“BEYOND BIRTH CONTROL:” THE YAZ/YASMIN CONTROVERSY AND THE RISK EVALUATION OF HORMONAL CONTRACEPTIVES

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ABSTRACT

Concerns about the safety of the pill have come to the fore recently, due in large part to the public outcry over deaths allegedly caused by popular contraceptives Yaz and Yasmin. Media reports link the drugs to at least 23 deaths in Canada and over 100 in the U.S. as well as thousands of injuries worldwide, as a result of a purported increased incidence of blood clots. The question of what should be considered an acceptable risk threshold for approved contraceptive pills has been contested by many groups, including regulatory bodies, medical professionals, epidemiologists, and consumers. This thesis provides an in-depth sociological examination of the Yaz/Yasmin controversy through qualitative analysis of stakeholder interviews and content analysis of key medical, regulatory, and legal documents. I examine the most recent safety debates in order to analyze the central phenomena that play a role in the regulation and risk/benefit assessment of oral contraceptives: managing data uncertainty, calculating reproductive risks against ancillary benefits, and the precariousness of informed consent. After an introductory chapter in which I situate the thesis within the larger scholarly conversations on contraceptive assessment specifically and technological risk more generally, the findings are presented in three article-length manuscripts. In the first article, I investigate strategies that regulatory bodies and professional associations use to assure the public of the safety of Yaz and Yasmin. I found that a discourse of pregnancy risks is employed in official risk communication. I argue that this has gendered implications for the development of contraceptives and their risk assessment. In the second article, I explore how pill users who have experienced side effects understand the risks of hormonal contraception and advocate for changes in risk communication and drug regulation. I found that women highlighted the inadequacy of risk information received from both doctors and pharmaceutical companies. In addition, affected users rejected the use of reproductive risk as the primary comparative risk when assessing pill safety. In the third paper, I look at processes through

which individual stakeholders measure and debate contraceptive risk. Here, I highlight how contraceptive risk assessment is characterized by systemic uncertainty and doubt. Furthermore, the paper stresses the tough choices that users have to make in a climate of indecision coupled with pharmaceutical companies' involvement in research and marketing. While we know that the history of the pill has been fraught with many debates about its safety, less attention has been paid to the current changing context and how different social actors still contest the measurement and meaning of contraceptive risk. I found that many questions about risks are unresolved or dealt with in ways that create divergence between professionals and affected users. In the concluding chapter, I discuss the sociological implications of my findings, the limitations of this study and potential directions for future research on the evaluation of contraceptive risk. The Yaz/Yasmin controversy has amplified contemporary critiques of the pill. In documenting and analyzing the dynamics of this risk debate, this thesis contributes to a deeper understanding of how the risks and benefits of contraception are currently assessed in the North American context.

RÉSUMÉ

Les inquiétudes concernant l'innocuité de la pilule ont récemment été au cœur de toutes les discussions et ce en grande partie à cause du tollé général provoqué par les décès vraisemblablement entraînés par les contraceptifs Yaz et Yasmin, très répandus sur le marché. Les rapports des médias associent ces médicaments à au moins 23 morts au Canada et plus de 100 aux États-Unis, ainsi qu'à des milliers de victimes à travers le monde par suite d'une incidence supposée accrue de caillots sanguins. La question de savoir quel devrait être le seuil de risque acceptable pour les pilules contraceptives approuvées a été débattue par de nombreux groupes, parmi lesquels des organismes de réglementation, des professionnels du milieu médical, des épidémiologistes et des consommatrices. La présente thèse fournit une analyse sociologique en profondeur de la controverse Yasmin/Yaz à travers une analyse qualitative des entretiens effectués avec les parties prenantes et une analyse de contenu de documents clés sur les plans médical, réglementaire et juridique. Nous examinerons les débats les plus récents concernant l'innocuité afin d'analyser les principaux événements qui influent sur la réglementation et l'évaluation du rapport risque/avantage des contraceptifs oraux: la gestion de l'incertitude des données, le calcul des risques liés à la procréation par rapport aux avantages complémentaires, et la précarité du consentement éclairé. Après un chapitre introductif dans lequel nous situerons la présente thèse au sein des discussions académiques plus étendues au sujet de l'évaluation contraceptive en particulier et du risque technologique en général, les résultats seront présentés sous forme de trois manuscrits de la longueur d'un article. Dans le premier article, nous enquêterons sur les stratégies déployées par les organismes de réglementation et les organisations professionnelles pour assurer au public l'innocuité de Yaz et Yasmin. À cette occasion, nous avons constaté qu'un discours concernant les risques de grossesse est utilisé dans le cadre de la communication officielle des risques. Nous soutenons qu'il existe des implications sexospécifiques dans le développement des contraceptifs et dans l'évaluation

