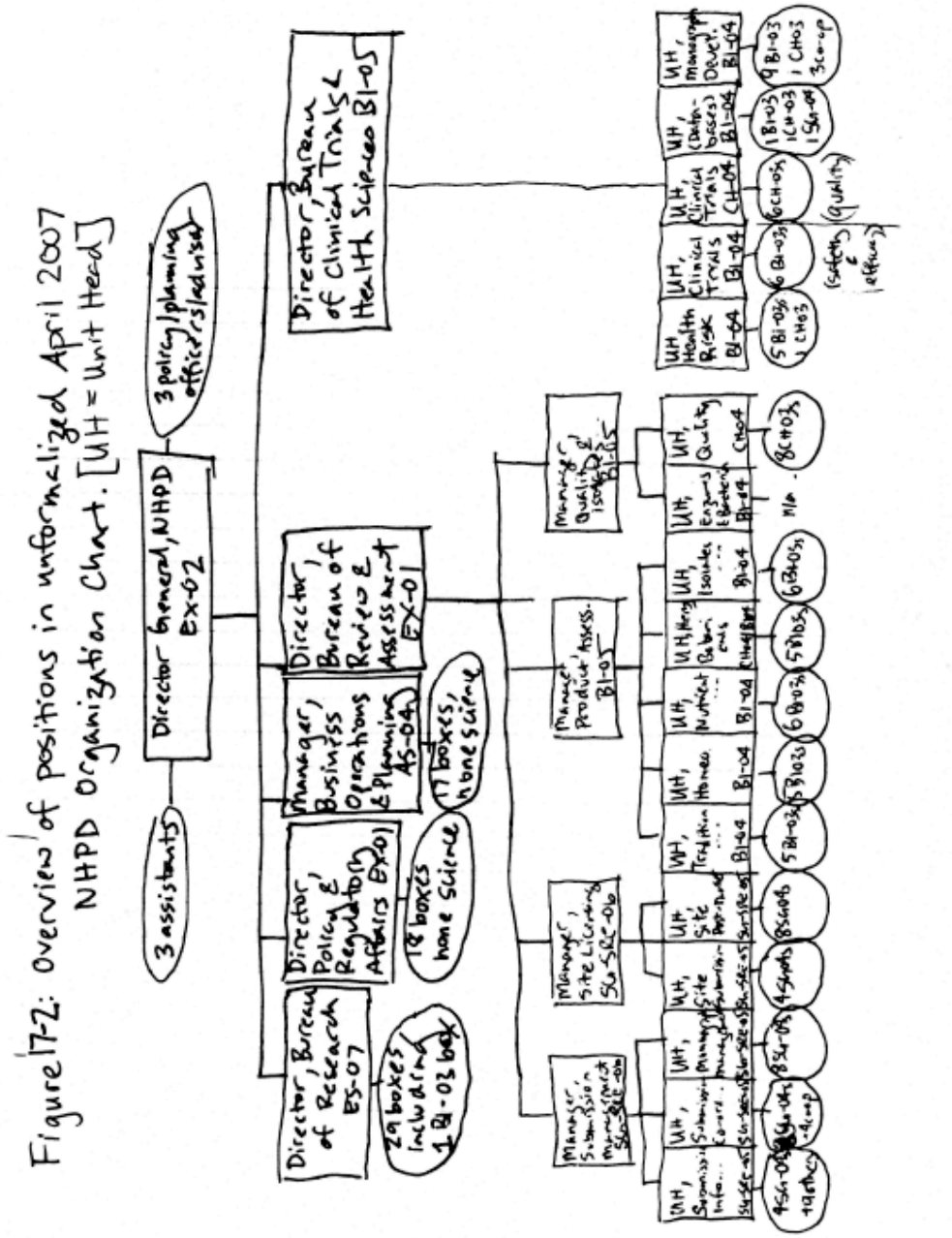


Figure 17-2: Overview of positions in unformalized April 2007 NHPD organization chart. [UH = Unit Head]
Director General, NHPD Ex-02
3 assistants
3 policy/planning officers/advisors
Director, Bureau of Clinical Trials & Health Sciences BI-05
Director, Bureau of Research ES-07
29 boxes including 1 BI-03 box
Director, Policy & Regulatory Affairs Ex01
18 boxes, some science
Manager, Business Operations & Planning AS-04
Director, Bureau of Review & Assessment EX-01
17 boxes, some science
Manager, Submission Management Site SSC-06
Manager, Site Licensing SS-SSC-06
Manager, Product Assess. BI-05
Manager, Quality Issues BI-05
UH, Submission Info...
UH, Site Transition...
UH, Technical Review
UH, Nonclin. Toxicology
UH, Microbiology
UH, Epidemiology
UH, Quality
UH, Clinical Trials
UH, Health Risk
UH, Clinical Trials
UH, (Deputy Director)
UH, Manager
4 SSC-05
4 SSC-05
5 BI-03
6 BI-03
5 BI-03
6 BI-03
5 BI-03
6 BI-03

Scientific positions in NHPD's org chart

What were the positions and organizational changes that were so avidly followed by scientific staff?

The NHPD's organizational chart represents each position, or staff member, by a box. The position is classified according to occupational category (e.g., as Biology=BI, Chemistry=CH, or Scientific Regulation=SG SRE), ranked at a specific level (e.g., BI-*05*, CH-*03*, SG SRE-*04*), labeled with its language requirements (e.g., English Essential=EE or some form of bilingualism such as BBB or CBB) and identified with a unique position number. In the org chart, boxes are clustered together in organizational units, and lines that lead upwards from those clusters represent reporting structures. Generally, the higher the box on the page, the higher the public servant's position within the government hierarchy.[15] Although interpersonal relations among all levels of scientists at the Directorate were typified as collegial, "like we're all still in university," in instances when I acted as such, management would tactfully remind me of the relevant hierarchies.[16]

Since its inception, the directorate has always employed many scientists (see Figure 17-3).[17]

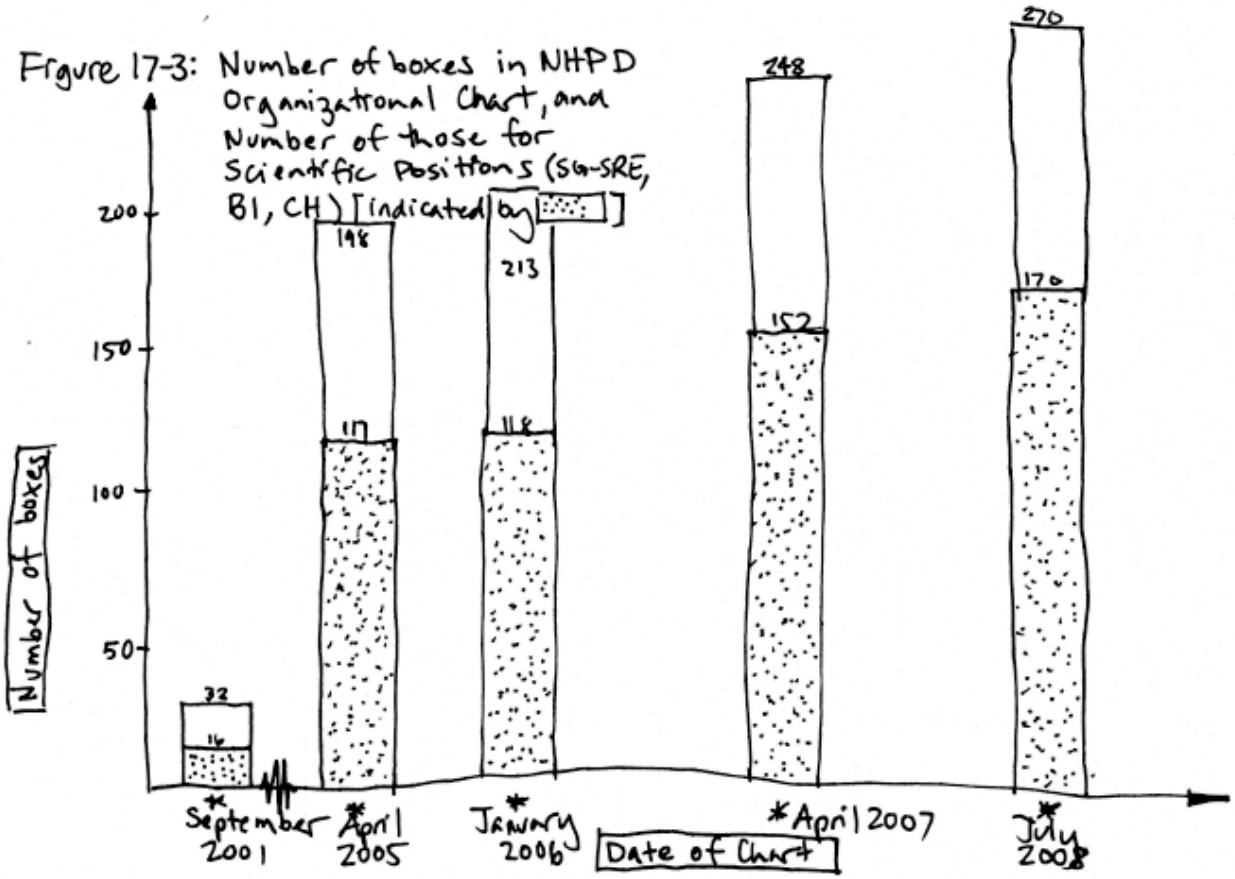


Figure 17-3: Number of boxes in NHPD Organizational Chart, and Number of those for Scientific Positions (SA-SRE, BI, CH) [indicated by]
Number of boxes
200
150
100
50
33
16
198
117
213
118
248
152
270
170
September 2001
April 2005
January 2006
April 2007
July 2008
Date of Chart

During the time of my participant-observation, of the 248 total positions included in the organizational chart of April 2007, 152 of those positions were for the "biological sciences" (BI), "chemistry" (CH) or "scientific regulation" (SG SRE). Although the term was not used at the NHPD, "scientific staff" is used in my analysis to denote staff whose job falls under one of those three classifications.

All three types classifications required that the employee hold a bachelor's degree in science as a minimum qualification; nearly all BIs and CHs held advanced degrees, and scientific staff born outside Canada almost invariably had extensive education represented in a Ph.D., postdoctoral experience, or health practitioner training. *Permanent,* entry-level positions in biology, chemistry, and scientific regulation at the NHPD (i.e. BI-03, CH-03, SG SRE-04 positions) were considered good jobs with excellent benefits and opportunities for training. The conditions of work associated with a permanent position in these BI, CH, and SG positions were considered so highly desirable that a few scientists jokingly referred to their permanent positions as "golden handcuffs," in the sense that the pay, benefits, and opportunities within government kept them from leaving their government positions to pursue careers elsewhere.[18]

Gossip and rumor among scientific staff

That mainstay of anthropological fieldwork – gossip – was not in short supply at the NHPD.[19] In the Directorate's maze of cubicles, around its water coolers, and over

its lunch tables, the most heated gossip among scientists, when it did not involve discussion of procedural change or a cantankerous applicant, nearly always pertained to staffing matters: who had won a competition, what supervisor was not allowing vacation leave, who still didn't meet the French-language requirements of their position, what jobs were being reclassified, who was acting two levels above their substantive, what group got special perks or opportunities, who was on assignment in another Directorate, what manager appropriated an employee's idea and presented it at a meeting, what tasks got shifted to another unit, who didn't get their contract renewed, who was an excellent unit head, who was overlooked for promotion, who was not doing their job, and so on.[20] This gossip was generally not of complex intrigue, but rather of daily events, slights, achievements, and annoyances.[21] The exception this came towards the end of my fieldwork, when some staff in tenuous appointments began suggesting a conspiracy, namely that upper management was conspiring to keep staff in tenuous appointments and intentionally stalling the promised permanent positions.

Much of the gossip regarding staffing matters was indeed "idle, or pleasurable talk," (cf. Taylor 1994). Some gossip served at least two important purposes for the scientific staff, in addition to filling any basic human need for gossip. First, as I have already explained, gossip was often one of the only means of gaining social and organizational knowledge, knowledge that was imperative for successfully meeting one's duties as a public servant. Although gossip was not always *instrumentalized* for this purpose, it still had this effect.[22] Second, gossip permitted

social comparison and the discussion of misfortune related to staffing.[23] As such, I believe the gossip was integral in the ongoing moral accounting centred on that deeply held, affect-laden value among many scientific staff, despite their diverse backgrounds: fairness. I will discuss this fairness in the next chapter, and in this chapter focus on the experience of misfortune.

In addition to gossip, there was a hardy rumor that flourished at the NHPD. Throughout my fieldwork, scientific staff was unsettled by a persistent rumor: If the NHPD couldn't clear its backlog, the Directorate, and all its jobs, would be entirely dissolved. Although many staff, when I pressed the issue, would admit the rumor was not entirely plausible, this rational implausibility did not appear to lessen the rumor's salience or demoralizing effect, such was the strong undercurrent of uncertainty regarding the Directorate's employment during my fieldwork. One of my colleagues in the Directorate commented that in the face of potentially sinking employment in the Directorate, "the smart rats were jumping ship" (herself included) and finding employment elsewhere in government. Sometimes the rumors were very concrete. In the last months of my fieldwork, the rumor that the NHPD's budget was cut by four or ten million flew; updates from lower management countered this rumor, reporting that there had been no cuts, but the budget had been exceeded by four million. Rumors creating a very tenuous existence for the Directorate recurred at regular intervals during my fieldwork.[24]

Not just idle gossip and rumor: precarious employment, morbidity and mortality

The point of discussing gossip and rumor in this chapter is not to establish their subversive or normative effects on scientists, or to discuss the morality of gossiping and spreading rumor.[25] Rather, I have used rumor and gossip as clues to important what mattered most to scientific staff, as indicators of important imaginaries (in the anthropological sense, not as a synonym of fictitious) and dynamics in my fieldsite. I should underscore that it is *not* the case that staffing matters are important *only* for gossip, or that this gossip of no effect. It is clear from large international studies that job insecurity, unfairness in promotions, organizational change without input – the matters of concern to these public servant scientists, as indicated by topics of gossip and rumor – predict increased mortality and morbidity among government office workers. One group of studies is of sufficient relevance to this chapter that the group merits a brief mention here.

The Whitehall studies examined morbidity and mortality among white-collar employees in the British Civil Service (Ferrie 2004). The original Whitehall study, begun in 1967, was a long-term, prospective cohort study following 18,000 male office workers with stable employment in the British Civil Service ("Whitehall.") After 10 years, the study found that men in the highest ranks of the civil service were significantly less likely, by about one third, to die prematurely than those lowest in the hierarchy, *independent of confounders such as income and habits like smoking*; in fact, there was a steep inverse association between grade of employment in general and mortality from a broad spectrum of causes. A follow-up

study, the Whitehall II study, began in 1985 with just over 10,000 London-based civil servants between the ages of 35 and 55, composed of two thirds men and one third women, and has followed their health using medical screenings and questionnaires (see www.ucl.ac.uk/whitehallII or Ferrie 2004). The findings from this follow-up study as well as other large cohort studies in other national workplaces have demonstrated that increased mortality or morbidity is predicted by: lower status in the government hierarchy, actual or self-reported job insecurity, poorly conducted organizational change, a high-effort little reward situation, and a low degree of control paired with high demand, among other things (Ferrie 2004). I believe that rumors of the NHPD's dismantlement, scientific staff's complaints about acting and temporary appointments, and the impossible task of licensing all products in "the backlog" correspond to these predictors.[26]

Misfortune and staffing

In the gossip that fell on my ears, misfortune at the NHPD– at least with respect to staffing, among non-management scientists – was usually one of two things.[27] The first type of misfortune was being kept in a tenuous employment situation. The second type of misfortune was being overlooked for a promotion or desired shift in duties, especially if unadvertised or unfair processes were involved. Extensive moral accounting was often involved in discussions of these misfortunes. The central questions in this moral accounting of misfortune were "why *not* me?" and

"why *not* now?" The goods in question were the desired appointments to particular boxes in the organizational chart.

These accounts of misfortune were often spurned by experiences of unfairness. Anthropological readers of this chapter will note the congruency with much of anthropology's investigation of gossip:

> Historically, in small-scale or community-level contexts, gossip about neighbors, always tinged with hostility arising from specific incidents of conflict and misfortune, or jealousy and resentment of the fortunes of others, has led to accusations of witchcraft and sorcery. Such local-level gossip has been influenced by more free-flowing rumors spreading from one community to another and reflecting wider historical changes (Stewart and Strathern 2004:xii).

In this fieldsite, not all gossip about coworkers was tinged with hostility – some gossip was in fact laudatory, and beneficial for the person being gossiped about. Outright hostility directed at a particular person was rare. While I encountered no accusations of witchcraft or sorcery, I did encounter a bureaucratic analogue: accusations of unfairness, which were plentiful. Interestingly, these accusations of unfairness were not usually directed at specific, named perpetrators of the unfairness. Fingers were pointed, if somewhere specific, at "management," "them", or even, ironically perhaps, "the government."[28] I could detect very little interest among the accusers in discovering the specific person(s) causing the unfair situation. Thus, one could perhaps best imagine these accusations of unfairness as "no fault witchcraft".[29] I will analyze the particular fairness enacted at the NHPD in these accusations of unfairness in the next chapter; however, for this to make any ethnographic sense, I must explain the variegated categories of temporary

work in the Canadian Public Service, because these lie at the heart of the two common types of misfortune at the NHPD.

Status and Health Canada employees

There were at least four ways of working as scientific staff at the NHPD. I will call these *statuses*, although they were not necessarily indicative of social status in any regular sense. I present these statuses in the order in which they were coveted, from most to least. The four statuses are in boldface type, and additional qualifiers of these statuses are underlined.

First, *indeterminate status*. “Indeterminate” is the Canadian public service word for “permanent”; workers with this status are full employees of Health Canada with benefits and job security. Indeterminate employees essentially “own their boxes” in the org chart – no one can evict them, and although the organizational chart can be rewritten, indeterminate employees are essentially guaranteed a job for life.[30] They are the stereotyped public servants who cannot be fired. Indeterminate employees must be hired on “merit,” ideally by winning a competition involving examinations and interviews although this is not always the case. There were a few employees at the NHPD who were hired through competitions into indeterminate positions, although during the time of my fieldwork these instances were rare, and most indeterminate employees had been appointed without a competition, often through word-of-mouth (“name referral”). This was taken so much for granted that during

one lunchhour a half-dozen scientists played an impromptu game, which involved speculating on the question, “So if you had not gotten your name referral to NHPD, what would you have done [with your life]?”

Getting indeterminate employment was assumed to be the primary objective of anyone flitting around the public service. From my first day of work, my colleagues enquired about my status, and offered many well-intentioned counsels on how I might obtain indeterminate status.[31] It simply did not cross anyone’s mind that I might not want indeterminate employment. Although I was not indeterminate, everyone agreed that as a term employee I was in a very good situation for achieving indeterminate status. Which brings me to the second status.

Term employees are hired for a specific length of time between 6 and 36 months. At the NHPD it was usually for one year. I was a term employee. This meant I was a full employee of Health Canada with benefits, with my own box in the org chart. As long as I was in my term of one year, no one could evict me from my box. Term employees must be hired on “merit.” Ideally, they are hired through “competitive processes,” although I believe most term employees were hired based on word-of-mouth and an interview. Many of NHPD’s indeterminate employees were originally hired on one year term contracts; at the end of their one-year term, they were renewed as indeterminate employees rather than for another one-year term. At the time, renewing a term seemed relatively assured provided the employee obtained

good reviews from the supervisor. After three cumulative, uninterrupted years of term employment, the term employee becomes an indeterminate employee.

Employees of Health Canada – this means workers with indeterminate or term status – have considerable temporary mobility within Health Canada. Employees can retain "their box" and status but temporarily work elsewhere, often in another box in an organizational chart although this is not necessary.[32] These temporary arrangements are often desired and sought out by the employee, unlike other involuntary types of temporary work arrangements I will describe later. If the employee is performing a job considered at the same level as the box that s/he owns, then the appointment is considered an "assignment" or a "secondment," depending where the appointment is held. During my fieldwork, many NHPD employees left on assignments lasting six or twelve months in another bureau, directorate, or a related agency. These assignments were generally initiated by the employee to gain experience, or to leave an undesired work environment; at the end of the assignment, the employee often had the choice of formally and permanently transferring his or her box owned via a "deployment." I never heard any complaints about the fairness of so-and-so's assignment, secondment, or deployment – probably because these were all lateral moves in the government hierarchy.

I heard many, many complaints regarding another type of temporary mobility, namely, when an employee was temporarily appointed to, and paid for, an "acting"

position.[33] An employee is “acting” if she performs a job that is higher in the government hierarchy than the box she owns.[34] While these acting appointments provided a myriad of opportunities for employees, they also fostered myriad jealousies and complaints of injustice. Acting appointments are common and generally understood to be necessary when a superior must take leave for reasons of vacation, maternity, paternity, training, illness, and so on. For instance, I had four different unit heads in the Monograph Management Unit during the course of my year working at the NHPD: the unit head who owned the box, and three others who acted for various lengths of time while she was on leave.

Although acting appointments are supposed to be truly temporary, as was the case in my unit, many other acting appointments at the NHPD continued long-term because in many assessment units, no-one “owned” the unit head box. Thus it was common for an assessment officer to act as unit head indefinitely. In one case the acting appointment lasted nearly three years. In such situations, accusations of unfairness seemed to fly in all directions. The acting employee sometimes got peeved because s/he felt s/he had amply demonstrated s/he was qualified for a full appointment at that level. His/her peers often got peeved because, based on an arbitrary process, they were denied the opportunity to gain the experience and increased salary that come with the acting appointment.[35] High rates of acting among unit heads also proved to be a difficult situation for the scientific staff as a whole for many reasons. First, in the words of management,

> It is clear that having experienced assessment officers in each unit helps to increase the productivity of the units…. Currently the challenge is that all experienced assessment officers are now Acting Unit Head.[36]

Second, acting unit heads were sometimes only appointed after the unit head position had been vacant for some time – and thus the acting unit heads were substantially overworked from the start. Also, acting unit heads often had not received training considered mandatory for those in supervisory positions, e.g., training on various human resources procedures and policies.[37] Furthermore, casual and agency staff felt that the high turnover of their unit heads resulting from the acting situation meant they were "left without allies" who were crucial to championing the temporary staff's quest for permanent employment.