des risques qu'ils présentent. Dans le deuxième article, nous examinerons la manière dont les utilisatrices de la pilule qui ont subi des effets secondaires perçoivent les risques de la contraception hormonale et militent en faveur de changements en matière de communication des risques et de réglementation des médicaments. Nous avons découvert que les femmes ont souligné l'insuffisance d'informations en matière de risques délivrées par les médecins et les entreprises pharmaceutiques. En outre, les utilisatrices affectées ont rejeté l'utilisation du risque sur le plan de la reproduction comme comparatif principal lors de l'évaluation de l'innocuité de la pilule. Dans le troisième article, nous nous pencherons sur les processus utilisés par chacune des parties prenantes pour évaluer et aborder le risque lié à la contraception. Nous soulignerons à quel point l'évaluation des risques liés à la contraception est caractérisée par une incertitude et un doute systémiques. Par ailleurs, cet article met en lumière les choix difficiles que doivent faire les utilisatrices dans un climat marqué par l'incertitude des risques encourus et l'implication des entreprises pharmaceutiques dans la recherche et la commercialisation des médicaments. Alors que nous savons que l'histoire de la pilule a été ponctuée de nombreux débats concernant son innocuité, une attention moindre a été accordée à l'évolution du contexte actuelle et à la manière dont différents acteurs sociaux contestent encore aujourd'hui l'évaluation et la signification des risques liés à la contraception. Nous sommes parvenu à la conclusion que de nombreuses questions concernant les risques restent en suspens ou sont traitées d'une manière qui entraîne des divergences entre les professionnels et les utilisatrices concernées. Dans le chapitre final, nous aborderons les conséquences sociologiques de nos découvertes, les limites de la présente étude et les orientations possibles pour des recherches futures concernant l'évaluation des risques liés à la contraception. La controverse Yaz/Yasmin a accru les critiques actuelles au sujet de la pilule. À travers la documentation et l'analyse des dynamiques de ce débat concernant les risques, la présente thèse contribue à une meilleure compréhension de la manière dont les risques et les avantages de la contraception sont analysés à l'heure actuelle dans le contexte nord-américain.

GLOSSARY

ACOG: The American Congress of Obstetricians and Gynaecologists
CDA: critical discourse analysis
DVT: deep vein thrombosis
HC: hormonal contraceptive
LARC: long-acting reversible contraceptive
LNG: levonorgestrel
OC: oral contraceptive
PMDD: premenstrual dysphoric disorder
SCOT: the social construction of technology
SOGC: Society of Obstetricians and Gynaecologists of Canada
STS: science and technology studies
VTE: venous thromboembolism

CHAPTER 1

INTRODUCTION

Following alarming reports of deaths and adverse side effects, the safety of new and popular oral contraceptives, Yaz and Yasmin, has been called into question by regulatory bodies, health care professionals, scientific experts, and the public. The Yaz/Yasmin controversy has revived debates about the risks of venous thromboembolism (VTE) associated with the birth control pill[1]. As a result of this controversy, stakeholders have engaged in discussions about contraceptive risk measurement and acceptable risk thresholds for oral contraceptive pills on the market. The current context, marked by class action lawsuits and reconsideration of Yaz and Yasmin's approval status, provides a unique opportunity to study how risks and benefits associated with hormonal contraceptives are assessed, evaluated, and ultimately understood by prescribing physicians and their patients. This thesis is an in-depth analysis of the Yaz/Yasmin controversy and what it reveals about the procedures used to evaluate oral contraceptives. I argue that risk/benefit assessments are influenced by sociocultural norms, standards developed 50 years ago for hormonal drug testing and evaluation, tensions between lay and professional perspectives, and systemic scientific uncertainty, all of which lead to a diffusion and devolution of responsibility in risk management.

Since its advent, the contraceptive pill has been seen both as a source of empowerment and a burden of health risks for women. On one hand, when it was developed, it offered users control of their fertility at a time when abortion was both illegal and unsafe. On the other hand, women initially experienced a range of side effects which were undisclosed and understudied due to experts' beliefs

1 Throughout the rest of this thesis I refer to the birth control pill simply as "the pill," as it is referred to colloquially.

that they were inconsequential. As documented by historians (e.g., May, 1999; Marks, 2000; Watkins, 1998), significant health concerns were minimized throughout the drug's research and development process and even after the technology became available to consumers. During the initial trials that took place in Puerto Rico in the 1950s, some of the health risks associated with estrogen (e.g., nausea, headaches, vision problems, depression) became apparent. However, they were not considered significant enough to stall the regulatory approval of the drug. Unplanned pregnancy and population growth were considered an undesirable and even dangerous alternative to the health risks posed by contraceptive pills (May, 1999). In light of revelations about the pill's more severe risks such as cancer, stroke, and VTE, pharmaceutical companies decreased the estrogen dose in the 1970s (Marks, 2000). While the chemical formulation of the drug's main components (estrogen and progesterone) has only changed slightly since the early 1990s, contraceptive marketing has been focused on emphasizing ancillary benefits as opposed to pregnancy prevention alone. The past couple of decades featured advertising campaigns that heavily emphasized the pill's lifestyle benefits, while downplaying health risks and negative side effects (Watkins, 2012). These campaigns highlight gendered aesthetic benefits such as the treatment of acne as well as the suppression of periods (Mamo and Fosket, 2009). Yaz and Yasmin are especially indicative of what Watkins (2012) calls "the lifestyle turn" in the way contraception is promoted. Problematically, it is unlikely that these new oral contraceptives have offered users decreased health risks when compared to the compounds released in the mid-1990s.

Yaz and Yasmin have been linked in the media to at least 23 fatal pulmonary embolisms in Canada and over 100 in the United States, as well as thousands of injuries worldwide. Following such reports, as well as the intensification of public disapproval, regulatory agencies, medical associations and lay stakeholders alike engaged in debates about the existence and acceptability of increased risks. Furthermore, Yasmin and Yaz's purported ancillary benefits, namely the treatment of acne and premenstrual dysphoric disorder (PMDD), have been heavily marketed to potential consumers, making

weighing risks against benefits a more intricate endeavour. The question of what should be considered an acceptable risk threshold for pills on the market has been debated by many stakeholders, including scientists, medical professionals, epidemiologists, and patients/consumers. For example, some studies have indicated that the new generation of hormones used in Yaz and Yasmin (which use a compound called drospirenone) increases the risk of VTE and gallbladder disease when compared to first and second generation hormones (Lidegaard et al., 2011; Wu et al., 2013). On the other hand, organizations such as the Society of Obstetricians and Gynecologists of Canada (SOGC) and Health Canada have stressed that the new pills are safe by comparing their risks to pregnancy risks and citing a specific set of studies that have found little to no increase in VTE risks. What constitutes "significant" risk is being contested in the case of drospirenone-containing pills.

The overarching objective of this thesis is to analyze the risk/benefit assessments that constitute the debate on acceptable risk in the case of drospirenone in order to reveal the more general processes and discourses prevalent in contraceptive risk evaluation. The Yaz/Yasmin controversy provided me with an empirically rich opportunity to explore the pill's current risk/benefits assessments. In light of my objective, I collected regulatory, medical, and legal documents pertaining to this debate and conducted in-depth interviews with 43 stakeholders. I explore the Yaz/Yasmin controversy and its implications in the three empirical articles that constitute the main body of this thesis. In the first article, I look at official professional discourses on the risks of drospirenone and argue that they problematically emphasize reproductive risks associated with women's bodies, thus potentially increasing risk acceptability thresholds for contraceptives on the market. The second article analyzes lay stakeholder perspectives and argues that these should be understood in a cultural context in order to better incorporate affected user concerns in medical and regulatory evaluation processes. Finally, the third manuscript looks at the systemic uncertainty surrounding risk measurement and risk/benefit weighing, with detrimental consequences for users, who are left to manage risk on their own.

Theorizing was facilitated by literature in science and technology studies, the sociology of risk, medical sociology, and feminist technoscience studies. In the rest of this introductory chapter, I provide readers with more details on the socio-historical context of contraceptive risk assessment, focusing on debates about VTE risks over the course of the decades following the market approval of the first contraceptive pill. I then review the relevant literature, describe the design of this research, and provide an overview of the three articles.