During the period of the study, as I have mentioned, many scientific staff were not even considered employees of Health Canada, and were thus ineligible for acting appointments altogether.[38] These staff members were not part of the union, received no health or sick day benefits, and were ineligible for internal competitions for indeterminate positions. These staff members had one of two tenuous work statuses: casual or agency.

Workers hired by Health Canada as *casuals* were permitted to work for no more than 90 days in any given calendar year.[39] They were paid by Health Canada at the same rate as employees. There was no competitive process for hiring casual workers.

Agency workers were not employed by Health Canada, but rather worked under contract for an external company.[40] They were hired through the following process. Health Canada advised one of Ottawa's many temporary help agencies ("the agency"), that workers with certain qualifications were required. The agency sent the resumes of workers meeting the qualifications to the NHPD. The NHPD interviewed and selected candidates from among that group of resumes. Hiring through temporary help agencies was not infrequently used as a covert "word of mouth" hiring process, as I am aware of several instances of staff or acquaintances being advised to submit their resume to a specific temporary help agency just before the call for resumes was sent to that particular agency.

The moneys involved in these contracts with local employment agencies were significant; according to an audit of the NHPD's hiring practices that I will refer to later, the value of NHPD's 185 "call-ups" for temporary help from April 1, 2005 to October 31, 2006 was approximately $3.5 million.[41] That figure involved 80 staff and 29 hiring agencies. The terms of the work contract varied across staff.[42]

In the hiring boom that began in fall 2006 and lasted until mid-2007, nearly everyone was initially hired as a casual or agency worker. Temporarily-employed scientific staff did not consider casual and agency status equivalent. Generally, casual status was preferred. First, as casual, staff could get a Health Canada Personal Record Identifier ("PRI") that enabled staff to participate in Health Canada enrichment and training courses.[43] More importantly, most workers were strongly

against the “wastage” that happens with the employment agencies, given that the agencies receive a substantial amount (at least four dollars, although I also once mis?overheard a minimum of eleven dollars) for each hour clocked by a worker; one contract worker, for instance, believed it cost 1.5 times more to have an agency staff than a term employee. Another one of my agency colleagues was angry and highly indignant about, as he put it, “having a pimp:” the agency. Nevertheless, one temporary worker told me she was relieved to be agency after being casual because she was finally paid correctly and regularly.

During the course of my fieldwork, most staff alternated between agency and casual status, the alternation being a means for getting around official time limitations for how long one could work as a temporary worker in either status.[44] An audit indicated that at least one NHPD staff member had flip-flopped from casual to agency and back for four years (Elliott and Plante 2008:4). [If the staff member had been term, s/he would have been “automatically” an indeterminate employee at the end of three years]. But neither agency nor casual status was satisfactory to most workers, who hoped to become employees, ideally with indeterminate status.

An awkard social position

To conclude my description of scientific positions and statuses at the NHPD: At the time of my fieldwork, a minority of the scientific staff at the NHPD held an indeterminate appointment to their position at the time. Term employees, myself included, were considered lucky; most scientific staff in tenuous employment

situations – the casual and the contract workers – were not even considered employees of Health Canada. At the beginning of my fieldwork in 2006, the atmosphere for the casual and agency staff was hopeful, upbeat, and positive; most temporary scientific staff believed the situation was truly temporary. Several had been told during the selection process that they were interviewing for a permanent position. Later, they were promised a competition so they could win indeterminate positions. But time went on in which these promises were not realized. Temporary staff were in the rather awkward position of being long-term short-term workers, or permanent-ish temporary staff.

By spring 2007, staff who began at the NHPD early in the hiring boom were demoralized. Some staff had moved their families for the job; others had moved away from their families, originally temporarily, until it was a "sure" job. Also, as more agency workers were hired, there was more competition for the promised indeterminate jobs. The by-then "experienced" agency staff hired in fall 2006 was expected to train and mentor the newer agency hires, who were "the competition."[45] Two tenuously-employed scientists reported that, uncharacteristically, they had no desire to become acquainted with any newer staff, "because you just want them to go away," because they represented competition and the experienced temporary staff "constantly fe[lt] like you're vying for position." Some of the agency staff were considered "high performers" by management, who then asked these temporary workers to give pointers to indeterminate employees, a situation which, as one supervisor pointed out, "is a bit of an awkward situation."

Even indeterminate assessment officers found the high levels of temporary appointments difficult, because while they had developed good working relationships with colleagues, they knew that about half their colleagues, essentially all the casual and contract workers, were actively looking for work elsewhere because permanent jobs did not seem to be materializing.

I argue this awkward position affected the work of assessing product license applications. I have already argued in Chapter 14 that the performance quotas, especially when applied on temporary assessment officers, lessened the chances that potential safety issues would be noticed in the first place. I will describe now how the particular misfortune of temporary appointment also appeared to encourage obsequiousness.

Misfortune begat obsequiousness

Scientific staff in temporary biology positions feared losing their positions. This appeared to apply equally to indeterminate workers in acting unit head positions, and to contract and casual assessment officers. To try and avoid losing their position, many temporary workers behaved in a way consistent with their imaginings of what “a good worker” should do. Apparently this entailed not contesting one’s superiors in any way. (This was not the situation in all parts of the Directorate). Such was the feeling of tenuous employment among many of the agency workers in BI-03 positions in product assessment, that I did not hear any of

them criticize *any* procedure, even constructively, until more than five months into my fieldwork – I had noted this as a milestone in my fieldnotes. In some cases obsequiousness was a conscious choice on the part of the assessment officer. Several agency staff openly declared to me that they acted in ways that would avoid them being labeled a "bad employee." (Ironically, as they were not technically employees.) For instance, upon learning that some biologist colleagues were interested in the contents of an audit that upper management had promised to make openly available to staff (but then had not made available), I asked these colleagues why did they did not ask for the report. One colleague, laughing, described to the group what would happen when it came to contract renewal time if they asked for the report: "Ya, they'll [management] be like *who*? *Oh, sorry, they've got black stars all around their names.*"

In other cases obsequiousness many not have resulted from a conscious decision. Of the scientific staff with indeterminate appointments somewhere at the NHPD, nearly a third were acting in supervisory positions, and during my fieldwork, never, at least to my knowledge, had an acting unit head in assessment "pushed back"against the requests or demands of higher management.[46] Perhaps this was because acting unit heads did not feel secure in their own jobs, relying on the good graces of those higher in management for the extension of their acting appointment.[47] Perhaps it was for other reasons. In any event, in my year at the NHPD, I noticed only two supervisors ignoring or obviously resisting management-

suggested changes like the introduction of (arbitrary) performance standards. These two supervisors were not acting, but owned their box.

A reasonable question on the part of a reader is, of course, to what extent these fears came about because of management's instructions, threats or actions, versus internalized expectations that never actually existed, or that were only enforced except by their peers. From the position of my research, taken from the perspective of assessment officers and their immediate supervisors, I cannot answer that question for the biologists. I believe in many scientific regulation positions, obsequiousness was not necessarily valued over constructive criticism; but this seemed to perhaps change according to microenvironment. When I asked an outspoken employee at the NHPD whether she felt her "reputation for being vocal" (her words) had affected her positively or negatively, she replied "I don't know. I think it would depend on who you spoke with." This may have been the case for those in biology positions. In my work unit, I had no fear of losing my job for reasons of criticism. Not only did I have supportive supervisors, useful criticism was so highly valued that a question in the intake interviews was included to ensure that the prospective worker knew s/he could question processes and superiors. I heard experienced staff mentoring new recruits and explaining that criticism was not necessarily frowned upon, citing examples of successful employees who were critical of processes. This must have been the case also in other Health Canada microenvironments, because more than one manager from another area made "poaching" attempts to lure me into a supervisory position

elsewhere in Health Canada because I spoke my mind at meetings and had critical opinions regarding the effects of policies on public health. That said, I was both directly and indirectly warned – however by non-scientific, non-NHPD staff – that I would not have my employment term renewed if I continued to insist that Health Canada pay me accurately, according to what I had signed in my letter of offer.

So it is perhaps best to leave this section with a description only: that many of the NHPD's biologists in tenuous work situations either consciously or unconsciously chose to act in ways they thought would please their superiors.

At the NHPD, misfortune was not classification or pay inequalities

The particular misfortune prevalent at the NHPD – the persistently tenuous appointment – likely had different consequences than a common staffing-related misfortune I heard from assessment officers in other Directorates. In the NHPD's two sister entities in the Health Products and Foods Branch, the Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate, there was open resentment on the part of reviewers who were classified as applied biologists (BIs) of those reviewers who were classified as medical officers (MOFs) and who received a substantially higher salary to the tune of $20,000 annually despite, the BIs argued, performing the same work.[48] This resentment was so overt that discussion of the inequality was forbidden by the Assistant Deputy Minister at one focus group I attended for science in the Branch, on the grounds that he feared it would take over the entire forum.[49] At the NHPD, misfortune as recounted

in gossip was *not* related to job classification. Although there was low-grade, day-to-day friction between the BI, CH, and SG SRE groups during the time of my fieldwork, all three classifications had nearly identical starting rates of pay (approximately $62,000 annually) for entry-level positions.[50] (Between these other directorates and the NHPD, a pay discrepancy in the form of an additional risk/clinical allowance given to certain ranks of BIs in the other Directorates, but not those in the NHPD, accentuated the tendency of new employees to train at the NHPD and then be "poached" by other directorates.[51] I believe this may have been experienced as a misfortune by NHPD's management, but that is beyond the scope of this chapter.)

Misfortune, upper management, and conspiracies

To some in upper management, the tiered system of employment, along with temporary appointments, apparently required no justification, or was unremarkable in the current job market.[52] Occasionally management explicitly tied temporary employment and appointment to "operational" or "business" requirements. There may also have been unstated budgetary reasons for the preference to for hiring contract workers, because I heard that the money for the contract workers came out of a separate part of the NHPD's budget than that for employees' salaries.[53]

When management required "immediate staffing," the use of hiring agencies was rationalized as a way of getting around "the quagmire"[54] that was Health Canada's

snail-paced, and severely understaffed, Corporate [central] Human Resources.[55] So, for instance, when an anonymous NHPD staff member submitted the question "Is there a limit to how long a person can flip back and forth between agency and casual?" into the box for the NHPD's Morale and Recognition Committee, the response was:

> Technically, flipping to and from agency to casual is considered bad HR [Human Resources] management practice. However our DG [Director General] has made it clear to HR Corporate Services that until we can fill the positions through competitive processes (some of which are already in process), we will need to continue the practice to maintain business continuity."[56]

Although the average time to process the hiring of an indeterminate employee at Health Canada was six months (Elliott and Plante 2008:7), at the NHPD the time varied greatly. One employee reported working in an indeterminate position six weeks after sending her resume to the NHPD, but for another employee it reportedly took a full year for Corporate Human Resources to do the paperwork involved in sending her a letter of offer (her job contract).[57] Those examples did not even involve formal competitions for the position. Two employees hired before 2005 said it took nearly two years between applying for a competition and beginning to work at the NHPD.

From the perspective of temporary staff, these various rationales were not necessarily persuasive, especially as some had originally been promised permanent work. As staffing became a charged issue in 2007, upper management needed to explicitly answer staff's increasingly pointed questions. So, for instance, a staff member (anonymously) challenged a statement upper management made

at a 2007 all-staff meeting that "NHPD's plan [was] to make people ‘more permanent’"—this staff member wanted to know:

> What is "more permanent"? Are there anticipated hurdles with these "more permanent" positions?

Upper management answered the anonymous question with the statement:

> The goal for the Directorate is to stabilize its workforce as much as possible, which means moving away from contracting or short term casual to more stable long term employment options.[58]

By mid 2007, however, such answers were not necessarily believed by scientific staff. A newspaper article entitled “Canadians say the workplace stresses them out” (Beauchesne 2007) appeared on the bulletin board in the kitchen, with a typeface heading added: “CONTRACT WORK CONTRIBUTES TO THIS TOO!”

In my interviews in the late summer of 2007, many entry-level staff felt the situation “seemed potentially toxic” (Buck). One temporary assessment officer reported being “frustrated, aggravated, infuriated, angry, totally pissed off” and began to blame management, but then changed tone:

> I can’t believe they would take advantage-- Actually I don’t even know that they intended to take advantage, I think they’re just so terribly disorganized, that they don’t think of how that affects people.

At the beginning of September 2007, the situation had reached the point that some agency and casual staff began toying with conspiracy theories, even sharing them with their immediate supervisors. In an interview in September 2007, I asked one scientist in lower management whether they thought part of the reason these

assessment officers were being kept in tenuous employment situations was to make sure they kept their performance numbers up:

> You know, it's interesting that you say that, because just this morning, [an assessment officer] brought up that exact point. She said, "it's not in their best interest to make us indeterminate." And I thought about, I thought, is it possible that an entire group of people, you know, the powers that be, could be, you know, have some nefarious plot and be malicious about it, and I don't think that's necessarily the case.
>
> I, I would, I would hesitate to say that it's something that is predetermined, or is consciously done, but [pause] I'm starting to feel like I can't dismiss that, because [pause] there have been so many promises to these, this group of people that have been broken, um, uh, not fulfilled, changed, and I [pause] I think that the people here that are trying to make those changes happen are, are genuine in that, but I don't think that they're the right people. They're not qualified, necessarily, or have the skills, and experience, maybe, to, to get the job done. I think the Directorate itself has its own issues, [about not being taken seriously at the Branch level].
>
> So I hesitate to say that people are evil! [both laughing] I just think that they're … maybe not the right people for the job.
>
> *At a certain point, though, you have to ask—*
>
> Yeah, yeah! I know some of the guys that are casual tell me, you know, that they're [upper management is] evil [both laugh].

As described in the previous chapter on performance standards, these conspiracies generally revolved around the motivations of distant upper management, to be distinguished from lower management with its daily contact with assessment officers. I did not hear of any conspiracy theories involving lower management. One agency staff member, when commenting that he did not feel valued at any level in the organization, then qualified this statement:

> Well, I have a unit head who says the competition will happen – but she is really nice, and does not represent upper management, so there is only so much she can do. The situation might upset her, but she can't do much.

Many temporary staff saw how upsetting the situation was to many in lower management. I will discuss this in the next chapter, which describes the particular economy of fairness at the NHPD.

Conclusions

I have taken gossip and rumor among scientific staff at the NHPD as indications of matters important to scientific staff, and have landed squarely in the realm of staffing matters. This is perhaps unsurprising given that these government workers need to know others to properly do their work, and given that just over half of NHPD's scientific staff was temporarily appointed in their position. Gossip also facilitated social comparisons, which were important in moral accountings of misfortune. In this labour context, misfortune, as it was manifest in gossip, often involved tenuous appointments or not getting a desired appointment (or, not discussed in this chapter, having a "bad supervisor.") In the next chapter, I will argue that fairness, or more precisely the experience of unfairness, was the arbiter in moral accounting of misfortune, and I will devote the chapter to teasing out the particular features of "fairness" at the NHPD.

While it would be appropriate to comment on the generalizability of my findings regarding temporary staffing to other parts of Health Canada and the Canadian Public Service, I have been unable to obtain data to do so properly. In general, there is a dearth of published research on the use of agency staff in the federal

government. This is probably because the numbers of agency staff are not centrally compiled for the Canadian Public Service (Public Service Commission 1999:8), and so the numbers essentially do not exist, and perhaps therefore formal Public Service Commission concern cannot exist. In a report by the Commission on “Alternative Resourcing Options,” published in November 1997 (Brisson et al. 1997), on the situation a decade prior to my fieldwork, notes that the number of “core public servants” – those hired under the *Public Service Employment Act* – was decreasing, and “the number of ‘non-employees’ is increasing.” That report could not provide a number for people in the government hired via outsourcing, because it could not provide a number for those hired by contract, and even the number of those hired as temporary help was estimated. (I am unsure, therefore, how they concluded that sixty percent of those working in government were in indeterminate positions! But such is the life of numbers). It may be that, by virtue of being in a Health Canada organization in the National Capital Region, the NHPD was an organization most likely to be using temporary help agencies: that same report, found that Health Canada was one of the five departments that accounted for 43% of all the temporary help used; and that across the country, the National Capital Region accounted for 69% of all temporary help used. The Public Service Commission’s report found that “6.5% of temporary help agency workers eventually join the Public Service under other work arrangements: 3.3% as casuals and 3.2% as term employees.” That was not a promising statistic for my colleagues on contract at the NHPD, and I am glad I was unaware of it at the time.

There *are* numbers, however, for other "non-standard" employment types. At last count in 1998, term, casual, seasonal, and part-time jobs represented nearly one-fifth of all Public Service jobs, having risen from 12.4% in 1981 (Public Service Commission 1999:1). In 1998, the rates of non-standard employment in the "Scientific & Professional" occupational category, at around ten percent, were much lower than in the general Public Service (Public Service Commission 1991:16).[59] A report by the Commission in 2007 indicated that in 1995-1996 there were 8,973 casual hires, whereas in 2001-2002 it was 17,304 (Public Service Commission 2007:7); this increase was especially notable in the Professional job category which includes scientists. From 1995-1996 through 2004-2005, Health Canada alone made 7,804 appointments for casual staffing appointments (Public Service Commission 2007:35). The Commission found that many casual appointments in the science categories (government-wide) were followed by the appointee's appointment to a term or indeterminate position in the public service: 48% for biological sciences (BIs), 52% for the chemists (CHs), and 77% for the scientific regulators (SGs) (Public Service Commission 2007:16). The NHPD must have substantially contributed to those numbers, because the Commission's findings for SGs were based on 138 appointments – from 2000 onwards, I would be surprised if many of those appointments were not in the NHPD.

But these numbers do not take into account the most frequent non-standard employment type among scientists at the NHPD in 2007: agency. Furthermore, these numbers are not specific to science-heavy organizations in the Health

Products and Food Branch, and could be affected by high numbers of seasonal scientific staff required in certain government operations such as in fisheries and national parks.[60] The paucity of documentation in this domain is partly why I have included such a detailed description of NHPD's tiered and temporary staffing situation. I hope this description highlights the importance of labour issues, specifically temporary and tenuous employment, in federal health protection.

Temporary staffing issues resolved after fieldwork?

Although the situation for NHPD's scientific regulators (SG-04s) who were agency or casual had been resolved by the end of my fieldwork in fall 2007 (see next chapter), the situation for the biologists (BI-03s) had only worsened, and most were actively looking elsewhere for work. At the end of September 2007, these temporary workers had a bit of relief, in the form of near-assured eight months of work – they were told they would be made casual until the end of 2007, and then renewed as casual until May 2008. By 2008, the Branch had run the competition for biologists, and although apparently (i.e. through the rumor mill's tentacles) many temporary workers had not done well in the Branch-wide competition, rates of tenuous employment had significantly decreased from the rate during my fieldwork, at least according to the organizational charts: between April 2005 and July 2008, there had been a fifty percent increase in the number of indeterminate scientific staff. Nevertheless, as I mentioned in the last chapter, this apparent increase in job security did not bolster morale among scientific staff.

The long reach of the rumor mill informed me that, at an all-staff meeting in 2008, upper management instructed *all* staff to begin looking for positions in other parts of government, because the NHPD would be downsized after clearing its backlog.[61] (And some staff obviously obeyed this recommendation, to their advantage: in mid-2009 I learned that several scientists who had been agency in 2006-2007 have since obtained secure, and in some cases much higher-ranked, positions in other parts of Health Canada and related agencies). In early 2009, the rumor mill informed me that *all* remaining temporary assessment officers had been "let go." But then in early 2010, the rumor mill informed me that there was a bevy of new scientific term employees, hired temporarily to deal with "the backlog," and whose term would end when the backlog was cleared.

Although I have not verified these rumors, my point is that in rumor and gossip at the NHPD, there seemed to be a circle of misfortune in the bureaucracy, akin to the chicken and the egg dilemma: tenuous directorate, tenuous appointments, tenuous directorate….

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[1] Many "leadership" [management] meetings of the Bureau of Product Review and Assessment pertained to hiring, and when I was given access to the minutes of these meetings for my research, I was told to keep the minutes confidential – but not, as I expected, because of so-called proprietary information in industry or scientific assessment issues, but because of staffing issues.

[2] "Permanently-hired," in the language of the Canadian public service, is "indeterminate." I will explain the public service categories later in this chapter.

[3] For the purposes of my analysis, I classify all casual and agency staff, term employees, and acting employees, as having "temporary appointments." The specific statuses will be explained for non-government readers later in this chapter. The terms "temporary appointment" and "temporary staff" were not often used at the NHPD itself; they are my terms for analysis. Nevertheless, these terms largely correspond to the meaning of "temporary job" in the public service literature, defined as a job "with a predetermined end date, or which will end as soon as a specific project is completed" (Public Service Commission 1999:3).

In the Canadian sociological literature, the most salient, analogous category appears to be "non-standard employment." (And my thanks to Leah Vosko for pointing me in the direction of the reports on temporary work in the Public Service). Non-standard employment is essentially everything that is not "standard employment." Standard employment in the public service is defined as a full-time indeterminate position (Public Service Commission 1999:8); in other types of work standard employment "is defined by continuous full-time, full-year employment where the worker has one employer and normally works on the employer's premises under his or her supervision" (Vosko 2003:27-28). Sociologists argue that standard employment originated after the First World War, and became the normative type of [white male] employment immediately after the Second World War (Smith and Neuwirth 2008:Chapter 1; Vosko 2003:28).

Non-standard employment in government includes term, seasonal, casual, contract, and student positions, as well as part-time indeterminate positions (Public Service Commission 1999). I have chosen to not use this categorization because it does not adequately capture the types of less desirable appointment at the NHPD (at least undesirable when continued long-term.) For one, the umbrella "non-standard employment" does not include "acting" appointments, because employees who are acting are generally appointed to a full-time indeterminate position. Also, "non-standard employment" includes the categories "student" and "part-time indeterminate," which were not categories that involved undesired temporariness or tenuousness at the NHPD. At the NHPD, all part-time scientific staff had themselves chosen to work part-time, and collective agreements stipulated that part-time employees got benefits (cf. the situation in the 1980s noted in, for example, the report of the Task Force on Barriers to Women in the Public Service 1990:84-86). Students could be "bridged" into indeterminate positions without a competition should they desire to continue working at the NHPD.

While there were gendered gradients at the NHPD, there were men and women staffing nearly all positions. There were more women overall, and there were definitively more women than men in administrative support positions, and scientific regulatory (SG-SRE) positions. Assessment officers were quite mixed, although there were definitively more men chemists. There also tended to be more men than women in upper management. These tendencies, however, were never absolute among scientific staff. It is not possible to speak of a gendered labour force in the same way as, say, Twohig does (2005; other analyses of the gendered division of labour in the production and evaluation of measures can be found in Daston 1994, Marks 1997:36, Rapp 2000:199-202).

In any event, there was definitely an increase in the percentage of women in the biologist (BI) and Scientific Regulation (SG) positions from nearly two decades previously, when the percentages of women holding such positions was 23% and 22% respectively (Canada. Task force on barriers to women in the public service 1990:19). Even up from the percentages of women in Health and Welfare SG (41%), BI (41%), and CH (31%) found by Sharon Katz in 1989, declared in a report for Health and Welfare Canada (1991). Vosko (2003) discusses the tenuousness of employment in the public service in the context of gender discrimination.

[4] In 2007, there were approximately two hundred staff working at the NHPD. This number is based on a head count I surreptitiously conducted at an NHPD "all staff" meeting; surprisingly, there was no way of finding a meaningful official number of total staff. To compile the counts and percentages of scientific staff used in this chapter for my analysis, I have drawn from two key sources: an electronic directory of public servants (GEDS, at http://direct.srv.gc.ca), and the NHPD's organizational charts (Health Canada ATI A-2008-00184). Neither "official source" reliably indicated which scientists were present at the NHPD during my fieldwork. Furthermore, reasonably often these two sources provided inconsistent information regarding the number, names, and positions of staff working at any given time (cf. Hacking 1990 on the difficulties with censuses). I am sure that had I consulted either of Health Canada's two internal electronic databases of employees I would have ended up with different numbers yet again.

For most counts and percentages in this chapter, I relied most heavily on organizational charts, because they seemed to be the gold standard at the NHPD. Nevertheless, the organizational chart was not always updated, and in the case of the July 2008 chart, it did not list at least 20 scientific employees working at the Directorate according to GEDS. Thus I used the charts to take my counts but I also added staff I knew to be working, but not on the charts. Thus the numbers and percentages in this chapter should be considered "flexible," just as they are in their native environment.

In all likelihood, there no way around these malleable counts in a situation where the staff has many employers. An official study of non-standard employment in the public service as a whole, completely ignored the workers hired via employment agencies or on contract, because the numbers of such staff are not centrally compiled for the Public Service (Public Service Commission 1999:8). But even locally at the NHPD, it does not seem these numbers are recorded. The authors of an Audit on the NHPD's staffing, using yet another database called "HR [Human Resources] Dashboard" to which I did not have access, were unable, for instance, to determine the numbers and rate of turnover of NHPD staff because of the high number of agency/contract staff who were not included in that database (Elliott and Plante 2008:14).

Studies of temporary work in the US note that companies "often feel pressure to hold down the size of their workforces and their payrolls in order to improve investors' and stockholders' assessment of how lean and mean they are," and using hiring agencies along with creative accounting allows the companies to obscure the cost and size of the actual workforce (Smith and Neuwirth 2008:187). In circumstances such as these, despite the modern organization's plethora of paper trails, it may be that "retro" field-based head counts are the only way to get the total number of employees in "flexibilized" work environments with their high rates of temporary staff.

[5] These percentages exclude positions in the organizational chart with no worker actually at the NHPD ("vacant" in Figure 17-1). In April 2005, 28% of non-vacant scientific positions were staffed by casual, term, or acting appointments; in January 2006, 30%; and in July 2008, correcting for the 20 staff (assumed temporary) not included in the organizational chart but listed in GEDS, 29%.

[6] There were, however, workers who were genuinely unhappy, and even happy employees complained of staffing issues and noted their impact on scientific assessment work.

[7] From fieldnotes, recorded immediately post-hoc.

[8] After a mere four months in the public service, I recorded in my fieldnotes that I had (almost) completely given up consulting internal procedural documents because, even disregarding the time required to locate in the applicable document in its correct version in the Directorate's messy "N-drive," in all likelihood I would still have to confirm with a colleague that the 'living document' had not recently undergone an unrecorded growth spurt or become obsolete.

[9] There seemed to be a subset of employees who were very career-minded and who changed position frequently. One such employee advised me over beer that "the more you move around, the more people know you and the better things are. People who move around tend to know each other, so you can make a really good name for yourself, but if you do a bad job, people will know."

[10] Similar information is available to the public through the Government Electronic Directory Services, a searchable database of all public servants (GEDS, at http://direct.srv.gc.ca).

[11] For the seriously-career minded, the automated Publiservice announcements were insufficient because the alerts were only sent out every 24 hours, causing undue delay [!] in the receipt of notices. Some employees searched the Publiservice website daily because "the early bird gets the worm."

[12] The org chart was less a "key symbol" (cf Ortner 1972) than a literal "key" to the organization of the Directorate.

[13] I cannot overemphasize the usefulness of the organizational chart at the NHPD. I would receive "invitations" for meetings, and the necessity of attending depended on the inviter's position in relation to mine, and although this might seem straight-forward, before I got the hang of the organizational structure through gossip, it was far from clear: I had five levels of superiors in the public service, and during my one year in the Directorate, the superior at each level officially changed at least once, with my superiors in two of those levels changing at least three times. Furthermore, because I periodically did work that fell under the ambit of two other divisions, I had to keep track of changes in those structures as well. That said, the org chart was helpful, but was usually understood as a stab at or trace of briefly held hierarchical reporting structures, and fell into the category of the infamous "living documents."

[14] The rumor went that Finance (primarily Anglophone) had posted the org charts on the notice boards without the consent of Human Resources (primarily Francophone at the time), upsetting Human Resources employees who claimed the org charts were their jurisdiction and, additionally, not public. This is but one of the many examples of categories of public documents reinterpreted as "confidential." I was told that technically, the org chart is public when it is finalized, in other words, when it is signed off by the highest-ranking employee on that page – and that the finalization should happen at least every 4 months. When the org chart is not finalized, it is confidential. At the NHPD, the org chart was probably always confidential because the finalization did not occur even yearly. I make this claim based on the documents I received in response to an request made under the Access To Information Act (A-2008-00184), in which Health Canada was unable to provide yearly org charts for the NHPD.

[15] Note that the place of advisors and assistants in the hierarchy are not usually represented by their height in the organizational chart. Refer to the preface matter for the hierarchy of public servants in the NHPD and Health Canada's Health Products and Foods Branch.

[16] Nevertheless, I do not believe this interpretation of social status along organizational hierarchy was internalized among most assessment officers, for whom "status" in the usual sense of the term (high social esteem) seemed to be a combination of one's place in the hierarchy, honor and integrity, interpersonal relations as well as scientific or medical competencies.

[17] In 2008, I made an official Access to Information Request for the organizational chart of the NHPD for every January since the Directorate's inception in 1999/2000, and, where the official org chart was out of date, for a copy of the draft chart used at that point (A-2008-00184). I only received one full chart from a January, draft or otherwise. I did receive 5 complete charts: September 2001, April 2005, January 2006, April 2007, and July 2008. I received a partial chart for December 2002 and January 2003. (That is not to say there were not many other drafts of the charts. When I was at the NHPD, I had managed to find an NHPD org chart from July 2001 on the shared N:/ drive, and I had been entrusted with a chart with effective date of late July 2007 by management in the Bureau of Product Review and Assessment. I assume these original must have been destroyed at the NHPD or was only a partial chart or I should have received it as part of the response to my Access to Information Request, as they were closer to January 2001 and January 2008 than the September 2001 and April 2007 charts I received in the response. Or perhaps I should more rightly assume this reflects the state of staffing turnover and of shared electronic drive (dis)organization).

[18] Often the benefits were simply inconceivable in the private sector. For instance, permanent employees could take paid, self-funded or unpaid leave for a variety of reasons including taking one year of maternity leave at 95% salary, and would accrue seniority with associated pay raises while on many kinds of leave.

[19] I take very broad definitions of these terms, using "gossip" as talk "between two or more people about the private [or in this case, employment] life of another, behind her back" (Taylor 1994:35). Gabriele Taylor points out that gossip is moral talk, in the sense that the topics that are most compelling to gossipers are topics with strong moral overtones. I loosely follow Stewart and Strathern's (2004) distinction between gossip and rumour. Gossip occurs mutually among members of a group or in a network. This is to be distinguished from rumour, which circulates in wider networks than gossip, is unsubstantiated information, and:

> represent[s] people's attempts to find or create a "truth" about events that helps them to make narratives about social values and judgments about the morals of others. They are "improvised news" and conversations "in search of the truth." (Stewart and Strathern 2004:195)

Stewart and Strathern 2004 strove to demonstrate that gossip and rumors help provide conditions leading to witchcraft accusations, and examine cases involving large-scale social unrest and violence. While Taylor (1994) examines gossip with less large-scale effects, she typifies gossip as essentially idle, pleasurable, and ideally disinterested, which clearly does not apply to many anthropological discussions of gossip. Thus the simple definition is perhaps most appropriate for this chapter.

[20] An employee's substantive is essentially the box that employee 'owns' in the organizational chart; this will be explained below.

[21] By intrigue I mean the standard *OED online* (2010) definition: "The exertion of tortuous or underhand influence to accomplish some purpose; underhand plotting or scheming." I suspect that among those in management, gossip took on a layer of intrigue and perhaps even scandal that I did not notice in the gossip of lower-level scientific staff (cf. Government Statisticians Collective 1979).

[22] As typified by fictional woman sleuths like Miss Marple (Code 1994) and perhaps now Alexander McCall Smith's Mma Ramotswe.

[23] As Jerry Suls and Franklin Goodkin point out in their introduction to *Good Gossip*, the social comparisons implicit (or explicit) in rumor and gossip provide direct evaluative information regarding oneself and one's actions (1994).

[24] Experimental work in the middle of the twentieth century by G. Allport and L. Postman showed that subjects were more likely to spread rumours when they experienced more uncertainty (Suls and Goodkin 1994:147); this rumor at the NHPD indeed seemed to flourish whenever there was uncertainty regarding upper NHPD and Branch management's approaches to the Directorate. This rumor regarding the disintegration of the NHPD, as circulated among entry-level scientists, was not related by the scientists to various private members bills introduced in Parliament that, if passed, would have effectively disbanded the NHPD.

[25] Like other examples drawn from the anthropological literature, all that can be deduced is gossip can both create and fracture in-group solidarity, and can either buttress or thwart the powers that be (Stewart and Strathern 2004:29-58); in some cases at the NHPD, gossip about colleagues' promotions perhaps jived with the desires of upper management, and in other cases it thwarted those desires.

[26] Clearly, not all things associated with increased morbidity and mortality among civil servants were subjects of complaint or gossip among NHPD scientists. I heard very little complaint about hierarchy at the NHPD, despite the Whitehall studies showing increased morbidity and mortality caused by lower rank, i.e. social inequality. For a broader review of the literature on inequality and health, see Ngyugen and Peschard 2003.

(If you are a government-employed reader looking for a "policy recommendation," find it in the plain-language summary of the Whitehall studies [available at http://www.ucl.ac.uk/whitehallII/findings/Whitehallbooklet.pdf].)

[27] A third, common, misfortune was having a "bad supervisor." I will not discuss the last type of misfortune because it would require detailing micropolitics.

[28] Being in management did not seem to stop employees from railing against management, as there was always someone higher up who represented management to those employees. This is analogous to the rants against "government" I heard within government. As Herzfeld points out in his discussion of bureaucracy, "while people often act as though clients and bureaucrats were two separate classes of human beings, separated by some Manichean division of good from evil, they are demonstratably participants in a common symbolic struggle, using the same weapons, guided by the same conventions" (1992:5). I suspect that in many large organizations where many remain nameless that there is ranting against some version of "the Man" -- a nameless, shifting conglomerate comprised of those higher in the hierarchy and to whom varieties of conspiracy are attributed without much thought – which is ironic, given that many outside of that organization could refer to the entire organization as "the Man". Perhaps we are all Evans-Pritchard's (1979) 1920's Zande – many of us unknowingly creating misfortune by having "the Man" substance lying dormant within us.

[29] As an analogy to Quebec's no fault car insurance, in which fault is not determined, all parties involved in the accident receive monies from their own insurance, and no one can sue.

[30] There are a few exceptions, of course, the most notable being for those in supervisory positions losing one's French. Although not directly related to my research topic, for the sake of completeness, here is a summary of the language testing issues at the NHPD, which, as part of Health Canada, is generally known among Francophones as an "English" department.

80% of NHPD employees had English, rather than French, as the first Official Language, and only 69% of employees met the language requirements of their position (Elliott and Plante 2008:2). There were no translators employed by the NHPD, as translations were outsourced. But because the translations were sometimes late, of poor quality, or postponed indefinitely because of budget constraints, the few francophone scientific staff members were highly solicited for their language skills, and did much additional work to ensure quality of service for French-speaking applicants.

Most supervisory positions at Health Canada require at least "BBB" status – meaning that in addition to fluency in English (or French), intermediate reading, writing, and oral communication in the other language is required of the position's incumbent. Upper management and communications positions often require having "CCC" status, meaning fluency in the second language. Although there are some positions that are classified as, say, "BBB-I", meaning BBB imperative and that the candidate cannot hold the position until s/he passes the test for BBB status, most positions are "BBB –N", meaning BBB – non-imperative. In the cases where the bilingualism rating is non-imperative, the incumbent usually has 2 years to pass the language requirement testing. Thus, during my fieldwork at the NHPD, nearly all incumbents of supervisory positions were Anglophones or other non-Francophones who had yet to pass their language requirements because they were in the first two years of their positions. Employees are paid for up to a year of intensive second-language training if their position requires it, and most pass the French exams eventually even if the exams are a source of much stress.

Unfortunately, French was rarely used among staff at the NHPD. The exception was in human resources, where for some time French was the default language. I believe I heard more Arabic and Mandarin being spoken among assessment officers than I heard French. One member of upper management, despite passing the French exams required, absolutely refused to use any French in communication with employees in public all-staffs, and this seemed to raise little ire among scientific staff (there were also perhaps some shyness issues involved). There were several higher-level positions for chemists and scientific regulators that were reclassified as "English Essential" rather than bilingual so that the Anglophone employee could remain in, or be appointed to, the position. I say Anglophone because, as far as I saw at the NHPD, employees whose mother tongue was neither English nor French always made an effort and met the bilingualism requirements, even if it was after multiple tries. In this primarily English-language environment, it is no surprise that many managers worried about 'losing' their French because they must continue to pass the test every five years, unless they score so highly on the first test that they are exempted (which usually only happens with true bilinguals). Failing to meet the language requirements of the position at that time could result in the loss of their management position. The NHPD was too new at the time of my fieldwork for this to have been put to the test.

[31] In case potential public servants are reading this, the consensus seemed to be that the easiest way of becoming an indeterminate employee is to first get work as a student (co-op or FSWEP) for a term, because there are "bridging" mechanisms that allow such student workers to be granted indeterminate employment at graduation without having to win a competition.

[32] If the employee is temporarily appointed in a box that someone else "owns", there is the risk that the "owner" might decide to come back to ther job earlier than expected, causing a chain reaction in which employees are forced out back into their original box.

[33] Noted on the organizational chart and GEDS by an "A/", as in, "A/Unit Head."

[34] This relative position in government hierarchy is determined across job classifications by comparing the highest pay in the pay scale of the respective positions; for positions to be equivalent, the highest pays listed had to be within four percent of each other.

[35] I should note that some employees did not want these acting positions; even some acting unit heads seemed to genuinely feel that the promotion was "not worth it", as it was approximately ten thousand dollars more annually but as they were now classified as management: no overtime pay and more headaches and responsibilities. Later in my fieldwork, some areas began rotating the senior assessment officers through the acting unit head positions every four months, in the interest of providing equal opportunities to equal candidates. Also, because of the contentiousness of these acting appointments, there was talk of running "mini-competitions" for any acting appointment for Scientific Regulators.

[36] From the record of decisions of the Bureau's Leadership meeting on March 26th, 2007. The quotations are corrected for typos and grammar errors.

[37] This was also noted in a recent audit of the NHPD (Elliott and Plante 2008:12).

[38] Only employees could "sign off" on certain paperwork, like assessment reports, required in the product licensing process. Thus casual and agency workers were unable to take any acting positions, because these supervisory roles require signing off on these files.

[39] "Casual" status was introduced in 1993 (Public Service Commission 1999:17), part of the many changes to the public service in the mid 1990s. Previously, there had only been staff working in "term" positions, with much less appealing conditions than come with current term employment: then, staff with term contracts frequently had contracts of less than six months, or were regularly laid off before the six month mark (and then rehired) so the government could avoid having to pay benefits (Vosko 2003:60).

[40] An overview of "Temporary help services (THS)" at the Government of Canada, see the Public Works and Government Services Canada website under headers "buying and selling," "acquisitions branch," "temporary help services," which on 1/4/2009 was found at http://www.tpsgc-pwgsc.ca/app-acq/sat-ths/index-eng.html. For the reader interested in the technical details, the Regional Master Standing Offer (RMSO Instructions) are available at Public Works's website, at: http:///www.tpsgc-pwgsc.gc.ca/app-acq/sat-ths/clients/ocpr-rmso-eng.html (Accessed 1/4/2009). I am not an expert on this matter; but given that Brisson and colleagues (1997) list both "temp. help" and "contract" under the heading Outsourcing in their report, "temporary help services" may not have been the means by which many of NHPD's scientific staff were hired.

Leah Vosko has written a history of temporary help agencies in Canada on the general labour market (2000), although she does not mention their use in providing federal government offices with workers. Vosko agues that in the middle of the twentieth century, temporary help agencies could be glossed as "half-way houses for housewives," providing clerical staff for "stop-gap" situations (e.g., holiday leave). In the 1970s, the temporary help industry began marketing itself as selling low-cost "staffing services"; the growth of the industry subsequently accelerated in the 1980s and 1990s (Vosko 2000:11-12).

I have been unable to find any documentation regarding the use of hiring agencies to staff temps in the public service, despite contacting academic experts. Two former federal employees have told me they were originally hired to (non-Health and Welfare Canada) federal government positions through hiring agencies in the late 1980s. Public Service Commission's report on non-standard employment, published in 1999, notes that it could not include in its analysis any contract employees or employees hired through temporary help agencies because the numbers of these categories were not centrally compiled (1999:8), so the practice was clearly underway in the 1990s. Should the reader be interested in more detail that should become available, contact Professor Timothy J. Bartkiw at Ryerson University's Faculty of Business, who at the time of writing was working on the topic.

[41] From page 3 of Health Canada, Forensic Audit and Investigations. December 6th, 2006. Internal Disclosure: Temporary Help Service – NHPD Call-ups. HF2-08-2-06-03. (In Health Canada – ATI A2008-00193)

[42] I do not have official numbers. Once I overheard that, in SG SRE-03 positions, the staff saw $26 of the agency's $33 per hour; the BI-03 and CH-03s saw $32 of the agency's $36. But this contradicts with another overheard conversation, in which it was stated that the agencies really were not interested in anything with less than a $10 hourly cut. In any event, the numbers serve as ballpark figures.

[43] Although I should note that external training was systematically denied to many evaluators (BIs) during my fieldwork, contrary to Health Canada policy, "because of the backlog". There were, however, some units in which training was encouraged and promoted. For instance, I was told that, according to Health Canada expectations, employees should get 5 days of elective professional development annually, in addition to any training specifically required for the position.

[44] Note that I do not believe this is supposed to happen; the many ways in which rules were creatively worked are described in Chapter 18.

[45] The resentment was neither personal nor overt, however; I would not have noticed had I not been told.

[46] I was informed that “push back” is a technical term, used in Health Canada supervisory training programs.

[47] Other possibilities for this lack of “push back” could be the young age of many unit heads, and the nature of authority in many lab-based sciences (i.e., the scientists, from their masters, doctoral or postdoctoral training were habituated to following directions without considering the opinion and direction of their superior contestable). On the other hand, some acting unit heads had been health practitioners, and several health practitioners told me they had found entering government slightly shocking, in that they went from a position of telling people what to do, to a position of being told what to do. My intuition is that it is the job insecurity factor that is most significant in this lack of “push back.”

[48] MOFs must have a licence to practice medicine in Canada. There has always been at least one medical officer position in the organizational chart of the NHPD but it had never been staffed, or only very temporarily (I got conflicting stories), prior to August 2007. Part of the problem is that the reviewer positions at the NHPD (BIs and the MOF) are classified one pay grade lower (to the tune of $15,000 annually) – than the analogous positions at TPD and BGTD.

[49] The workshop for science employees was held in June 2007 at the Holland Cross Building, Ottawa, and was associated with the Health Product & Food Branch’s “Building a Branch Strategic Science Plan.”

[50] The friction often occurred when tasks in the assessment of files overlapped or were unclear. There was also snide denigration of the quality or importance of the work done by the other groups. A summary of the main snide comments are classifiable by job category. Scientific regulators would demean the communication skills of biologists and chemists and complain that these scientists did not know, or properly refer to, the Regulations. Biologists and scientific regulators would demean the tasks of the chemists, saying how the chemists’ evaluation involved saying yes or no to questions in a checklist, with no thought involved (this was also said of the officers in my particular work unit). Biologists and chemists saw scientific regulators as a catty bunch, sometimes controlling processes in assessment when it was not their business, and for being overly regulatory and bureaucratic; when one biologist stated that a particular scientific regulator “is such a born regulator”, this was not a complement. Clearly not all scientists made or believed these snide comments about scientists in the other groups!

[51] The NHPD had thus become known as the “training ground” for the Health Products and Foods Branch, as new employees often worked for a year or two and then were “poached” by other directorates and agencies, into higher-paying positions, much to the chagrin of lower management and peers. Among the BPRA’s management, it seems concern for retaining qualified staff has existed since at least 2004 (according to the Record of Decision of a BPRA Leadership meeting December 16th, 2004). The rumor went that the positions in the NHPD’s original organizational charts had been consciously classified under the appropriate levels to minimize the projected budget for the endeavor.

[52] The reasons or non-reasons offered at the NHPD did not seem significantly different than those documented in the Public Service Commission’s 1999 report on non-standard employment in the Public Service as a whole. Reasons given by managers and directors in human resource units included the “need for staffing flexibility in response to budgetary constraints, and uncertainty regarding the future of departmental programs” (Public Service Commission 1999:18) and cost-savings (1999:4). At the time, Health Canada directors and managers stated they use “non-standard employment [in BI positions] as a recruitment vehicle as well as for the flexibility it provides management to terminate staff following the sunset of programs” (Public Service Commission 1999:25.)

[53] The NHPD was in a tenuous funding situation at the Branch level, in the sense that it is not allocated permanent funds in the Branch’s budget (called A-base funding), but must beg for its operating budget each year, at least according to its upper management. This could perhaps explain some of the difference in the presumed higher rates of agency staff in the scientific sections of the NHPD rather than in those of its sister directorates.

Vicki Smith and Esther Neuwirth, in their study of the temporary employment industry in the US (2008), note that companies, to appear “lean and mean” to shareholders, obscure the actual number of workers by hiring temps and paying them out of the budgets for "materials and supplies", "services", and "overhead," rather than out of the budget for "personnel and payroll" (2008:187.) I have no idea whether pressure to appear “lean and mean” operates at the levels of upper management at Health Canada. Leah Vosko mentions that in the 1970s or 1980s there was a “range of financial incentives, discouraging managers from increasing their operating costs through the provision of fringe benefits to permanent employees and encouraging them to increase indirect employment costs by hiring casual employees, contributed to this trend” (2003:61.)

[54] From an interview.

[55] “Corporate Human Resources” at Health Canada is at the main Health Canada campus, Tunney’s pasture, in the central Ottawa area. This was a reasonable distance (twenty minutes by car, forty minutes by bike or bus) from the NHPD offices located in one of Ottawa’s western suburbs, close to Kanata. In addition to the distance, corporate human resources was extraordinarily slow and largely unhelpful to the NHPD during the time of my fieldwork (see also Elliott and Plante 2008:12).

It must also be kept in mind that the Corporate Human Resources was apparently severely understaffed, which was not independent of the subsequent high rates of burnout and turnover. This appears to be largely consistent with the current fate of many central HR departments in US corporations. A study of the US “flexibilized” work environments noted how many human resource departments – as non-revenue generating units [!] -- have been cut, causing delays and burnout and more delays, trends which also encourage the company’s use of temporary hiring agencies to circumvent the central Human Resources department (Smith and Neuwirth 2008:127). The authors cite a study showing that 91% of large companies surveyed were planning to, or had already, outsourced elements of their human resources (Smith and Neuwirth 2008).

[56] From the meeting of the morale and recognition committee July 7th, 2007. [internal document circulated after meeting]

[57] Employment at the NHPD required getting the lowest security clearance, “Enhanced Reliability.” This process was done by Health Canada’s centralized Human Resources and seemed to take forever – especially for those potential employees with common names like “Smith” and, because of the population of China, many Chinese names.

Once hired, employees waiting on the central machinations of Health Canada noticed little speed increase – I had been working more than two months before I received any pay, and a colleague had to wait even longer.

[58] From the meeting of the morale and recognition committee July 7th, 2007 (internal document circulated after meeting.)

[59] But another government report states that, in December 1988, fully half the women in that same occupational category were on terms of less than six months (Task Force on Barriers to Women in the Public Service 1990:85.)

[60] A January 2008 organizational chart from the Therapeutic Products Directorate shows very few scientific staff in agency or casual employment. This situation of widespread temporary work among scientists may be specific to the NHPD in the Health Products and Food Branch, as I believe the NHPD is the only wholly new directorate, rather than a directorate that splintered off the old Drugs Directorate. Detailed organizational charts from the Health Protection Branch through the 1980s and 1990s are not available, at least via Access to Information (Health Canada – ATI A-2008-00194). In response to my request for organization charts for the Therapeutic Products Directorate and its precursors, and the related Inspectorate, every five years from 1945 onwards, I received: yearly (or more frequent) organizational charts yearly-ish for the Veterinary Drugs Directorate 1993-2008; Inspectorate organizational charts 2002-2007; quarterly organization charts from the Therapeutic Products Directorate October 2003- 2008. (Usually Canadian federal government departments have permission to destroy general administrative records after their retention period has expired, so the fact there are no records from earlier periods is unremarkable.)

[61] Again, this seems consistent with Vicki Smith and Esther Neuwirth's analysis of the flexibilized work environment in the US, where, unlike with the original "standard employment model," managers now try to dispel any expectations on the part of workers for loyalty or attachment from the companies where they work (2008:127).

Chapter 18
Fairness in staffing, fairness in assessment
Canadian nice

> Times have certainly changed since I was a student… And they have certainly been changing in the corporate world and in the public sector.
>
> But some fundamental things don't change, do they?
>
> Fairness and honesty are values that never go out of fashion.
>
> So I think the challenge is – as some wise person once said – to "adjust to changing times and still hold on to unchanging principles."
>
> Sheila Fraser, Auditor General of Canada, addressing the 10th Annual McGill Graduate Business Conference on March 21st, 2003[1]

Fairness was not only an explicit, official value in the Canadian Public Service and at Health Canada, but a value that, I argue, held an important place in the moral economy of scientific assessments at the NHPD during the time of my fieldwork. As important as fairness was to discussions of scientific assessments, its importance in those discussions paled in comparison to its omnipresence in discussions of staffing matters.

Lower managers' emergent conundrum: fairness

This chapter explores a very specific dynamic of fairness at the NHPD. As described in the previous chapter, during the time of my fieldwork, 51% of scientific staff at the NHPD were either temporarily hired, or temporarily promoted, to their position. Once staff had been temporarily hired or promoted without competition, lower and middle management appeared to be in a moral bind. On the one hand,

the laws governing public service employment stipulate that hiring processes should exemplify the values of access, fairness, transparency, and so on; and the gold standard for ensuring the presence of these values was to run open (to the general public) competitions for entry-level positions.[2] On the other hand, lower and middle management felt a moral obligation to support its current staff, temporary or otherwise. These managers had not only spent considerable time bringing the temporary worker or supervisor into the thought collective, but they also believed that some of their best employees were "stuck" in casual and temporary appointments. Several lower-middle managers voiced precisely this conundrum during my fieldwork.

Managers did not grapple with this conundrum in a detached manner. In interviews, several employees in supervisory positions told me that they were very stressed and upset about the staffing situation, even losing sleep. It was not unknown, towards the end of my fieldwork, for scientists in lower and middle management to be so upset over their supervisee's staffing situation that they had to take time off – and at least one leaving the office in tears.

I am interested in the conundrum of lower and middle NHPD management as a means of exploring the particular meaning of fairness at the NHPD. While I first explore fairness in the context of widespread tenuous employment, fairness in the context of the evaluation of medicines largely followed the same dynamic, as I will explain in the second half of this chapter. A key feature of this particular fairness

was that it was taken from the perspective of known persons. By *known persons* I mean actual interlocutors: in the case of staffing, the known persons were the temporary incumbents of scientific positions, and in evaluation, the known persons were the applicants for product licences. The consideration that had to be shown to these interlocutors was kept in check by the threat of complaint from other interlocutors. Individuals who were not interlocutors were irrelevant to this fairness. I use each of the next sections to outline a constituent element in the particular meaning of fairness among scientific staff at the NHPD. Subsequently, I abstract the fairness in detail, and then discuss its relevance to evaluations at the NHPD.

Fairness applies only to those known personally

There were many ways in which NHPD scientific staff in both management and non-management positions took fairness from the perspective of the temporary incumbents of scientific positions. First, all avenues were explored for extending the temporary appointments of the incumbents. Generally the avenues chosen were ones that seemed to allow management to get around the rules "transparently," and by this I mean meeting the letter if not the intention of public service staffing rules.[3][4] This included appointing acting unit heads via a continuous series of appointments lasting four-months-less-a-day, even when management knew the total appointment would be for a longer period; I was told that in this way not only could formal competitions be avoided, so too could the French-language requirements of supervisory positions.[5] Scientists hired through agencies were given directions to put their resume on file with a specific agency; the next call for

temporary help would come from that agency. When agency staff had their contracts renewed the maximum number of times permitted annually, an apparent loophole, something about getting a different director's sign-off, was exploited until disallowed by someone on the main Health Canada campus, or so the rumor went. After these contract renewals and extensions were exhausted, many agency staff members were rehired as casual staff. Also, contract and casual staff were directed to place their resumes in specific, rather obscure government databases like the Science and Technology Inventory,[6] because managers could then conduct a formal, "transparent and open" hiring process by searching such inventories: of course, inclusion in database was partially word-of-mouth.[7]

The ultimate way of being fair to current temporary scientific staff – and the option most sought by the agency and casual staff themselves – was to help staff get indeterminate appointments to their current positions. Strategies for this varied according to job classification, so I will discuss each scientific job classification in turn, beginning with the scientific regulators.

A few members of lower management pushed higher management for processes allowing them to get all scientific regulators (SG-SREs) into indeterminate appointments. An SG SRE-04 competition was called in spring 2007.[8] The competition was designed as an open competition, so that the current casual and agency workers could apply.[9] More than three hundred applicants were "screened into," or considered qualified for, the competition.[10] That competition, however, was

never completed. In the meantime, management had succeeding in getting SG SRE-04s listed as a “shortage group” in the National Capital Region. When a particular specialization becomes listed as a shortage group, “name referral” can be used to appoint workers to indeterminate positions and no competition need be held. Thus, during the end of my participant-observation, all the agency and casual workers temporarily working in SG SRE-04 positions were appointed to indeterminate positions without a competition, and term employees had the option of being renewed as indeterminate employees. Here, fairness is clearly not taken from the perspective of the entirety of the three hundred applicants screened in to the competition.

The bulk of the casual and agency workers, however, were in BI-03 positions, and the drawn-out difficulties were acute for the BI-03s.[11] Management tried to get BI-03s listed as a shortage group like the SG SRE-04s, but they were unsuccessful. Management eventually initiated a competition for the BI-03s, but suffered innumerable setbacks. The first competition poster had apparently been incorrectly drafted, so the competition could not proceed.[12] In the process of this fiasco, other Directorates in Health Canada learned that NHPD was running a BI-03 competition, and they wanted to be able to hire based on the results of NHPD’s competition. Thus the new competition was made Branch-wide, which had the effect of increasing complexity, co-ordination and timeline. Furthermore, it meant that it was not possible to include qualifications specific to the NHPD, making it more difficult to hire employees with expertise in traditional or herbal

medicines, or to privilege NHPD's temporary incumbents of BI-03 positions.[13] Although the competition was thus potentially fair in a hypothetical, dictionary sense, after the NHPD lost control of the competition processes, I did not get the sense that the competition was *experienced* as fair by either management or non-management NHPD staff. The competition was still in process of being posted at the end of my fieldwork.

(The chemists were a very small group of about a dozen of whom only a few were agency. Although management spoke of running a competition for the CH-03 positions, they said the CH-03 competition would be scheduled after the BI-03 competition. But as the two CH-03 contract workers won competitions run outside of the Directorate and left for other positions in government, the point of the competition apparently became moot. I also never heard accusations of unfairness regarding the acting unit head at the beginning of my fieldwork, and at the end, the remaining two employees in the Quality Unit alternated acting as unit head, a situation that obviated complaints of unfairness).

The ways in which low- to mid-level management was generally understood as acting fairly to those in temporary positions helps us understand one facet of the particular meaning of fairness at the NHPD. This is not fairness in the sense of a priori adherence to widely-known rules. Management strove to work the rules to the advantage of the temporary incumbents of the scientific positions as long and as much as was possible, and this was largely regarded in the Directorate as being

fair. Fairness was taken from the perspective of those in one's range of acquaintances; as a form of empathy or niceness, it simply did not apply to hypothetical persons like faceless applicants in the formal, cancelled, SG-SRE competition.

Fairness as similar opportunities for staff in commensurable positions

Another feature of the particular fairness at the NHPD was that all members of a group should be treated equally. During my fieldwork, scientific staff vocalized concerns that certain employees would get preferential treatment in organizational changes, because the changes would be arranged informally – with management considering the opinions of those employees it favored or consulted most frequently – and then the changes would be presented as a done deal. The concern was that those who did not have upper management's ear would have fewer opportunities to select preferred positions. This fear of informally-arranged organizational change resulted in much emotion-laden gossip. This gossip sought to detect whether changes were currently being informally considered, and if so, what was predicted. Complaints of unfairness and favoritism invariably resulted when there was the possibility that certain groups would get opportunities not open to others. One employee who was in no way a disgruntled employee – she took great pride in her work and the accomplishments of the NHPD – told me in an interview

> I do not feel like I'm being taken into account. Maybe there is a plan for the reorganization of the NHPD, and I'm not aware of it. I feel so out of the loop – I have no idea what is going on.

(Although she continued by speculating, “maybe the NHPD does not actually know what is going on…”)

I assume accusations of unfairness continued up the chain of command, although I was not privy to the gossip of managers among themselves. It is clear, however, that at least some unit heads expected higher management to automatically treat the various work units equally, just as entry-level staff expected automatic equal opportunities for themselves and their peers. Unit heads, like entry-level scientific staff, often became upset or indignant when things seemed unfair, for instance when their peers received a good they did not. In one photocopy room conversation, a unit head, who was visibly upset, explained how she was so tired of finding out second-hand that other, vocal unit heads were bestowed something for their unit and that higher management had not thought to bestow this good to all units. This unit head was nearly in tears with what I understood as anger, frustration and indignation at the unfairness of the situation. This episode dovetails with other complaints made spontaneously by several unit heads in interviews: that the “workers” (e.g., the scientists who completed their work and worked to improve processes) were often rewarded with more work, and the “talkers” favored by upper management received recognition, non-competitive promotions, and benefits for their units. I take from these examples and others that many scientific staff, including those in lower management, expected that management would treat all employees in the same units or same classification equally, independent of personal affinities and connections, personality, or way of working. Fairness thus

also meant that management consider and treat all commensurable positions – at least within its social network – equally, automatically.

Fairness as equitable social recognition

Providing equal "goods" to all commensurable acquaintances and units was necessary, but insufficient to acting fairly at the NHPD. The fairness in evidence at the NHPD also required a show of empathy. I must emphasize the importance of empathy in this local understanding of fairness because of one instance, several employees were treated equally by higher management – but equally in the sense all existing relationships were denied. This occurred when there was a competition to permanently staff the assessment unit head positions (the BI-04 positions), which happened at the end of my fieldwork. In this competition, management interviewed about a dozen scientists, the vast majority from the NHPD. The competition was a high-stress affair for many of the candidates, because not only had some candidates been acting unit head for more than two years and were afraid of losing their (acting) position – "which would look really bad" according to one candidate – but also the competition was largely among friends and colleagues. Several of the interviewees described how the interview was particularly difficult because the interviewers, the supervisors with whom the interviewees had worked for years and had positive relationships, treated the interviewees as if they were nobodies, completely negating their relationship. These employees told me they found this process entirely unfair, inappropriate, troubling, and difficult, in two cases, employees stated this was because the

interviewers had (other) favorites. One colleague opined “I don’t think I’m one of the chosen ones. I get the impression that I’m not liked, but I do not know why. I get the job done; I’m nice” and when I countered, but there’ll be a competition, she replied “I think the results will just be whatever they want them to be.” Another interviewee, who felt that the lack of response on the part of management indicated s/he had incorrectly answered an interview question and would thus be excluded from the pool of qualified applicants, vehemently charged the whole competition process with being a sham: “they’ve already picked out their favorites and their minds were already made up before the competition, it is all just a sham.” Although these two employees were ultimately successful in the competition, this was not known at the time we spoke. The strong, emotional reactions of several of the scientists in the competition indicate that fairness was not a matter of simply treating all candidates equally. Fairness also stipulated that management treat all candidates with empathy, and honor existing social relationships.

Fairness and its relation to complaint

Other features of fairness at the NHPD are perhaps better explored through accusations of unfairness. Accusations of unfair appointments were endemic in situations in which no formal competition had been held. Often inchoate feelings of anger, disgruntlement, or unjustness were expressed as informal complaints made in passing to close colleagues and left at that; sometimes these feelings would be so strong that the employee would seek work elsewhere in Health Canada by

making a lateral move, even if the employee did not make a formal complaint or grievance. When an employee's feelings or suspicions were rendered as full-fledged accusations of unfairness in accounts to colleagues and, in cases where formal accusations were made, to management, she would usually name no particular "perpetrator" of the unfairness. The accusations were usually made against the lack of process or, occasionally, against "management."[14] Unlike the archetypal analysis of witchcraft in medical anthropology (Evans-Pritchard 1976), these accusations were generally not made to ferret out the culprit, and did not seek vengeance against either the culprit or the recipient of the appointment.[15] These accusations of unfairness did not implicitly seek to answer "Why me? Why now?" that many medical anthropologists relate to explanations of witchcraft; rather, these accusations nearly always implicitly asked the question "Why *not* me? Why not *now*?" Gossip regarding the fortunes and misfortunes of others often seemed to affect whether an employee would make informal or formal accusations.[16]

In some instances, when those questions were, in the mind of the victim, at least partially answerable, there was often grumbling to close colleagues, as mentioned above, but no sustained or formal action ensued from the accusations of unfairness. For instance, several employees separately told me how management appointed a particular assessment officer as a permanent unit head without any process, and how they or others felt this was a little unfair or deceptive, because management had promised a competition for the position. Nevertheless, each

employee telling me this story stated that they had nothing against the recipient of this particular appointment (for whom they were happy) and that they understood why the appointment was made without a competition, and that the reason for this particular appointment (which could be glossed as affirmative action) was important.

In other instances, satisfactory answers to the questions “Why not me? Why not now?” were not found. Accusations of unfair appointments were formalized in some instances, and could be made internally at the NHPD, through the public service commission, or through various tribunals. Most complaints I heard had to do with favoritism, although there were also some relating to discrimination based on attributed colour or ethnicity.

Formal complaints and grievances did have an impact on procedure. This was not always a direct impact for the complainant, in the sense that complaints did not necessarily result in the desired promotion for the complainant. Despite the process for complaining and grieving being made explicit – for instance instructions for how to complain were advertised in every Public Service Staffing Announcement of appointment – complaining and grieving could often serve little constructive purpose.[17] Announcements were sometimes posted months after the appointment, and in some cases after the acting appointment was over.[18] Nevertheless, the *possibility* of complaint shaped the processes management chose to use in making appointments. In other words, when management

promoted employees, the formality leading to the promotions seemed to be the least formal method that would mitigate formal complaints. At least one informal promotion was stopped because, supposedly, of the possibility of complaint -- an employee recounting this story to me said point-blank: “I would have complained.” Essentially, fairness was only due to those who could complain. By the time of my departure, disgruntlement regarding acting appointments had reached sufficient force that management began saying that “mini-competitions” would be run for all acting appointments, at least for scientific regulators.[19]

Fairness at the NHPD

The *Canadian Oxford Dictionary* has the following primary definition of “fair”: that which is “just, unbiased, equitable; in accordance with the rules.”[20] This definition does not do justice to the robust, specific interpretation of what scientific staff at the NHPD considered fair behaviour on the part of lower management during my fieldwork. The fairness at the NHPD is clearly not entirely that of strict, universal rule-driven bureaucracy idealized in utopias and dystopias described by Lewis Mumford (Miller, ed. 1995); in other words, it was not the “distributive fairness” described by Mallard et al. (2009). In fact, following rules in certain situations, for instance strictly following public service staffing rules, was decried as unfair (and unreasonable) in the context of high rates of tenuous employment.

What was this fairness in staffing at the NHPD? I have characterized this particular fairness as:

(1) Kind and considerate behavior,

(2) that hinged on the manifestation of empathy for the staff member concerned,

(3) and which included a "disposition to concede every reasonable claim."[21]

But this behavior has a clearly limited application. Fairness

(4) was not applicable to hypothetical people or groups, but only to known interlocutors.

(5) Considerate behavior towards any person was counterbalanced by the consideration and empathy due to other, comparable, persons,

(6) because in any instance, all commensurable interlocutors must be considered and treated equally.

In other words, to be fair, one must be partial to those among one's acquaintances and act with empathy, but be impartial within that group. Of course, in practice, the limits of the group to whom fairness seems to apply is essentially determined by the limits of reasonable complaint.

Fairness as niceness

The particular fairness I have described is quintessentially stereotyped Canadiana: it is indistinguishable from *being nice*. One cannot "be nice" to hypothetical persons, nor is one nice if one privileges select interlocutors. This particular

fairness requires that one works in such a way that all parties in one's extended social network are satisfied, and, ideally, that complaint is avoided – or even obviated.

I suspect this fairness, in many incarnations, is a value that underlies many heated or passionate conversations in the Canadian Public Service as a whole, not just at the Directorate. While perhaps the centrality of this value could be traced, to the official value of fairness in the public service;[22] or, perhaps, dynamics ensuing from tenuous appointments in the public service;[23] or, as John Ralston Saul does in his latest book, to a particular idealized Métis identity at the root of Canadian institutions and identity and that is concerned with social equality (2008); or, in another vein, to a technocratic approach to governance (cf. Porter 1995); or, in a functionalist anthropological perspective, to an elite strategy obviating the witchcraft accusations that might otherwise come with a sedentary, high-density population like workers stuck in cubicles (Stewart and Strathern 2004:30); I must take an agnostic perspective to the origins or purpose of the centrality of fairness at the NHPD simply because there would be no way of meaningfully ascertaining its origins.

Furthermore, it is difficult to determine the extent to which this fairness is culture-bound. Mark Graham, in his fieldwork-based study of Swedish welfare officials (2002), found a similar fairness. He argues that in his fieldsite, the bureaucrat's emotional expression reproduced "the ideology of the welfare state."[24] In contrast,

Michel Herzfeld characterizes bureaucracy as “the social production of indifference” (1992) and Didier Fassin to some extent follows in this vein (2005:366). I am unsure whether this is due to a difference in national political culture (Canadian and Swedish versus Greek and French), or, more likely, a difference in the object of study: Herzfeld and Fassin study publicly circulating accounts of the state’s actions, while Graham’s (and my) attention is to the moral accounting *within* the bureaucracy. I suspect that the overall grumblings against the unfairness and indifference of The State of which Herzfeld speaks would also be heard among applicants to the NHPD. The determination of culture-boundedness is complicated by Craig Hoag’s (2010) recent report of South African bureaucrats’ reasoning and judgement regarding immigration cases. Hoag’s fieldwork was within the bureaucracy and many facets of his description are consistent with my findings, but he does not mention that the bureaucrats he observed were preoccupied with fairness. For my dissertation, it suffices to emphasize that fairness was an organizing value at the NHPD, a key expectation of most scientific staff.

I have characterized this fairness using the example of the bind in which lower and upper management found themselves in 2006-2007. Fairness, as characterized above, was also a robust organizing value of evaluation. Fairness in both cases was a moral economy. There are many ways of defining a moral economy, as is evident from the growing literature on the subject (Thompson 1971, Scott 1976, Daston 1995, Busch 2000, Rasmussen 2004, Fassin 2005). Because fairness was

such a key organizing value, and one that I suspect is not restricted to the Directorate, it is worth detailing the ways in which it was a moral economy. The way in which fairness was a moral economy in staffing was different that the way in which fairness was a moral economy in evaluation. With respect to staffing, the moral economy involved a literal accounting of the value of the self, related to the emotions of self-assessment, as characterized by Gabriele Taylor (1985).

Moral economies I: emotions of self-assessment

The philosopher Gabriele Taylor does not use the term "moral economy," but her discussion of the moral emotions describes a literal accounting of the self. Taylor examines a group of emotions, "the emotions of self-assessment," that she argues "resemble each other in requiring the same sorts of beliefs" (1985:1). She is uninterested in the exact labels for emotions, noting that these will depend on the purpose of the author, although she singles out pride, shame, and guilt. Rather than the emotions themselves, she is interested in their dynamic, specifically how:

> in experiencing any one of these emotions the person concerned believes of herself that she has deviated from some norm and that in doing so she has altered her standing in the world. The self is the 'object' of these emotions, and what is believed amounts to an assessment of that self. (1985:1)

Taylor describes a literal moral economy of the emotions, in which various emotions have currency in intra- and interpersonal dynamics, acting to (re)adjust the believed worth of the self. They are likely applicable to any self comprised not only of a psychological element (mind) but also a moral one (obligation) (cf. Young 1995a).

An example of this sort of literal, emotional and moral accounting of the self in ethnographic context is found in organizational studies. Poul Poder draws from five months of fieldwork and interviews in a large pharmaceutical company in Denmark, to examine emotions during a reorganization of the company's corporate human resources (2008). Poder was particularly interested in expressions of anger when unaccompanied by aggression, because he holds that anger, when directed towards someone who is held responsible for a loss, or an insult, may provide a social signal leading to a repair in the relationship where "the angry person may not be sufficiently acknowledged as a person" (294), or where, using Gabriele Taylor's language, the angry person believes her self to have been undervalued or slighted. The range of anger Poder presents in his three case studies, which I would characterize as anger possibly blended with indignation or frustration, was similar to that expressed by my colleagues; the crux of the accounting in the first two cases of three, was fairness.

Poder's first case example is of an "angry or bitter employee" (2008:297-298), who felt that upper management's justification for the reorganization – that the reorganization would increase "professionalism" – implied that the previous unit had been unprofessional. The employee contested this interpretation, and when answers were not forthcoming regarding why the previous unit, contrary to the opinion of the unit and its clients, was unprofessional, he was furious. Nevertheless, he did not criticize the reorganization outside of his unit and upper management. The basis for his anger was unfairness: "as long as he thought they

[the old unit] were not being treated fairly, he could feel anger" (Poder 2008: 297). Poder argues that without any support in his interpretation of justified anger from his colleagues, there was a chance that his anger would be reinterpreted as bitterness.

The second example, of an "angry or frustrated employee," describes the interaction between an administrative employee and her boss when she did not get her preferred position in the new department. The disappointed employee stated in an interview:

> I remember I reacted strongly because I thought they [the management] had changed the guidelines. And I though they should have informed us. That would have made it fairer ….
>
> [Her manager] came into my office after a couple of days and asked if I was feeling better. "Certainly not," I told him. I was still as upset – and angry and disappointed and sad about the situation. And when I asked him if the complaints procedure, which he had given such a good press, was worth anything? Well, he though that it was. And so I asked him what I was supposed to do, and then he explained how I should proceed. I told him that I knew what to write, I just wanted to know if I would get anything out of it. Would I actually get anything out of it? No, he didn't think so. So then I thought "I don't give a damn" (Poder 2008:299).

Poder argues that the manager refused to acknowledge the employee's anger, and instead recognized sadness and disappointment; this was perhaps facilitated by the employee herself, who excused her angry behaviour as "unfair."

The third case example was of an employee who likewise saw no point in expressing anger. In an interview, she asked "Who could you get angry at? The company? Then you could write a hundred times 'I'm angry with the company?' I don't know … I unwind by doing other things […. And] it's good that retirement isn't

that far away." When Poder suggested her colleagues could get angry at the managing directors, she laughed, and noted that people would think "How long will I keep my job?" (2008:302-303). Like among my colleagues, there were different ways of expressing anger, but subordinates were less likely to express negative emotion, especially until they felt they had a sufficiently secure position and there was reason for the managers to value the employee. Poder argues that strategically not expressing

> one's anger to the assumed offending party is also a self-weakening act, in the sense of abandoning the possibility of fighting for one's interests and working out a solution. This practical implication concerns an increased inequality of social relationships. (2008:307)

Poder's argument is that because anger was not directly confronted between employees and their managers, there was no possibility of repairing the relationship, the self that employees felt was slighted.

At the NHPD, while the slighted employees expressed anger and frustration, at least when they became more confident that their supervisors were concerned for their well-being (e.g., more confident in the relationship and that the supervisor would recognize the need for the proper recognition of the employees), their expression of anger led to other (negative) emotions of self-assessment in the Directorate. Specifically, the lower and middle managers, because they did not wish to slight their staff, appeared to experience shame that motivated them to act to repair the damage (pursue staffing actions); but the managers themselves were slighted when blocked from providing the fairness in staffing they were responsible for providing, but ultimately unable to provide. Through perhaps little fault of their

own, they were breaching the social rules of fairness, which, as Mallard et al. (2009) point out, created a sense of unfairness as well as the emotion of anger, which in some case may have been directed at themselves. I suspect that for some of these lower and middle managers this was experienced as a loss of honour or integrity (cf. Taylor 1985) which, at the NHPD, was achieved through being fair.

This literal accounting with emotions are dynamics therefore inseparable from the thought collective, its cosmology, and institutions in which it is embedded. Poder argues that emotions such as these "can have a short-lived or longer existence depending on the durability of social context which is a constitutive part of emotion" (2008:294). I believe this sort of moral economy, the literal accounting of the emotions of self-assessment in interpersonal relationships, is *part* of what Ludwik Fleck was alluding to when he undergirded the importance of "themes such as propaganda, imitation, authority, rivalry, solidarity, enmity, and friendship" in epistemological theory, because these are "themes which could not have been produced by the isolated thought of any individual" (1979:43).

I say *in part* because this literal accounting is predicated only on the definition of the self. I suspect Fleck, with his attention to historical detail and change, was also interested in values important to the thought collective and that changed through the time period of interest, and were not so directly tied to the perceived value of the self. Fairness remained a moral economy in scientists' premarket evaluation work, but in this second case, the moral economy was more of the type described

by Lorraine Daston (1995). First I will turn to a discussion of fairness in science-based evaluation (assessment).

Fairness in assessment

Fairness, as I have outlined it above, was also in evidence in the directorate's scientific assessment. In this regulatory culture, the very nature of being human (being social) predisposed one to consider the known other, the interlocutor. The crux of the matter is: applicants ended up figuring in discussions of fairness, whereas hypothetical people or abstract entities like "the Canadian public" were irrelevant to this particular fairness. I examine the way in which very mundane interactions involved with the regulatory process – without any whiff of direct lobbying, threats, or money – populated, peopled the moral economy of fairness in scientists' reasoning. To indicate the extent to which I am really speaking of the mundane, let me begin, therefore, with the blinking light on a scientific regulator's phone indicating a message.

(1) Essentially kind and considerate behaviour

Fairness in assessment, like in staffing measures, was kind and considerate behaviour. Consistent with the *Public Service Code of Ethics* (2003), fairness as a basic "people value" in the public service was captured in the NHPD by the mantra "we're here to help." During an interview with a scientific regulator that I will call Oria, I was telling her about my surprise at a few "poaching" attempts by managers

elsewhere in Health Canada when I had spoken up quite critically at employee consultations about the impacts of certain practices on public health protection; this scientific regulator, who was highly appreciated by her colleagues, widely viewed as an excellent public servant, spoke of the importance of communication. From there, she launched into a narrative her workday:

> You know what, well every morning I'll come in a bit early, grab a big coffee, and that is sort of how I start day. Just going through, cleaning up my e-mails. I mean half of it you can just about trash anyways…But it bugs me to have them build up. You know, I don't know how people just ignore it. I can't.
>
> So that's ... maybe that's why I do enjoy working [as a scientific regulator] and dealing with people, and being a resource person just because I don't mind talking to people. And it can drive me nuts sometimes, which is why I have to cover the little blinking light [the voicemail indicator on the phone] …. if I'm really busy working, and I can see that there is [a message] – like the light is blinking – sometimes it just drives me nuts, and I really do have to focus on my work, I'll take a sticky note and cover it because it really bothers me to not respond to it. And … I'll go home 15 minutes late in order just to clear up my messages and stuff. And I kind of take it that is how everybody behaves….
>
> And that's something really important and maybe underemphasized. If you're dealing with the public – if the Canadian public are our clients in general, whether they're clients because they're taking the products or whether they're clients because they're trying to sell the product – you know, I think showing a little bit of attention and really quick common courtesy is important. And it doesn't have to be much, you know, a 30 second response and they really appreciate it….
>
> I do get a lot of positive feedback just from people that phone me up and say "I know it's not your area but I'm really having a lot of trouble" and they'll go on, and you know I'll just take 30 seconds and try and give them a little pep talk and point them somewhere else. I've had so many thank-yous, it's almost embarrassing, they'll send me a little thank-you reply by e-mail or a little note…, saying we just want to let you know that it was so nice…. Adding a little bit of a personal touch on it is really appreciated. I think that people take it as a matter of fact that nobody cares, and they're just going to be you know pass the buck to somebody else.

Scientists' dedication to serving the public who called, wrote, or visited, de facto became scientists' dedication to serving applicants. (For many very practical reasons, scientists were only authorized to speak about specific files, which meant that, during the work day, if they spoke to anyone outside government at all, it was applicants).[25]

This kind and considerate behaviour did not have to stem from any affinity to the applicants. During my fieldwork, Dorrie had shared my shock and horror at what some applicants thought was evidence (opinion website printouts and the like). When I asked her, in interview, how she felt that "respect for philosophical and cultural diversity came into play in her assessment work," she (half-) joked:

> That may mean not making mean remarks about these licencees: how stupid do they think they are? [laughing]
>
> I realize we do have to respect them the way they are. Which is why we have to vent and gnash our teeth – in private.
>
> Because the bottom line is, they're who we're serving, because they're a part of the Canadian public, and they're serving the Canadian public. And we serve both of them. And that's our job, to help them to do what they do.

(2) Fairness hinged on the manifestation of empathy for the interlocutor.

In interviews, I often asked evaluators to think of a concrete file that they had assessed earlier that day, and when they had one in mind, I asked them to tell me about how then felt when they first sat down with the file and as they proceeded with their assessment. One assessment officer decided to tell me about a submission for a medicine made with emu oil. She said that the minute she sat

down with the application, she knew there were going to be problems, because it was unclear whether the applicant was going for a traditional use, or a non-traditional use, label claim; these applications required different types of evidence but the application in question provided neither. She sent several information requests sent to the applicant, who each time continued to send non-relevant abstracts and animal studies, which were insufficient evidence for whatever claim they might want. The assessment officer was convinced that the medicine could have been licenced in the traditional assessment stream, because there was traditional use in Australia, she stated; but the applicant continued to send irrelevant evidence. Eventually she recommended the submission be rejected for insufficient evidence. When I asked her to tell me about some of the feelings she had while working with the file, she responded:

> Oh, it's horrible, it's because… because you want to help them, but we're not allowed to help them as much as they need help [laughter]. But then this particular [applicant] just wasn't grasping the nature of the evidence that was being required.
>
> So despite multiple discussions via phone calls with the [submission co-ordinator], [the applicant] still just didn't know what we wanted. So it was really hard to reject. [Long pause] Necessary though.

Similarly, another scientist stated "I find that I'm smiling when I'm doing an approval. Approvals are easier to do than refusals." From my knowledge of these two scientists, I cannot attribute this to any innate disposition or desire for any and every proposed medicine to be licenced; I attribute it, instead, to the valuation of kind and considerate behaviour towards one's interlocutors.

(3) Fairness included a disposition to concede every reasonable claim

Scientists' disposition to concede every reasonable claim was inseparable from the position of authority into which they were interpellated as well as the organization of evaluation activities in the Directorate. There was a disposition that emerged from the scientists' assessment of their self-efficacy as regulators which, as described in Chapter 13, often included the recognition that the regulators had very little authority with which to oppose even a remotely reasonable claim. In product licencing, there was also the pragmatic recognition that there was nothing stopping applicants from resubmitting an application after it was rejected in the hopes that the second assessment would lead to a licence. With twenty thousand applications in backlog, and high rates of staff turnover, it was entirely possible that no government offiicial would notice the repeat application. There was also nothing stopping applicants from taking legal action against the Directorate for anything considered unreasonable, something that applicants often threatened and did do.[26] Thus, although scientists felt they were "ensuring safety," in situations of uncertainty regarding what could be considered acceptable evidence, I left with the impression that the decisions were favorable to the applicant's position. Rather than speaking of scientists' disposition to concede every reasonable claim, it is perhaps more accurate to say that scientists found themselves in a position in which they were unable to do anything but concede every reasonable claim.

(4) Fairness was not applicable to hypothetical people, but only to interlocutors

In Anderson's (1983) discussion of the "imagined community" conjured by the nation-state, he distinguishes between people one (literally) knows, and people

one (literally) does not (also taken up by Herzfeld 1992:98-99). For scientists at the NHPD, applicants are their literal interlocutors. “The public” is not a literal interlocutor. While applicants (industry) are known in this literal sense, “the public,” “the people of Canada,” and so on are imagined communities, groups.

For many, this is a dilemma. I see no way around this dilemma. In the public service-oriented ethic of Health Canada, it would perhaps be inappropriate to encourage scientists to be mean or altercational instead of nice. Being altercational was, and I suspect still is, not a possibility for regulatory scientists at the NHPD given the Directorate’s tenuous existence and the lack of any inspection and enforcement action. Except in the most draconian state, or one totally eschewing the ideal of the free market, one cannot expect a regulatory body to have absolutely no interface, and therefore no relationship, with industry.[27] This creates a conundrum for states around the world: what is the appropriate relationship? (for Japan, in banking, see Riles 2004:395-396).

The possibility of counter-balancing correspondence with industry with correspondence with the “public” is not feasible, given the fundamental imbalance of interests. To put it bluntly, what is important to a member of the public with a vested (monetary) interest will rarely be what is most important to “the general public,” by definition. Interfacing with the government requires time, patience, and tact; individuals without any special interest in natural health products will never engage in dialogue with the NHPD in the same way as commercial concerns and

other persons who organize their activities with and around natural health products. Furthermore, if “the public” is part of a patient or consumer group, chances are extremely high that they have a vested (monetary) interest, if only an indirect one.[28]

Health Canada, like regulatory institutions worldwide, was addressing this dilemma. The approach taken during my fieldwork, like in many other similar institutions, was to “consult” with “stakeholders” – industry, health care practitioners, academics, and the general public, to name the categories of stakeholders more frequently used.[29] There was even an office in the Health Products and Food Branch devoted to holding public consultations (“OCAPI”). This office did consult widely, and then, as far as I was aware, was completely at a loss of what to do with all the incommensurable interventions received -- testimonials, anecdotes, manifestos, suggestions, all directed at slightly different objects, standards, procedures, values. To return to Strathern’s dilemma (2004a), what is most important to the regulator and the regulated after years of a relationship may not be that which is most important to other interlocutors, who wish to move the discussion elsewhere. Furthermore, during the time of my fieldwork in 2006-2007, there was no connection that I could see between the work of the OCAPI office and my everyday reasoning, in my cubicle, as a regulatory scientist.

The dilemma is a long-lasting one. It is not restricted to the blinking light on the phone, although that is part of it. It is also about the development of the standards

used in the assessment itself. More than twenty years ago, Liora Salter points out this dilemma for the regulatory project in public health protection more generally:

> Regulatory standards are less public than they first appear. Industry plays a significant role in developing them, by virtue of its proprietary control over the data, and its continual presence in the deliberations concerning the standards. Every regulator knows that a good deal of negotiation goes on between industry and government about standards and their enforcement (1988:179)

Salter notes that these participants often refused to acknowledge what she argues is the obvious relationship between standards and economics. She attributes this to the fact that aspects of that relationship cannot be easily discussed, because either "they contradict commonplace assertions about standards, or they draw attention to another side of standard setting, one that is not easily acknowledged, understood" (1988:169).[30]

As a scientific regulator, I definitely experienced the inability to discuss the relationship. To take another utterly banal example: after a few months on the job, I received several holiday cards from applicants with whom I corresponded on a regular basis regarding submissions in the licencing process. While in any other social situation, I might have appreciated this consideration and appreciation shown by acquaintances, in this case, I was ashamed, embarrassed, at a loss at what to do. While at the time my strong emotional response led to the fastest and most bureaucratic of solutions (shoving them in the back of the file drawer), I can now analyze my inability to discuss the relationship. On the one hand, through banal phone conversations there was a clear building of a relationship with my interlocutors so we could both achieve our respective purposes (me: health

protection, them: licencing) more quickly, efficiently, and pleasantly. These “good relationships” saved me as a regulator much time. When there was a deficiency, rather than having to send a formal information request notice, I could simply call the applicant that I knew would promptly respond and, in a minute-long phone conversation, ask her to fax me the form or other information to address the deficiency. On the other hand, the minute this relationship moved into a recognition of a social relationship through things such as holiday cards, it was impossible.[31] It would require the recognition that, in situations of uncertainty when the course of reasoning is not entirely algorithmic and abductive reasoning comes to the fore (Chapters 7 and 12) – that this relationship may make the concerns of the applicants circulate more frequently than those of the general public in the environment in which scientists reasoned.

The impossible relationship, of course, was not only featured in reasoning in situations of uncertainty. If one examines many of the standards used, including the ambit of the definition of natural health product (Chapter 3), including the many pharmacopoieae, one notes that many were created in large part by, or in dialogue with, representatives of commercial concerns. The creation and administrative structure of the Directorate itself is in a way a product of industry groups, lobbying the Minister in the late 1990s and then, as the Transition Team, creating the administrative structure. This, however, is nothing “corrupt”; this situation was largely directed, recommended, or endorsed by elected members of Parliament (ministers, parliamentary committees, and so on). Public servants administer laws

and the governing party's programme – serving the public as represented by elected officials.

This situation appears to be endemic to regulatory bureaucracies. In her study of standards pertaining to pollutants and contaminants used in Canada, Liora Salter points out:

> Standards are measurements generated for the purposes of economic activity, and they govern contaminants, products, activities or industrial processes that are created or used by industry….Consideration of the economic consequences of a standard is intrinsic to its creation. As well, industry plays an important role in standard setting, even when standards for health and safety are being considered, because standards are designed with industrial activity in mind and are implemented by industry. Indeed, without industry participation – voluntary or coerced – standards would have little significance. (1988:23)

If we go back a century, even Max Weber believed that bureaucratic administration is necessary for the co-ordination of flows of goods in capitalism (Giddens 1971:160). If what philosopher Conrad Brunck (2007) argues is true, and global trade agreement have made risks to humans and environments the *only* justification for trade restrictions, it is unsurprising that determinations of safety have become enmeshed in this bureaucratic administration of trade. Scientists gets included in this mix, argues Brunck, because science is the only non-arbitrary, non-political, and therefore ideal decision tools for risk assessment available in a liberal pluralistic society.

At a panel on ethics at the 2006 Heath Canada Science Forum, an upper manager was asked about the perception by the public that industry is a major stakeholder.

The manager replied that from his chair, that was absolutely not a problem; he was worried only to the extent that the perception is a problem. He articulated a rationale similar to that general rationale was:

> We maintain our regulatory independence from external stakeholders while valuing their perspectives (Health Canada - HPFB 2007:5)

From my chair, that statement is simultaneously: absolutely true and absolutely problematic. As I have already explained, there is clearly independence in the sense that there is no corruption. But the problem remains: if one values another's perspective, does that not, to some extent, mean one is thinking, empathizing if not sympathizing with that perspective? And then more likely to reason with the considerations and standards produced in that perspective? Speaking of "independence" is a very complicated matter indeed, in the thought collective of regulatory scientists. But in an era of little authority, where regulation is nominally government-based but is predicated on external stakeholders' voluntary compliance, is there any other option?

So although the simultaneous impossibility and necessity of the regulator – regulated relationship has existed for at least a century, I suspect the details of that relationship have changed. For instance, fifty years ago:

> The regional food and drug divisions […] maintain close relations with industry and trade and carry out educational programs to inform the manufacturers and business men what is required by the law (Food and Drugs Directorate 1957:10)

I suspect those manufacturers and "business men" let those inspectors know what was reasonable, and what not. In some ways, though, the statements separated by

fifty years remain very different, in addition to calling public relations something other than “consultation”:

> Public relations, in so far as the Food and Drug Directorate is concerned, includes the dealings of the members of the Directorate with business, industry, the trade, other government departments, foreign agencies and above all, with the consumer. The Food and Drugs Act is a consumer's act and the consumer is, therefore, of paramount interest to those administering that vital legislation (Food and Drugs Directorate 1957:22)

Part of the difference is that trade groups and industry were called trade groups and industry – and not mixed up with any possible interlocutor (“stakeholder.”) So while the constitutive dilemma – that, for regulatory scientists, applicants are their literal interlocutors, whereas “the public” is not – may have shifted in its internal dynamic, the dilemma itself has existed for decades. Speaking of “regulatory capture” is difficult when the entire process of regulation is predicated on the simultaneously necessary but impossible relationship between the regulator and regulated.

Any solution to this dilemma would have to address the sociological – in the sense of, done by humans with social emotions – dependence of all reasoning. That would include the issue of blinking voicemail messages, not only public relations statements.

(5) Considerate behaviour towards any person is counterbalanced by the consideration and empathy due to other, comparable, persons.

The counterbalance, then, in the moral economy of fairness was not the imagined public, but other applicants. These applicants did call, and therefore become non-

imagined interlocutors, in a way that the public could not. The dichotomy of public: imagined community :: applicants : interlocutor community is not so simple. Applicants were also imagined, conglomerated, into the backlog, even if this was not the imagined community into which the scientists placed themselves. Nevertheless, the imaginary of the mass of applicants – the backlog – was brought into the daily reasoning of assessment officers through performance quotas, tracking databases, in a way that the public was not.

Take the following text from a presentation given to assessment officers in the spring of 2007. In no way would I characterize the scientist who developed and made the presentation as espousing a managerial approach. Nevertheless, this efficient assessment officer was approached by management to present tips for increasing productivity to fellow evaluators. The text from the third powerpoint slide read:

> In my opinion, what should we be doing?
>
> We should
> - Carefully consider all the evidence
> - Give the applicant a fair shot
>
> We shouldn't
> - Make "guesses" at information missing from the PLA [Product Licence Application Form]
> - Summarize evidence that has no chance of supporting the product
> - Do extra work / research on the applicant's behalf (except for safety).[32]

This slide, to me, characterizes the moral economy of fairness at the NHPD. The scientists' disposition was not exactly to be at the beck and call of applicants, but

rather do what was possible for the applicant whose file was under one's nose; and, out of consideration to applicants with submissions in the backlog, scientists should not pursue research.

(6) in any instance, all commensurable positions within one's social network must be considered and treated equally.

In the section Textual Standards, I have already detailed the extent to which scientists would go to ensure consistency in their regulatory assessments.[33]

Moral economies II: fairness as balanced system of emotional forces

Lorraine Daston describes a *moral economy* as a "web of affect-saturated values that stand and function in well-defined relationship to one another," and that is a "balanced system of emotional forces, with equilibrium points and constraints," whose stability is tied to specific forms of activity (1995:4). Moral economies, she specifies, are not individual, nor are they synonymous with "motivation"; nevertheless, moral economies are "integral" to science in terms of the "sources of inspiration, its choice of subject matter and procedures, its sifting of evidence, and its standards of explanation" (1995:6). Daston argues that objectivity is a moral economy, the moral economy of science, stabilized by activities such as precision measurement and collaborative empiricism. Through many articles, Daston details the emergence of different types of objectivity in various historical periods (1992, 1994, 1995; Daston and Galison 1992; cf Porter 1992a, Cambrosio et al. 2006).

It is difficult to characterize the scientists' work in the Directorate in terms of objectivity. I only heard the word twice, in the contexts of: a scientist decrying financial interests in a seemingly public bocy, and a refusal of a scientist to reason appropriately (cf Chapter 12) because of an entrenched personal "bias,"; in other words, I only heard the word in the exclamation: "that's not objective." It was not that the scientists were objective, or conversely that the scientists were not objective; objectivity was simply not a moral economy into which the scientists were interpellated in the Directorate. The moral economy into which they were interpellated, was fairness.

Fairness, in the directorate, was a balanced system of emotional forces. The emotions of self-assessment, anchored by the literal and definitional accounting of the self, provided an equilibrating force. Other forces were specific to the fieldsite in regulatory science. One force was the imperative of the Canadian public service: to be of service to one's interlocutors. This was counterbalanced by the possibility of complaint if one would be more of service to one interlocutor than another. Fairness was anchored by numerous activities to ensure consistency in decisions. While "cutting and pasting," "recursive reference to documentary texts" and "tracking in performance measuring databases" do not prima facie seem to be analogous to "precision measurement" and "collaborative empiricism," these are activities that I suspect are becoming widespread in cubicle-bound offices. This moral economy, as a balanced system of emotional forces, was "integral" to regulatory scientists' reasoning in the premarket evaluation of medicines, in terms

of regulatory scientists' formulation of the relevant comparisons to be made and choices of standard. This was not a fairness of a benevolent, all-powerful authority. Scientists' self-assessment of their (non-)authority as regulators shaped the constraints of fairness as moral economy, constraints captured by mantras such as "If it doesn't affect safety, we have to let it go" and "We can't make it too difficult."

I began Chapter 3, my discussion of the order of natural health products, with a quotation from Machiavelli's *The Prince* to which I was directed by a scientist in the Directorate:

> It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. For the reformer has enemies in all those who profit by the old order, and only lukewarm defenders in all those who would profit by the new order, this lukewarmness rising partly from fear of their adversaries, who have the laws in their favour; and partly from the incredulity of mankind, who do not truly believe in anything new until they have had actual experience of it. Niccolo Machiavelli (1469 – 1527)
>
> (As cited as epigraph in the *Report of the Expert Advisory Committee on Herbs and Botanical Preparations to the Health Protection Branch, Health and Welfare Canada* published in January 1986 by authority of the Minister of National Health and Welfare).

The text immediately following the quotation used in an epigraph is:

> It is therefore necessary when examining this matter [of the prince's precarious position] to ascertain whether the prince introducing the new order can act alone or must depend on others. In other words, he must seek help or use force to achieve his innovations. If he seeks help, he will always end up badly and accomplish nothing. But if he relies on his own skill and can use force, the innovator will rarely be in harm's way. (Machiavelli 2007:24).

[1] Speech at http://www.oag-bvg.gc.ca/internet/English/sp_20030321_e_23852.html (Accessed 12/29/08)

[2] See the Public Service Employment Act (2005) and the Public Service Modernization Act (2003).

[3] I am not qualified to judge the appropriateness of staffing practices according to public service guidelines. For readers inclined to make such judgments, there are at least two audits of NHPD's staffing practices, which I obtained through ATI request A-2008-00193 / kc. The post-fieldwork audit of the NHPD found that managers were aware of the purpose and advantages of proper, advertised processes "however felt pressured to use alternate approaches because of unsuccessful processes or the corporate preference for collective staffing" (Elliot and Plante 2008:7). But it is an earlier audit that leaves me convinced that I do not understand the rules governing public service staffing, because while I thought the audit had concluded that there were substantial problems at the NHPD, upper NHPD management stated at an all-staff meeting that the same audit had "exonerated" the NHPD.

During my participant-observation, the NHPD's Director General announced at a winter holiday all-staff that the Assistant Deputy Minister of our Branch had received, each year, an anonymous complaint regarding the NHPD's staffing measures. We were told that each year, there had been an investigation into the complaint of unfair staffing, and each year, no problems were found. That fall, however, a formal audit had been conducted, and, according to management, the audit had again exonerated the NHPD. In any event, management said it hoped that the audit, which would be made available, would put the concerns to rest.

The audit never made its appearance, and my fellow temporary employees told me they did not feel comfortable asking for it, because they felt that requesting the audit would make them appear guilty of making the original complaint. When I finally got around to asking for audit in the spring (I had nothing to lose), I could find nobody who knew where it was, and although I was assured it would be sent to me immediately when it was found, I never received it. It was only after filing an official Access to Information request a year later I received a report dated December 6th, 2006, which is all likelihood the same audit the Director General referred to at the December 2006 all-staff meeting. (The report "Temporary Help Service – NHPD Call-ups" was produced by Health Canada's Forensic Audit and Investigations in December of 2006, with code HF2-08-2-06-03; it was the result of an audit conducted because of an anonymous letter received September 3rd, 2006 by the Assistant Deputy Minister of the Branch, a letter alleging violations of: (1) Treasury Board Secretariat's Contracting Policy, (2) Code of Ethics and Values with respect to hiring, (3) Official Languages Act.)

(continued next endnote)

([4] continued from previous endnote) Considering the first sentence of the report states that the investigation "demonstrate[d] that the Natural Health Products Directorate (NHPD) contravened the Treasury Board Contracting Policy", and that "little documentation [was found] to indicate that even minimal efforts had been made to comply" with the policy, there must have been some amount of exquisitely-worded spin in the all-staff announcement that led me as a keen listener to record in my fieldnotes that the audit's findings indicated that things were generally above-board or I simply do not understand public service staffing guidelines. (Note: A key finding of the Audit was that "NHPD management exercised due diligence when reviewing staffing actions initiated to build human resource capacity and prevented staffing inequalities," so perhaps management felt personally exonerated, and this was communicated). "Problems" enumerated by the Audit included using one employment agency without due diligence, "pay rolling", which was defined as hiring specific individuals through hiring agencies, and the lack of use of the lowest priced supplier as well as considering changing the linguistic profile of a position to hire a specific non-French speaker.

[5] Basic bilingualism is required for most supervisory positions at Health Canada for appointments of four months or more.

[6] This inventory was managed by the Public Service Commission, and was open for a brief period of time; the inventory expired November 2008 (according to http://www.psc-cfp.gc.ca/sas-sde/stf-dot/prgrm/clct-stf/fcp-crnt-eng.htm, accessed October 24, 2008).

[7] I am unsure, however, if in the end that strategy was actually used, although according to an audit, it was used to avoid a competition (Elliott and Plante 2008:7).

[8] The competition was technically advertised as an SG SRE-03 competition, but the level was in the process of being reclassified – a process that began a year before I started working at the NHPD and was completed by spring 2007 – and so effectively it was an SG SRE-04 competition. In general, I have ignored the reclassifications in this dissertation, referring to both pre- and post-classification groups in scientific regulation and biology as SG SRE-04s and BI-03s, respectively.

[9] Auditors later suggested that when running competitions, processes could be open to "persons employed" in the public service instead of "employees", which would allow casual and agency staff to apply (Elliott and Plante 2008:10). I do not believe that was known to management at the time of my fieldwork, otherwise it would have been exploited.

[10] Statistic taken from the minutes / record of decision of the BPRA Leadership meeting, May 10th, 2007.

[11] At the beginning of this competition process, a manager had joked to a colleague of mine, who had just announced her pregnancy, that she shouldn't worry because the BI-03 competition would not be completed until after she had given birth; the irony was that the competition had not even *started* until after she gave birth full-term.

[12] NHPD management openly blamed bad advice from Health Canada's corporate human resources.

[13] The draft Statement of Merit Criteria in September 2006, and in a previous NHPD BI-03 competition from April 2005 at the NHPD (selection process number 05-NHW-HF-CCID-0-14) included essential qualifications such as: "Experience in the assessment of clinical and/or scientific data," "experience in the preparation of critical reviews of clinical and/or scientific data" and "knowledge of factors pertaining to risk/benefit assessment of natural health products." The cancelled SG competition begun in April 2007 (reference number SHC06J-006155-000265) also had the essential qualifications and "Knowledge of the organization and the fundamental responsibilities of the Health Products and Food Branch, and the responsibilities of the Natural Health Products Directorate" and "Knowledge of safety issues and quality issues related to natural health products or vitamins and minerals". These content-specific criteria clearly privilege incumbents. This is not specific to the NHPD, however; the NHPD posting did not differ strongly from the drug- or device-specific merit criteria used in BI-03 and SG-SRE-04 positions at TPD, as published on the Publiservice website in June- July 2007.

[14] An interesting example from other Directorates in Health Canada is found in the memoirs of Shiv Chopra (2009). Chopra makes many accusations, however in reading his memoirs I was struck by his accusations against management in general but also specific managers. He was interested in naming names. I should note that in his memoirs, there is much intrigue that was simply not present, to my knowledge, among scientific staff at the NHPD. Perhaps this has to do with the formal processes in which he engaged -- Chopra has won several cases against Health Canada, which would have involved legalistic processes for attributing blame (and thus naming names.)

[15] Which is not to say that there were no scientists that held grudges – some clearly did, and for years. But in those cases the strategy of most scientists seemed to be to make lateral moves within government, to avoid having the person against whom one held a grudge as one's superior.

[16] This is consistent with much of Stewart and Strathern's analysis in *Witchcraft, Sorcery, Rumors, and Gossip*, for instance their examination of how rumor and gossip may coagulate previously inchoate suspicions into a struggle; in this examination, "[r]umors and gossip are used as crucial tools in the gathering of information against people and the development of a consensus about who is responsible for deaths, illnesses, misfortunes, thefts, "unnatural" weather, and the like. The processes involved are gradual and incremental until they read a point of explosion through the catalyst of a particular event and the interpretations people make of it" (2004:195).

[17] At the end of the announcement, the complaint period is specified (it is usually two weeks from the date of the announcement), along with a description of who may complain (often "Persons employed in the Health Products and Food Branch, Health Canada, in the National Capital Region" in the case of appointments at the NHPD), and the eligible grounds for complaint. For appointments at the NHPD, the eligible grounds were often: "abuse of authority in the application of merit"; "abuse of authority in the choice of process (advertised or non-advertised)"; and "failure to assess the complainant in the official language of his/her choice." Details are also given regarding where to address the complaint, which is lodged with the Public Service Staffing Tribunal.

[18] For instance, in one acting appointment for a Submission Manager in BPRA, the announcement was posted in August 2007, while the appointment had begun at the beginning of April 2007. "Information Regarding Acting Appointment, Selection Process Number: 07-NHW-HF-ACIN-133", viewed on August 8th, 2007 on the Public Service Staffing Advertisements & Notifications at: https://jobs-emplois.psea-lefp.publiservice.gc.ca/cli105.do?id=31562&lang=eng.

[19] Auditors noted, however, that the promise of running mini-competitions had not always been kept (Elliott and Plante 2008).

[20] "fair[1] *adjective*" *The Canadian Oxford Dictionary*. Katherine Barber. Oxford University Press 2004. *Oxford Reference Online*. Oxford University Press. McGill University. 30 October 2008 http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t150.e23944

[21] From Definition 10a of "fair" from the Oxford English Dictionary, second edition, 1989. (This characterization is based on staff discussions of leave requests not discussed here because it gets into micropolitics).

[22] The *Values and Ethic Code for the Public Service* lists four types of values: democratic, professional, ethnical, and people values. The people values entail "[d]emonstrating respect, fairness and courtesy in their dealings with both citizens and fellow public servants." (Minister of Public Works and Services 2003:10)

[23] "Because managers see the [hiring] system as a maze of red tape to be circumvented, employees, who see the system being circumvented, have become suspicious of its capacity to ensure fairness and suspicious of the good faith of managers" (Public Service Task Force on Staffing 2000, 1990:3, cited in Kernaghan and Siegel 1999:566). There is no doubt that, at the NHPD, some managers did see the system as something to be circumvented. In the words of one manager: "I'm very impressed with the enthusiasm that people bring to the job here, as well as the knowledge that they bring. So I try and encourage that, cultivate them as much as possible, give them the opportunities that they need, within the constraints of working in a government system. Sometimes that can be frustrating: for example, you can't promote based on merit; you have to promote based on the competition … So you have people doing an exceptional job, and limited ways in which you can recognize them, other than tell them they're doing an excellent job, which, which is always helpful, but sometimes you'd like to be able to do more, so there are certain challenges of working in a government system."

[24] Timmermans and Berg also note that the bureaucrats they studied empathize with the applicants (2003:117-141).

[25] As mentioned previously, there are protocols for whom inside the NHPD can speak to whom outside the NHPD. Many assessment officers (BI-03s and CH-03s) never spoke or wrote directly to the public. Their requests for more information would be communicated by scientific regulators, and if the applicant contested, the unit head (BI-04 or CH-04) would perhaps speak to the applicant. In any event, most scientific staff, if they did speak to the public, could only speak about specific files; this meant they could only speak to the applicant. General inquiries from the public or non-file-specific inquiries went through the communications unit, staffed by non-scientists.

[26] Certain trade and lobby groups representing natural health product concerns were quite something. I had people from other parts of Health Canada – in areas having nothing to do with natural health products – tell me that they were "terrified" of the NHP lobby, to the extent that when a policy had nothing to do with natural health products, they would write in clauses saying that it does not apply to natural health products, "to avoid problems with the lobby."

[27] Liora Salter nicely characterizes an alternative:

> The proposal to make standard setting exclusively public in orientation is a radical one. It would require government testing of chemicals, and a dismantling of the proprietary nature of the information used in chemical assessment. It would require forced disclosure of information, extensive record keeping and an active, properly funded inspectorate. It would require regulators to be cordoned off from the industries they regulate, a proposal that alters the nature and function of regulation. Perhaps this is preferable to the current situation, but it is wrong-headed to believe that these changes can be accomplished by a modest program of reform. (1988: 179)

[28] I know of very few groups in Canada advocating for the public in the domain of medicines regulation, and that consistently eschew direct and indirect industry funding. Women and Health Protection, the Therapeutics Initiative, and perhaps the Canadian Women's Health Network and affiliates are, as far as I know, organizations that eschew such funding, but all are perhaps better typified as academic-activist than public.

Health Action International (HAI) makes the point that the majority of "public" or "consumer" representation at the European Medicines Agency was funded by industry. HAI surveyed the patient and consumer groups with representation at the European Medicines Agency and found that two thirds were funded partially or mostly by industry or trade concerns, and that more than half did not meet the financial reporting required of such patient and consumer groups at the Agency; research paper available online at <http://www.haieurope.org/11082010/11_Aug_2010_HAI_Europe_Article-Patient_&_consumer_orgs_at_EMA_Financial_disclosure.pdf>

[29] For some indication of the recent attention to public consultations in the social science literature see Goven 2006, Rothstein 2007. For earlier work on consultations by scientific regulatory bodies see Salter 1988 and Epstein 1994.

[30] These features include the paradoxes: (1) That “standards are an instrument of aggressive competition and trade relations” intra- and internationally, while simultaneously requiring international co-operation (Salter 1988:170); (2) That standards are required for free trade while they simultaneously often act as non-tariff barriers to trade, and can cause “predatory trade practices” including dumping* (countering the ideology of the workings of free trade on an international scale), (3) The loose network of standard-setting organizations “contributes to the coherence and co-ordination of capitalism as a system of economic relations,” in which “the relationship between standards organizations provided the opportunity for face-to-face discussion among those with competing economic and national interests” and remain up-to-date on potential trade issues (Salter 1988:171).

*Dumping, according to Salter, “is not more, or less than the result of choices made about the manufacturing operations or the sale of products in relation to the existence of different standards in different jurisdictions” (1988:171); a point which I made internally at the NHPD, worrying that the lack of incorporation into the *Natural Health Products Regulations* of the minimal and basic food standards of the *Food and Drug Regulations* might result in the perfectly legal intranational ‘dumping’ of subgrade food products into natural health products.

[31] Another example, but from the other perspective, pertains to the formation of the Natural Health Product Research Society of Canada, which is coeval with the NHPD. While in formation, I was told by a non-government scientist, the scientists at the NHPRS had close relationships and ties to officials in the NHPD – who were encouraging and supporting the formation of the society – the minute the NHPRS was officially formed, the relationship changed, as it was impossible informally. To the confusion of non-government scientists, a previously friendly relationship instantly changed to one of formality (cf Herzfeld 1992).

[32] From powerpoint slide taken from internal presentation entitled “Speeding up the PLA Process: Suggestions for Increasing Productivity,” made May 4, 2007, as part of the AO Information Series.

[33] There was a certain amount of “the squeaky wheel gets the grease,” as openly admitted by two managers in the context of my research. By this I mean that certain files may have jumped the assessment queue and assessed before they would have been had there not be complaints – but in the words of one manager, “I figured we may as well deal with it now”, because otherwise, “I know they’ll complain to the minister.” There were also the occasional orders from higher up the hierarchy to give a certain file a second look. Some scientists decried this as unfair; others did not expect context-independent systems of rules and conduct in a hierarchical organization, with its need to pragmatically obviate complaint. I do not believe that this queue-jumping, or second-look, necessarily led to licencing decisions in favor of the applicant. Whereas, in situations of uncertainty, I believe that the moral economy of fairness, the sustained but utterly mundane differential in blinking voicemail lights did, at least in situations of uncertainty.

Conclusions

The sociological dependence of all reasoning

> For better or worse, individuals really do share their thoughts and they do to some extent harmonize their preferences, and they have no other way to make the big decisions except within the scope of the institutions they build.
>
> Mary Douglas (1986:128)

Chapter 19
Summary
The sociological dependence of all reasoning

Puzzle an old one

The dissertation's central puzzle is as old as ethnography. It is a puzzle regarding the strangeness of others, a strangeness that somehow partially disappears when one lives among them (cf Allan Young in Duclos 2009:115). My account of fieldwork, like so many accounts of fieldwork, was: I went to work among them, and initially found some of their reasoning to be odd, even problematic. But as I continued working among them, I found I came to reason in precisely the same way. Even though I continued to find the reasoning odd and problematic when I stepped out of my daily activities among the collective, there was no way to reason otherwise when I was among the collective. I, like the other scientists working in public health protection, was interpellated into a style of reasoning.

There is ultimately no simple story of this interpellation. There is no mechanism proceeding through time for this interpellation, that I can detail. It is difficult to make an argument, or even a moral parable out of this interpellation (cf Rosenberg 1998:728). There are no heroes and no villains. There is no unambiguous progress, or punishment. There is, in a way, no story.

An empirical study, an ethnography, of scientists' reasoning

I approached reasoning empirically as an observable, collective and inherently social endeavour. Instead of a story, I have provided an ethnographic account of scientists' reasoning. The ethnography details scientists making piles with files, cutting and pasting text in electronic documents, their affective responses to blinking voicemail indicators, their intermittent but sustained engagements with myriad computerized databases with propensities for crashing, and their consideration of the extent to which a particular textual standard is "living." As Alex remarked, "it's pretty boring." This is what these regulatory scientists do, day in, day out, in their computer-equipped, cubicle-bound individual workstations. Their often solitary workdays are punctuated by interactions with other bureaucrats in meetings, cubicle visits and consultations, and breaks. Reasoning is not separate from these activities; it proceeds through such mundane, materially and socially situated activities, and in no other way.

Scientists generally attributed the uniformity in their judgements to two features in the style of reasoning:

(1) recursive reference to textual standards (regulations, guidelines, standard operating protocols, standard lines, templates, and so on)

(2) consultation of peers, including, in situations of uncertainty, readily incorporating the reasoning and judgements of expert peers.

These two features of the regulatory scientists' style of reasoning cannot be overemphasized. A senior laboratory scientist from elsewhere in Health Canada

asked me, as a scientific regulator, “Don’t you, you know, feel uncomfortable doing assessment about all these things outside your area of expertise?”, as we were chatting at a Branch-wide consultation. My reaction, which was a surprise to me, was an emphatic “No, because there are clear standards to follow, and when I am unsure I can consult my colleagues.” This affective transformation on my part, in a mere eight months, should not have surprised me, given that nuclear weapons become as benign as vacuum cleaners to the scientists working with them on a daily basis (Gusterson 1996).

While scientists’ reasoning was inseparable from these textual standards, this formalized doctrine for reasoning was never self-evident: there was a cascade of documents, always insufficient for scientists to reason as one. Scientists’ consultation of their peers normalized their reasoning, and the pyramidal hierarchy of the Canadian Public Service permitted managers to establish norms. It was the never-fully determined structuring of evaluation activities in the Directorate, however, that strongly shaped the most striking features of scientists’ reasoning. Scientists’ reasoning activities, especially reasoning activities characterized by taxonomies and comparison, developed scientists’

(3) common affective disposition towards certain attributes of files such as their “easiness” or “messiness,”

(4) selective notice of certain, but not other, “issues” with files.

This selective disposition and directed perception were also fostered by the tools and practices of managerialism, part of the scientists’ style of reasoning as their

(5) explicit consideration of the backlog,

(6) interactions with a plethora of electronic databases.

The moral economy into which the scientists were interpellated included their:

(7) acute, explicit sensitivity to fairness,

(8) acute, explicit awareness of the limits of their own authority,

with some constraints in this moral economy captured by

(9) the repeated use of phrases such as “we have to be flexible” and “if it doesn’t have to do with safety, we have to let it go,” especially in moments of uncertainty.

This moral economy was entrenched by the tenuous appointment of over half the scientific staff to their position, combined with the simultaneous introduction of productivity quotas. The moral economy of fairness, an innocuous-sounding Canadian public service value, directed scientists’ consideration to interlocutors, not an imagined public (cf. Anderson 1991). This is, I have argued, a constitutive dilemma of government regulation, and has been for at least a century.

It is difficult to imagine a way out of this situation; if there were not those internal norms, routine ways of going about reasoning, there would be others. The purpose of ethnography is not to strip away those mundane standards to expose “real” reasoning – an impossible endeavour – but to examine the ways in which the features of the thought collective’s style of reasoning nestle together, mutually support each other. I have chosen to loosely organize this ethnographic account by

the types of standards shaping the reasoning of the thought collective: official standards, other textual standards, other numerical standards, and peopled standards, inspired in a very general sense by Laurent Thévenot's (1984) description of forms in Taylor's *Principles of scientific management* [1911]. The focus, however, has been on the scientists' reasoning in the thought collective, and the ways in which various standards and activities interpellated the scientists' into a uniform way of reasoning – with features describable, but not predictable, in their details (cf. Daston 1995).

Belief, multiculturalism and managerialism

All of the scientists with whom I worked appeared deeply committed to their role in public health protection. By virtue of their activities they were required, sooner or later, to act as if they trusted, as if they believed, in the textual standards and their colleagues' judgement. There was no other possible way of behaving in a reasonable manner. Therefore, even though evaluators made recommendations on the acceptability of a proposed medicine's safety and efficacy according to the *Natural Health Products Regulations*, the style of reasoning allowed scientists to remain agnostic about whether medicines "really worked" as this was outside the ambit of what regulatory scientists needed to, and were permitted to, judge. The style of reasoning about the evaluation of medicines' efficacy, did not necessarily have anything to do with individual scientists' beliefs.

Multiculturalism is perhaps best characterized using Fleck's descriptions of "hazy proto-ideas," despite the official policy having been established for nearly forty years in Canada. Its spirit can be found everywhere and nowhere at the NHPD. Scientific regulators are not the only professionals in Northern Europe and America who have come to reason in this formalized, embedded and contextualized manner, under the rubric of respect for cultural and philosophical diversity (cf Mallard et al. 2009, Epstein 2007, Graham 2002.) On the one hand, "appropriate" reasoning is about recognizing diversity through explicitly recognizing and valuing contextual reasoning (see also Mallard et al. 2009). At the NHPD, this meant recognizing a range of standards and the expertise required to make appropriate judgements. On the other hand, "not needing to regulate each product in the same way" – like in broader approaches to "progressive licencing" at Health Canada – is inseparable from concerns with "using resources wisely," to use the words of the Therapeutic Products Directorate's Chief Scientific Adviser (Maher 2007). In such contexts multiculturalism may become manifest as a tool of managerialism.

I have defined managerialism as the belief in or reliance on the tools of project management and the vision of leaders (professional generic managers), as the best and only way to formulate human endeavour. I described how mundane tools, technologies and imaginaries, such as work quotas, tracking databases and the backlog orient scientists' activities and thereby direct their perception and their affective dispositions in the premarket evaluation of medicines. This affective transformation was accentuated by the high rates of scientific staff in tenuous

appointments, and the imposition of quotas on inexperienced regulatory scientists. This affective orientation occurred *irrespective* of scientists' buy-in to project management and other features of managerialism.

This ethnographic account is simultaneously a study of scientists' reasoning and an account of the local moral worlds of entry-level public servant scientists and their managers in a 21st century bureaucracy. The "bureau" at least in this part of the Canadian Public Service is no longer extant except in name. In the place of the bureau is the computer-equipped cubicle (work station). There are no longer rooms with dozens of desks whose occupants are subject to the watchful gaze of overseers. There are no longer authorities sitting behind individual desks in offices. Instead, there are entire floors with dozens upon dozens of cubicles whose occupants can be overheard but not seen by neighbours, but whose every judgement is tracked in multiple ways electronically. Somehow the new set up, rather than making everyone an authority, seemed to increasingly allow the tools of management (through tracking databases and so on) to shape the daily activities of professionals, and thereby the styles of reasoning possible therein.

> Every epistemological theory is trivial that does not take th[e] sociological dependence of all cognition into account in a fundamental and detailed manner (Fleck 1979:43).

Appendices

Appendix 1. Employment, research methods and permissions

The main overview of research methods is found in Chapter 1, specifically pages 26-29 along with chapter endnotes 36-40. This Appendix provides additional detail on some elements of my fieldwork at the Natural Health Products Directorate.

Why fieldwork through employment, in part?

Employment was not my first choice as means to enter the Directorate as anthropologist; but as the only viable option for entering my proposed fieldsite, after months of seeking permission to enter, I was happy to accept a manager's offer of employment. It was only after I began working did I realize how important her offer had been, because of the nature of the activities and physical layout of the workplace. My research fieldsite was essentially a maze composed of cubicles arranged up to four rows deep, completely encircling the building's concrete-encased central area containing stairs, elevators, washrooms, copy room, and staff lunchroom. I do not use the word "maze" as embellishment; it was not unusual to see a recently-hired evaluator walking around the floor in circles trying to find the washrooms or to relocate his or her cubicle. Simple observation in such a situation clearly has its limitations, and participation was only possible by having official duties. So although I had not originally intended to do fieldwork through paid employment, I am most thankful to my hiring manager because I am now convinced that the only way to do meaningful participant-observation in a cubicle-based workplace is to be a worker; and to do meaningful participant-observation in a culture with a strong insider-outsider division, is to become a (partial) insider. This utility, of course, does not help to reduce the discomfort that sometimes come with such dual roles.

Fieldwork inside the Directorate beginning with participation as part-time employee

I entered the Directorate as a part-time, term employee (scientific regulator) on August 21st, 2006. I had never previously worked for the Canadian federal government, nor had I pursued employment by the Canadian federal government

other than as part of my anthropological research project. When I began work, I had permission from my hiring manager at the NHPD to do my fieldwork by drawing from my own experiences as an assessment officer, with certain caveats.[1] My fieldwork was in no way covert.

During the first four months of my employment-as-participant-observation, I did little more than try and learn to be a competent assessment officer in the unit in which I was formally appointed. During this period I gained competencies necessary for any new employee, competencies also important for my research: basic social, emotional, and organizational ken for a worklife in the NHPD and the Canadian public service; a detailed understanding of my work; and a general understanding of the NHPD's processes and how, in practice, medications were evaluated therein. I lunched with different groups of scientific staff, volunteered, and participated in workplace-affiliated sports. Especially during this initial period of participant-observation, doing my research well coincided with doing my job well, because both pursuits required gaining basic competencies in the workplace. I wrote fieldnotes off work time, but not on work time, although occasionally I would jot down key words or ideas during my regular work hours.

The risk in a cubicle-bound fieldsite is that participant-observation becomes overly idiosyncratic and heavily-weighted on one's own activities, and one's own work unit. There were several ways I tried to counter this.

To help broaden my experience with the NHPD's evaluation, I took advantage of every opportunity to familiarize myself with any procedure related to the evaluation of traditional medications and other plant-based medicines. For instance, beginning in my fourth month of participant-observation, I received permission to work one of my four workdays weekly in a second unit in a second Bureau, a unit that developed standards (monographs) for the evaluation of traditional and other plant-based medicines. Throughout my year as a public servant, I also took advantage of invitations to attend Branch-wide events to learn more about the evaluation of

medicines in the larger Health Products and Foods Branch.

I also began to complement my participation-heavy research methods with methods from the other side of the participant-observer spectrum. I obtained permission from the Director of the Bureau of Product Review and Assessment to -- off my work time, on my "own" time -- shadow staff at work, track files, use internal documents, and attend meetings unrelated to my employee duties but that substantially addressed the scientific evaluation of traditional herbal medicines. An e-mail was circulated to all staff in the Bureau of Review and Assessment (and many other scientific staff as well) by the Director on April 12, 2007 with a statement of support for my research project as well as a summary of the research I had prepared (see Appendix II for the text that was circulated). I began that work in BPRA in April 2007, and similar work in another bureau, the Bureau of Clinical Trials and Health Sciences, after permission was obtained from its Director in May 2007.

Strict observation

After obtaining their permission, I spent half-days or full days in the cubicles of scientific staff, observing them evaluating medicines. This was important to ensure that my research would not be entirely focused on my own *practices* juxtaposed with other scientists' *narratives* given in interviews. This also provided me with the opportunity to observe scientific staff working on evaluations in the Traditional Medicine Stream, the Homeopathic Medicine Stream, and in the Clinical Trials Unit -- essentially, I observed evaluation work that I would not otherwise encounter through the course of my work duties as an assessment officer, but that was important to my research project. I also observed the work of support staff to observe the government activities that shaped the physical and electronic files before their arrival on the desks of assessment officers. I "tracked" three Product Licence Applications through the Directorate from the moment they arrived by courier or mail, and I observed these staff's work on the application: the application's processing in the mailroom, its dressing as a file, the electronic data

entry of its information, and various levels of screening.

Given the cubicle-based environment, any observation I conducted outside of closed-room meetings would have been evident to all neighbouring staff.

Interviews with NHPD staff and affiliates

Because it was impractical to observe a substantial percentage of scientific staff in their cubicles, interviews provided a way to learn about evaluation processes that I myself had not encountered through participation or observation of NHPD activities. (With few exceptions, if I observed a staff member I did not also interview him or her). It also provided an opportunity to hear scientists' personal opinions. Between April and October of 2007, I interviewed 40 of the NHPD's current scientific staff, in interviews lasting from one to three hours in a location of the interviewee's choosing. The semi-structured, occasionally unstructured interviews centred on the staff's daily work in the evaluation of medicines, their likes and dislikes regarding this work, the personal attributes they felt were necessary for this work, and the place of their evaluation work in their lives in general. (Sample questions are available in Appendix II). As much as possible, I tried to keep the questions concrete, focusing on the interviewee's work that day, or on an actual person who the interviewee thought was an excellent assessment officer. Nearly all such interviews ended with a 5-question, structured questionnaire (also in Appendix II) delivered orally.

Although an open call for participation was circulated to most of NHPD's scientific staff via e-mail, I solicited interviews individually. I purposively selected most of the 40 interviewees, some for their particular perspective, but most simply to maximize the diversity of work, training, and life experiences of interviewees. I had an excellent response rate among public servants *with whom I was personally acquainted*, however minimally we were acquainted (e.g., face-name recognition). I recall only one public servant with whom I was acquainted possibly sidestepping my request for an interview. (I would not initiate the rescheduling of interviews if I

felt any scheduling difficulties were an indication of hesitation regarding participation; I refer to this possibility as the potential interviewee possibly sidestepping the request). Conversely, nearly every public servant with whom I was *not* personally acquainted sidestepped my request for an interview, or responded months after my approach for an interview and when I was no longer in my fieldsite. I do not recall *any* flat-out refusals; but if a public servant redirected my request, did not reply to my request, or had repeated difficulties scheduling the interview this enabled the potential interviewee to sidestep the interview. (In addition to my consideration of scheduling difficulties, I stopped approaching possible interview participants if any three attempts to request an interview, for instance a phone message, e-mail, and conversation, did not yield a reply to the effect of "yes, I am willing to be interviewed on X day.")

The stark contrast of response rates between public servants who knew me and those who did not is an indication of the strong sense of insider versus outsider at the NHPD and, I suspect, the Health Foods and Products Branch more broadly. This is at least partially due to confidentiality issues regarding what can be disclosed to an outsider. There were very strict rules for speaking, as a public servant, with people outside the Directorate regarding government business. For instance, as an assessment officer, I was expected to communicate with industry representatives regarding their *particular* applications (files), but I was not permitted to speak to industry representatives or anyone else about NHPD procedures or policies in general. I was expected to reroute requests for general information to the NHPD's communication unit, a unit staffed at the time by fully bilingual non-scientists. With the exception of a few NHPD scientists who had completed the Health Canada course known as "Talking to the Media" (and who were permitted to speak publicly on behalf of Health Canada), scientific staff were not supposed to field calls from reporters. I felt public servants with whom I was not acquainted were very wary of my interview requests and classified me as that particularly threatening type of outsider, the reporter. (N.B.: I approached interviewees as an anthropologist, not a public servant, although the informed

consent form had a disclaimer about my public servant status, as described in Appendix II).

This is not to say that I was unambiguously viewed as an "insider", even by public servants with whom I was acquainted. A young public servant scientist explained why she had enjoyed the interview experience:

> In some cases I've been asked my opinions before, in meetings, but I've never I guess had to… um, explain… [pause] I don't want to refer to you as an outsider, but you know why, I guess. It's always been well "yes I think this," and I guess with some of my close peers here we've gone into discussions of why, but to explain it to you, an outsider, it's, um, a benefit to do that.

For context and history, I also interviewed ten other affiliates of the NHPD, including past scientific employees, current non-scientific staff, and advisory committee members. I often had specific issues I wanted to discuss with each of these ten interviewees. Interviews with current non-scientific staff tended to address general procedures, documents or events affecting the evaluation of traditional or herbal medicines. Interviews with advisory committee members tended to focus on specific decisions regarding the evaluation of NHPs that had been taken before the time of my fieldwork.

Considerations of consent and understanding

My colleagues who participated in interviews and individual cubicle observation periods gave their individual informed consent. In those formal situations, I have to assume my colleagues understood my research methods, as they gave informed consent. (Some of these same interviewees were the ones examining informed consent forms for human clinical trials).

In the more amorphous situation of participant-observation, I am still unsure to what extent the issue of informed consent was possible: did my scientist colleagues, even those very interested in my research project, really understand what I meant by fieldwork and participant-observation? I am not sure. The issue

was not the availability of information. I spoke of my research project widely, received permissions from the appropriate levels of the organizational hierarchy, had e-mail notices of the research project circulated, posted a project description in the kitchen, and was very sensitive to interpersonal dynamics and respected any colleagues who seemed to want to avoid me for whatever reason. Nevertheless, I am still unsure what exactly my colleagues understood by "fieldwork" and "participant-observation." Some of these colleagues did not seem to need to understand; several evaluators with PhDs stated their empathy for my position as a PhD student, offering support or participation in solidarity with my educational process, without, apparently, having any desire to understand the methods of social anthropology. Of those colleagues who seemed to have an interest in my research methods, their grasp of my methods was invariably mediated by an analogy to science. Some colleagues engaged me in conversation about my research methods but were clearly bewildered that social research could be something other than falsifying hypotheses through the use of structured questionnaires. For instance, upon hearing of my research, one colleague, Naavah, asked the apparently inevitable question: "So are you using questionnaires?" After I provided a lengthy explanation of anthropological fieldwork, Naavah wryly commented "Ah. I get it. You're up in a tree watching the gorillas." I concurred with the analogy, and clarified "Except I'm a gorilla too." That scientist-colleague, I felt, "got it," although perhaps not through an analogy I would have chosen myself. Other colleagues, while extraordinarily helpful, often made me feel like my research methods were those of an extraterrestrial. For instance, take Ommy's kind offer:

> [Entering my cubicle] OK: I read about your research and we want you to get your PhD So what questions exactly do we need to answer, so you can get your PhD? Let me know, and we'll schedule a meeting next week to get you the answer to your questions.

It was sometimes very difficult to convey that what I was studying – actual practices, enacted attitudes, affects, and judgments – could not be provided via a one-hour meeting. And that – sometimes I did not even attempt to explain this one

– that there may not be one answer to any of my questions, and that might be just fine for ethnography. I could explain, but I could not force understanding. So despite my best efforts, and not for lack of information, I am unsure whether my colleagues really understood anthropological fieldwork; such is the uneasy method of participant-observation in general, where what is of most interest to the anthropologist is not of most interest to others in the community (Strathern 1991).

Other structured research methods used in fieldwork

To provide some indication of "cultural diversity" among scientific staff so frequently referred to in interviews, and to get a wider range of attitudes regarding the NHPD's mandate to "respect cultural and philosophical diversity", I created a participative survey in the second floor kitchen designed to be completed anonymously by scientific staff, at their leisure (see Appendix II for the description circulated to staff).

I searched for, and analysed, internal government documents pertaining to the evaluation of traditional and herbal medicines; these searches were not generally successful because of classificatory and technological limitations (e.g., the organization of certain areas of the shared electronic drive was somewhat chaotic, and keyword searches of electronic folders and drives were not feasible as a rule because the computer would crash before the search was completed).

Analysis of fieldwork

My analysis is based on my fieldwork experience and a repeated rereading, rethinking, reorganizing and reworking of the materials in light of my fieldwork experience. My fieldnotes, interview notes and transcripts and other records from the field fill four drawers of a lateral filing cabinet. I coded and analyzed these materials in an iterative process, refining themes, arguments, and codes with time. I did not use specific computer software for the analysis or coding. Although the main chapter themes were established by the end of 2007, it took well over a year after the completion of my fieldwork for me to feel I had sufficient distance to begin

writing a dissertation in anthropology.

Writing of dissertation

This dissertation is an ethnographic account of scientists' reasoning. The research project was never conceived of or conducted as an evaluation of any organization nor does it contain policy recommendations (with the exception that public service managers should read the executive summary of the Whitehall studies.) In the course of my duties *as an employee*, I responded to nearly every Directorate- and Branch-wide call for comments that came through my inbox, critiquing proposed policies and positions *from my position as a scientific regulator*. I was perfectly comfortable making comments and suggestions as an employee. That time is now over. At no point did my research project strive to evaluate NHPD's processes in terms of "good" or "bad," and therefore I do not feel comfortable making suggestions or evaluative comments *as an anthropologist*, for instance in this dissertation. I also hope I have managed to write the dissertation in such a way that it does not lend itself to others using it as the basis for such evaluative comments, because this was never the intention of the research project. (The passage of time is also of assistance to that end.) I hope that there are no negative implications on the NHPD from this dissertation; not only did I genuinely like and respect the scientists with whom I worked, but I am in full support of the Directorate's health protection mandate.

Because my fieldwork centred on the work of scientists in an identifiable organization, however, as a courtesy, a week after submitting my dissertation to McGill University in August 2010, I submitted a copy of that initial submission to each of the Directors of the two Bureaus in which I had done my fieldwork at the NHPD for their consideration. I offered to meet each director in November 2010 to hear any comments they might have, and possibly take those comments into consideration. I met with the one director in November and am thankful for his updates, and corrections and clarifications on foreign regulatory regimes. (I never heard back from the other director, who I had never met because he began after

my fieldwork; from my correspondence with an administrative assistant, I do not believe he looked at the dissertation.) As there were no concerns aired about the dissertation draft, none were taken into consideration for edits for the final submission.

[1] The manager who hired me, and who was aware and supportive of my research, did not want to sign a formal agreement regarding my research; instead she explained that it was my responsibility to ensure that I abided by what I was required to solemnly affirm as a public servant:

> I solemnly affirm that I will faithfully and honestly fulfil [sic] the duties that devolve on me by reason of my employment in the public service of Canada and that I will not, without due authority, disclose or make known any matter that comes to my knowledge by reason of such employment (Oath and Solemn Affirmation Form, signed August 21, 2006).

When I explained my concerns about the clause "make known any matter that comes to my knowledge by reason of such employment" – because the whole point of me working was indeed to report on my experiences in my dissertation – this manager explained that I could report on my experiences but I would need to consider the Privacy Act in considering what information would be inappropriate for me to report outside the public service. Training in the Access to Information and Privacy Acts was mandatory for new public servants; I participated in training sessions within the first couple months of my research. Given my love of clarity and structure, this arrangement had the disadvantage (for me) of leaving nearly everything in my judgment; I have tried at all times to respect my solemn affirmation, and I believe I have been successful, I hope in a way that others interpret the affirmation as well. In any event I clearly take full responsibility for my choices.

As a new public servant, I also I filed a Conflict of Interest Confidential Report (usually used for reporting financial interests), and an executive director somewhere inside Health Canada's mysterious Corporate Services Branch, determined that, on the basis of the information I submitted about my dissertation:

> your research for your PhD in Anthropology does not constitute a conflict of interest with your Health Canada responsibilities provided it is not based on privileged Health Canada information. However, upon completion of your dissertation, prior to publishing or presenting it, you may be required to submit a new Confidential Report, specifically if your dissertation contains any privileged Health Canada information, contradicts the department's position, or goes against any departmental objectives or policies (Letter dated November 17, 2006).

When I explained to a Senior Labour Relations Advisor in that Branch that I would not have worked in the Public Service for at least two years when submitting my dissertation, she clarified that I would only need to submit an additional Confidential Report if I were still in the Public Service of Canada (phone conversation November 21, 2006). When I remarked that I was unsure how this academic dissertation will be perceived in relation to "the department's position," the Senior Labour Relations advisor explained their concern was regarding whether the dissertation would contradict what one would expect of a public health agency. (Three simple findings at the NHPD that contradict what I would have expected of a public health agency – the absence of any laboratory evaluation, the high rates of tenuous employment and appointment, and the use of a quota system for evaluators' work – are already public knowledge (e.g., have been stated by NHPD officials in industry or public forums) and so I have to assume that these findings will not contradict "the department's position.")

Soon after I submitted the dissertation to McGill University in August 2010 (initial submission), I contacted the person at Health Canada who had been Senior Labour Relations Advisor in November 2006. She explained that because I no longer worked at Health Canada, I did not need to do any further reporting at Health Canada.

Appendix II. Notices and protocols

A. TEXT OF E-MAIL CIRCULATED TO SCIENTIFIC STAFF BY DIRECTOR OF BUREAU OF REGULATORY ASSESSMENT (a.k.a. BPRA) on April 14, 2007

Good morning,

Please find below, details pertaining to dissertation research being undertaken by Jennifer Cuffe, Monograph Management Unit, Submission Management Division that is related to our work across application types. I have spoken with Jennifer and support her research. Please contact myself or Jennifer, should you have any questions.

Thank you

[Director]

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Title of Research: Number and cultural diversity in the evaluation of traditional herbal medicines in Canada

Researcher: Jennifer Cuffe, Ph.D. Candidate, Department of Anthropology, McGill University, [e-mail and phone]

Research Supervisor: Professor Allan Young, Department of Anthropology, McGill University, [e-mail and phone]

Purpose: To investigate, ethnographically, the production and scientific evaluation of traditional and herbal medicines in Canada. Background: In anthropology, discussions of incommensurability are central, addressing how one should make appropriate comparisons across cultures given varying values, beliefs, languages, and practices. This project approaches the literal meaning of 'incommensurability' – the lack of a common measure – by documenting and analyzing the numbers, measures, statistics, standards and so on used in the evaluation of the efficacy of medicines associated with different medical traditions.

Central research question: How are medicines, used in various traditions, made commensurable by a regulatory body and a research community that value cultural diversity?

Methods: This project uses the methods of social anthropology to investigate the measures used to evaluate the efficacy of herbal medicines in Canada. The focus will be on actual instances of the evaluation of herbal medicines, rather than on statements of how the evaluation should proceed. Fieldwork will be done in sites of

herbal medicine production and scientific evaluation in Canadian government, research meetings, research labs, and industry; archival research is also underway.

Methods at NHPD: Research methods include: participant-observation, analysis of public and non-public documents, interviews with current and past NHPD employees, shadowing, and lunchtime events such as film screenings or focus groups.

At NHPD, what is involved in participating in the research:

1. In participant-observation: nothing. My fieldnotes are focussed on my own experiences with my work at NHPD (not that of my co-workers) and on work processes. No person other than myself is identifiable in my fieldnotes.

2. In interviews: The method, length, and scheduling of the interview is up to you. Participation is entirely voluntary, and off work time. You would have to provide informed consent before any interview proceeds, and you may withdraw at any point; confidentiality and /or anonymity will be maintained unless you explicitly state you would like to be named. There are two types of interviews I will conduct. One type is a work-experience interview, in which I will ask I will ask questions about your own experience in the evaluation of traditional and/or herbal medicines. The other is a topic-interview, in which I will ask questions related to the development of a specific document (e.g., standards of evidence document), value/concept (e.g., NHPD's commitment to 'cultural and philosophical diversity'), or process (e.g., an SOP, co-ordination with other jurisdictions). Please contact me should you wish to participate!

3. Shadowing: Participation would be entirely voluntary, and on work time (and so you may want to ask permission from your supervisor). I would shadow you throughout your daily workday routine. It would be up to you whether I am a "fly on the wall" scribbling notes, or whether you choose to put me to use helping you. Informed consent would be sought before any shadowing proceeds and you may choose to end the shadowing at any point. Confidentiality will be maintained and you would not be identifiable in any disseminated research results unless you (as a participant) explicitly state you would like to be named. Nevertheless, your participation could not be totally anonymous within NHPD, because your colleagues may notice me hanging around in your cube, following you to meetings, etc.

4. Lunchtime events: I may circulate an invitation to NHPD employees for a lunchtime event, for example a film screening followed by discussion, and/or a discussion group or focus group. The invitation would explain what is involved in participating in that particular event.

Participating in my dissertation research project should not bear any consequences, positive or negative. No one at the NHPD will have access to my research notes (see notes on confidentiality and anonymity below). There is no compensation for participation, although: 1. if the discussion or interview is conducted over drink or food, I will pay for the drink or food, 2. while shadowing, you may put me to work.

Additional information for interested parties:

Confidentiality and anonymity: I am the only one who will have access to any raw data or notes, including interview transcripts, fieldnotes, participant lists, etc. These materials are coded and stored in such a way as to make it impossible to identify them directly with any individual. For instance, when taking notes (e.g., in interviews and shadowing), I do not use people's names but a series of codes. These notes are always on my person or in a locked cabinet, and unless they are from a research activity that same day, they are kept off Health Canada premises. Therefore, no one else at Health Canada will have access to this raw data, or learn from me who has participated in the research.

Proprietary and private information (e.g., submission-specific information, company names): will not be recorded in my research notes or used in research activities/dissemination. I will be using Health Canada's ATI and Privacy procedures to the best of my ability to screen out private or proprietary information from my research notes.

Micropolitics are NOT part of my research.

Concerns arising: If you have any concerns about my research, please feel free to contact me directly at any time (see contact information above) or to leave an anonymous type-written note on my chair or in my inbox (Cube B-224). If you do not feel comfortable contacting me directly please contact my academic supervisor Allan Young (see contact information above) or my employment supervisor at NHPD [named] (who has no connection to the research project). Should I sense that there are general concerns that need to be addressed, I will provide a brief lunchtime presentation of my research project with ample time for discussion.

Debriefing: At the end of my participant-observation in the NHPD (ideally Winter 2007-8), I will present my research results in a venue that NHPD employees may attend.

Research dissemination: The results will be written up in a Ph.D. dissertation, and at the time of the completion of the Ph.D. an executive summary will be available and will be sent to those who requested one. The results will be presented at various conferences, and may be published.

* This is an abbreviated version of both the research proposal as of March 21st, 2007 and of the procedures. For more information, please feel free to ask at any time *

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B. NOTES ON INTERVIEW PROTOCOL USED FOR CURRENT NHPD SCIENTIFIC STAFF

The interview began with the procedure for informed consent (see section C below for text). Although it was noted as an option on the informed consent form, I did not usually explicitly offer entry-level scientific staff the option of releasing their identity, unless they specifically asked. Because the identity of all these interviewees is confidential, I use pseudonymous first names in this dissertation. I did offer public servants in management, and other NHPD affiliates, the option of having their names released.

Most interviews were taped if the interview gave permission. Except in one or two cases, I also took copious notes during each interview.

The interviews usually began from a conversation. If the conversation faltered, or if I did not know enough about the interviewee, I would pursue a prepared line of questioning, as appropriate:

- How did you come to work at the NHPD? [sometimes followed by questions regarding a person's positions at the NHPD, and his or her hopes for the future. Sometimes followed by questions asking about differences between the interviewee's experience at the NHPD and that at previous/subsequent organizations]
- What are some of the ways you think [or your partner or your family etc. think] you've changed since beginning to work at the NHPD?
- Tell me about what you have done so far today at work, to give me an idea of your work in the evaluation of medicines.
- Is there anything that you are especially proud of?
- What types of files are you happy to see?
- Is there any type of work/file you dislike/dread? That makes you feel uncomfortable?
- Have you ever lost sleep because of a file in your evaluation work?
- I don't need this person's name, but I'd like you to think of someone who you think is really good as an assessment officer. Do you have someone in mind? [If yes:] What do you think makes this person so good at their work?
- Do you use statistics in your evaluation of medicines? How?
- How do you think herbal [or traditional or homeopathic or so on] medicines *should* be evaluated?

In most interviews, I asked questions specific to the interviewee's work: on the development of a particular standard operating procedure, on the role (or lack thereof) for a statistician in the directorate, the development of tracking and other databases, "the backlog", the history of decision-making among scientific staff, the use of the term "healing paradigm," the relationship between the NHPD and TPD, and so on. Questions specific to the interviewee's specific work ranged in importance from side note to being the major topic of the interview.

When the interview was drawing to a close, I explained that I had a structured questionnaire composed of 5 lines of questioning and designed to ensure that certain issues were addressed consistently for all interviewees. [But really just to make sure I asked the questions of all interviewees. When the rationale for a question's inclusion is not self-evident, I offer the reader a brief rationale below, in square brackets.] The five questions were:

1. What do you do with your calculator?
   [meant to elicit a concrete list of measures manipulated by evaluators]
2. Do you take natural health products yourself? Which ones? How has your use of NHPs changed since you began working at the NHPD?
   [anthropological context: attitudes towards NHPs in non-work life]
3. Do you consider yourself a religious or a spiritual person? Do you feel you bring your (insert interviewee's term) to your assessment work in some way?
   [anthropological context: fishing expedition regarding beliefs and their intersection with scientific judgment]
4. Is there anything (else) in your background or your identity that you feel comes into play in your work at the NHPD?
5. Does the NHPD's mission to "respect philosophical and cultural diversity" come into play in your daily work? Why / Why not?

In general, when one of these five questions addressed a subject the interviewee had previously discussed in the interview, the interviewee offered an additional or a more in-depth narrative.

At the closure of the interview, time permitting, I often asked some variation of "Is there anything else you'd like to add?"

While a few interviewees appeared to experience frustration with the occasional question, most interviewees appeared to find the interview a mildly pleasant change from routine. Some interviewees took the opportunity to discuss issues that must have been emotionally-charged for them, although the emotional charge was not always evident to me as interviewer; more than one interview participant, at the interview's completion, made a comment like Violet:

> I feel like I should be giving you $150 for the session … you know, talking about my feelings et cetera.

As stated on the informed consent form, all recordings of non-identified interviewees were destroyed after I transcribed or otherwise analyzed the material on the tapes (removing identifying features). Recordings of identified interviewees will be kept for a short period after the dissertation is released, and then destroyed.

C. TEXT OF INFORMED CONSENT FORM FOR INTERVIEWS WITH NHPD STAFF (variations cleared by McGill's REB were used for other situations)

Title of Research: Number and Cultural Diversity in the Evaluation of Herbal Medicines in Canada

Researcher: Jennifer Cuffe, Ph.D. candidate
Anthropology Department, McGill University
[e-mail and phone]
Research Supervisor: Professor Allan Young
[e-mail and phone]

Purpose of the research: This research project investigates the production and evaluation of natural health products in Canada. I am interested in your work, experience and views related to the production and evaluation of natural health products. The central purpose of this research is to document and analyze the types of statistics used in the evaluation of natural health products in Canada.

What is involved in participating: I will ask you a few questions relating to the production or evaluation of natural health products. These will be focussed on your own experiences. The method, time and length of the interview will be at your own convenience.

Your participation is entirely voluntary and you can choose to decline to answer any question or to withdraw at any point from the interview. Your decision to participate or not in this research does not bear negative consequences. I have [Director's] permission to carry out this research as an independent researcher, and he is aware that he will not have access to lists of who participated, or any confidential information you may provide.

Anything you say will only be attributed to you with your permission, otherwise the information will be reported in such a way as to make direct association with yourself impossible. If you choose for the interview to be recorded, tapes will be transcribed omitting any identifying features, and once they are transcribed they will be destroyed. No other person or organisation will have access to the interview materials and that they will be coded and stored in such a way as to make it impossible to identify them directly with any individual. In other words, the confidentiality and anonymity of the information you will provide will be ensured, unless you explicitly state that you would like to be named.

Please note: To gain a better understanding of the evaluation of natural health products at Health Canada, I am working at Health Canada part-time, as term employee until August 2007. Nevertheless, the interview I would like to conduct with you is separate from this employment. The interview is part of my dissertation research for my Ph.D. in Anthropology. It was in no way commissioned or instigated by Health Canada. In other words, no one else (including anyone at

Health Canada) has anything to do with this interview, and no one else will have access to any confidential information that you provide.

Your signature below serves to signify that you agree to participate in this study.

Consent: I have read the above information and I agree to participate in this study.

I agree that this interview can be tape-recorded: Yes _____ No _____

Signature: _____Researcher's signature:_____

Name: _____Date: _____

To be completed after the interview, only if desired by the participant:

I give permission to be identified: Yes _____ No _____

Signature: _____ Researcher's signature:_____

D. TEXT OF E-MAIL DESCRIBING SURVEY OF NHPD STAFF RE: DIVERSITY

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Title of Research: Number and cultural diversity in the evaluation of traditional herbal medicines in Canada

Researcher: Jennifer Cuffe, Ph.D. Candidate, Department of Anthropology,McGill University, [e-mail and phone]

Research Supervisor: Professor Allan Young, Department of Anthropology, McGill University, [e-mail and phone]

Purpose of dissertation research: To investigate, ethnographically, the production and scientific evaluation of traditional and herbal medicines in Canada.

Purpose of 2nd floor kitchen survey at NHPD: The survey is designed to:

1. document the diversity of birthplace and language backgrounds of NHPD assessment officers, their unit heads, managers & directors. This documentation is a follow-up to interviews with AOs, because many interviewees have stated that one of the things they enjoy in their work is working with colleagues from so many different places & with different experiences.
2. measure whether NHPD employees involved in assessment feel on the part of NHPD's role – to "respect philosophical and cultural diversity" – comes into play in their day-to-day work.

Methods: Who should participate: Anyone involved in scientific assessment. Participants would include AOs in B(P)RA and BCTHS, as well as their unit heads, managers & directors. (This includes non-traditional, traditional, MDU, CTU, ingredient database, and site AOs etc. It also includes people in SG boxes but who are doing assessment, for example, Compendial and site SGs). Participation is voluntary and anonymous.

What is involved in participating: Answering the following questions at three stations in the 2nd floor kitchen:

1. Where were you born? [Indicate response with a pushpin on a world map]
2. In which languages can you speak or read about NHPs? [Indicate response by putting a tally mark beside the appropriate language(s). If a language is not on the chart, please add it and add a tally mark]
3. Part of NHPD's role is to "respect philosophical and cultural diversity." Do you feel that "respect for cultural and philosophical diversity" is relevant to ***your*** day-to-day assessment work as an officer/unit head/manager? Why or Why Not? [Answer question on ballot and place in box]

Participants may choose to only answer 1 or 2 questions. The survey will close August 21st, 2007 at 5pm.

Permissions & how data will be used:

-Permission to conduct the survey in the second floor kitchen has been obtained by the a/ Director of B(P)RA (KR). She is aware neither she nor anyone else other than Jennifer Cuffe will have access to the raw results from question 3.

- The data will be used for Jennifer Cuffe's dissertation research. How the results will be used:

1. Birthplace map (station one). The results will be reported in the dissertation in a way that does not pinpoint exact birth locations. Example of statements that could be used: "Birthplaces spanned 4 continents. Of the 40 people who responded to the survey, 20 were born in Canada, 5 in India, 3 in North African countries, 2 in the Middle East, 6 in Eastern Europe/Russia, etc.. Of those born in Canada, it appears that 14 were born in major urban areas (over 1 million people)." I will NOT report specifics such as "One Assessment Officer was born in La Esperanza, Honduras."
2. Language tally (station 2). All results will be presented. The number of tally marks in the English section will be used as the number of people who participated at station 2.
3. "Cultural and philosophical diversity" question (station 3). The results will be analysed and presented. Any identifying features such as names and qualifiers in the responses (e.g., "As a 66-year-old Honduran-Canadian,") will NOT be reported. Only the amalgamated responses will be made available in the dissertation and to requestors.

Note: After August 21st, 2007, the world map and language tally will be left at the NHPD in the hands of the morale & recognition committee to use as it sees fit (for example as decoration or for a subsequent activity to include everyone from the NHPD).

- General information about Jennifer Cuffe's dissertation research was circulated to B(P)RA in spring 2007 by [director]. A copy is behind the survey instructions in the kitchen. If you would like a copy of this e-mail, please write [assistant] and/or Jennifer Cuffe. If you would like other details about Jennifer's research, please speak with her directly [e-mail and phone]

- If you have concerns about Jennifer's research, please speak with her or her academic supervisor (see top of page). [Work supervisor] has also agreed to field concerns if you are more comfortable speaking to someone at the NHPD.

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Appendix III. List of conferences and other NHP-related sessions attended outside work

Health Canada sessions attended outside of employment

Health Products and Foods Branch

- Drug, Food, Natural Health Product Interactions: The Health Canada International Symposium. February 9-10, 2006, Aylmer.

Natural Health Products Directorate

- Standards of Evidence Consultations. November 28th 2002, Montreal.
- Natural Health Products Regulations [Public Information Session]. November 25-28th 2003, Laval.
- Clinical Trials [Public Information Session]. June 21st 2005, Ottawa.

Other natural health product related events attended, by organization

Canadian Interdisciplinary Network for Complementary & Alternative Medicine Research (IN-CAM)

- 4th Annual Research Symposium: *Coming of Age: Emerging Issues and New Directions in CAM Research.* November 2nd-3rd 2007, Vancouver.
- Regional IN-CAM Symposium: *CAM Research: From Experience to Evidence.* February 2nd 2007, Montreal.
- 3rd Annual IN-CAM Symposium: *Integrating CAM Research and Practice: A Focus on Outcome Measures.* November 4-5th 2006, Calgary.
- 2nd Annual IN-CAM Symposium: *CAM Research in Canada: Sharing Successes and Challenges*. November 12-13th 2005, Toronto.
- First Annual IN-CAM Symposium: *CAM Health Services and Policy Research in Canada - New Directions*. December 4-5th 2004, Toronto.

Consortium of Academic Health Centers for Integrative Medicine

- North American Research Conference on Integrative and Complementary Medicine [First Annual]. May 24-27th 2006, Edmonton.

Natural Health Product Research Society of Canada (NHPRS)

- Fourth Annual Meeting: *Tradition to Technology.* May 10-13th 2007, Saskatoon. (This meeting was conducted jointly with the Canadian Herb, Spice and Natural Health Coalition.)
- Third Annual Meeting. March 3-5th 2006, Toronto.
- 2nd Natural Health Products Research Conference. February 11-13th 2005, Vancouver.
- First Annual Meeting. February 20-22nd 2004, Montreal.

Western Canadian Functional Food & Natural Health Product Network (WCFN)

- Annual Conference: *Eastern Traditions & Western Trends, China-India-Korea.* November 15-16th 2007, Vancouver.

Tropical Conservancy Symposium

- Biodiversity & Health International Symposium: *Focussing Research to Policy*. October 25-28th 2003, Ottawa.

Chalmers Research Group

- Systematic Review Workshop for Researchers Interested in Natural Health Products. May 14-15th 2005, Ottawa.

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Health Canada – Access to Information
A-2008-00183 Response to request: The statement of merit and work descriptions for [specific] positions in the evaluation of natural health products.
A-2008-00184 Response to request: NHPD Organizational Charts, yearly since the inception of the ONHP.
A-2008-00185 Response to request: Submissions from the public regarding the Standards of Evidence document and its precursor drafts at the NHPD.
A-2008-00186 Response to request: Input from any expert consultations regarding the Standards of Evidence document and its precursor drafts at the NHPD.
A-2008-00187 Response to request: A list of all the meetings and agendas of the ONHP's Transition team, as well as those of two of its subcommittees on Standards of Evidence/Efficacy/Safety, and on Research. For the subcommittee on Standards of Evidence/Efficacy/Safety, also its:

membership list; minutes; as-was-said; list of correspondence topics (if work done by correspondence); anything the subcommittee presented to the Transition team as a whole; the as-was-said (or minutes, if the as-was-said is unavailable) for the Transition Team meeting sections related to the work of this subcommittee.

A-2008-00188 Response to request: The minutes, as-was-said, and materials pertaining to the August 1999 meeting of the Transition Team.

A-2008-00189 Response to request: [Various materials to help trace] the origin and development of the ONHP mission statement, as developed by the Transition Team.

A-2008-00190 Response to request: [Various materials to help trace] the origin and development of the Transition Team's statement regarding "cultural considerations."

A-2008-00191 Response to request: [Various materials to help trace] the origin and development of the Transition Team's definition of natural health products.

A-2008-00192 Response to request: Meeting agendas, minutes, and as-was said of the NHPD's Expert Advisory Committee since its inception.

A-2008-00193 Response to request: A list of all audits done of the NHPD or its processes since its inception as the ONHP; and the report of any audit that bears on hiring, diversity, or scientific assessment.

A-2008-00194 Response to request: The organization charts for the Therapeutic Products Directorate (and its precursors: the Drugs Directorate and the drug-related sections of the Food and Drugs Directorate/Division) and the related Inspectorate, when separate. Request one organizational chart every five years beginning in 1945 (or the earliest date for which there are organizational charts).

A-2008-00195 Response to request: List of pre-1997 files still held by Health Canada that are centered on the work of the:

A. Expert Advisory Committee on Herbs and Botanical Preparations

B. Regional Scientific Liaison Group on Traditional Medicines

C. Advisory Panel on Herbal Remedies

and

D. any other files from 1976-1997 and internal to the Drugs Directorate or Health Protection Branch that are encountered in the search for A, B, or C, and that have titles/subjects including terms such as "herbs", "herbal", "botanical", "traditional medicines", "ethnic medicines", "traditional Chinese medicines", or "Ayurvedic medicines."

A-2008-00553,

A-2008-00554,

A-2008-00555,

A-2008-00556. Response to request: [More pointed reiteration of request A-2008-00195, because in Health Canada's reply to 00195 it was clear that no attempt had been made to locate files under its control in offsite Federal Records Centres and private storage facilities – where government files sit in purgatory after being evicted from active central registries, but before being destroyed or officially archived]

A- 2009-00336 Response to request: Contents of the following inactive file in storage for the NHPD: HPFB-NHPD3-1275 “The Chamber of Chinese Herbal Medicine of Canada – the survival of Chinese.”
A-2009-00337. Response to request: Contents of the following inactive file in storage for the NHPD: HPFB-NHPD3-162 “TPP Response to Advisory Panel Final Report.”
A- 2009-00341 Response to request: Contents of the following inactive file in storage for the NHPD: HPFB-NHPD3-270 “Advisory Panel on Herbal Remedies.”
A-2009-00342 Response to request: Contents of the following inactive file in storage for the NHPD: HPFB-NHPD3-1275 “Advisory Panel on Natural Health Products – Meeting – Jun 19-20, 1997.”
A-2009-00391 Response to request: Contents of the following inactive file in storage for the NHPD: HPFB-NHPD3-198 “Traditional Herbal Medicines.”
A-2009-00417 Response to request: Contents of the following inactive file in storage for the NHPD: HPFB-NHPD3-175 “NHP Regulatory Framework / TPP Response to Advisory Panel Final Report.”

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1998 Final Report of the Advisory Panel on Natural Health Products: Regulatory Framework for Natural Health Products. Prepared for Health Canada and the House of Commons Standing Committee on Health. [Ottawa].

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