A BRIEF HISTORY OF THE PILL AND VENOUS THROMBOEMBOLISM (VTE) RISKS

The history of hormonal contraceptives has been linked with several debates about their safety. Most notably, VTE risks have been debated by professionals and patients alike in numerous instances (Marks, 1999; Lackie and Fairchild, 2016). Historians (Tone, 2001, 2012; Marks, 2001; Watkins, 1998; May, 2010) have outlined the social context within which such disputes took place. The controversies surrounding the pill's risks started right at the beginning of human subject research, with its developer Gregory Pincus and the first clinical trials his team conducted. In the 1950s, laws against birth control prevented clinicians from running large-scale clinical trials in mainland United States. Hence, Puerto Rico became the main testing site, and poor women of colour the trial participants (Briggs, 2002; May, 2010). The initial estrogen levels in the combined pill (composed of estrogen and progesterone) were high and caused numerous side effects among the trial participants, with many of them dropping out of the study as a consequence. At the time, Pincus did not discuss the carcinogenic potential of the drug's estrogen component (Watkins 1998). Although the trials proved the pill's efficacy at preventing pregnancy, questions remained about its long-term safety. Doctor Edris Rice-Wray, the medical director of the Puerto Rico Family Planning Association, informed Pincus that 17% of the women in the study complained of nausea, dizziness, headaches, stomach pain, and vomiting (Watkins, 1998). She thus suggested that the 10-milligram dose of Enovid (Searle's brand name for the first pill formulation) should not be approved for market sale. Pincus and his associate John Rock dismissed patients'

complaints as psychosomatic. While some claim that Rock and Pincus violated ethical standards, others underline that informed consent standards in the 1950s were minimal, regardless of the drug being tested (Marks, 2001). Most notably, however, three women died during the trials and no investigation was ever conducted to see if the deaths were related to the pill (Watkins, 1998).

Confident in their product, Rock and Pincus pushed for market approval. The pill was soon hailed as a wonder drug that could rid the world of overpopulation problems. Moreover, as abortion was illegal in North America at the time, many women wanted to ensure that they would not get pregnant. Conservative attitudes towards sexuality and gendered responsibilities for contraception contributed to the (negative and positive) hype surrounding the pill. At the time, social and cultural norms did not dictate that contraception should be a shared burden within a couple. Although some men would participate in fertility limiting practices (e.g., withdrawal, condoms, vasectomies), the ultimate responsibility was placed on women's shoulders. These social norms contributed to Margaret Sanger's wish for a contraceptive pill that would allow women sole control of their fertility (Tone, 2001).

Enovid was approved for the treatment of menstrual disorders by the FDA in 1957. Two years later, the FDA also approved it for use as a contraceptive in lower doses of synthetic estrogen. In Canada, it became available in 1960. The pill was initially marketed for “cycle control” as a consequence of social, legal, and political obstacles that made its intended use for contraception taboo. In the U.S., the Comstock Law, established in 1873, prohibited public discussion and research on contraception (McLaren and McLaren, 1997). In Canada, under the 1892 Criminal Code, any discussion of birth control could also be prosecuted. Although the pill was available by 1960 for “menstrual regulation,” it was illegal to discuss contraception or prescribe the pill for the indication of pregnancy prevention until 1969, when the Canadian parliament decriminalized birth control by passing amendments to Section 251 of the Criminal Code (McLaren and McLaren, 1997).

A couple of years after the FDA approved the pill, discussion emerged within the closed circle of the agency and pharmaceutical companies that the pill might pose more serious side effects than previously thought. There were reports of blood clots, strokes as well as possible links to cancer. As early as 1962, Searle received reports of 132 cases of blood clots in pill users (Watkins, 1998). Eleven of these cases resulted in death. Searle maintained that there was no conclusive proof that the pill caused those deaths. The FDA assured medical professionals that the drug was safe. In addition, it was very common for women to have their complaints dismissed by their doctors. When it came to the more serious health risks associated with the pill (cancer, blood clots), there was little information on its potential dangers. Gynaecologists were not always aware of risks associated with the new drug. Neither the drug companies nor the FDA provided doctors with much information on the potential side effects of the pill.

In the mid-1960s, several U.S. newspapers began reporting on problems related to pill intake. At the time, aside from some inconclusive FDA probes, little action was taken to investigate the problem of VTE risks thoroughly. It took years for major concerns about VTE risks to materialize. Watkins (1998) notes that several factors contributed to the underestimation of the pill's risks, including difficulties associated with data collection and the challenge of determining causal associations. Because medicine had become very specialized, there was also little communication across medical professions. Throughout the 1960s, the ensuing pill discussions were not only a technical debate, but eventually became a full-fledged public controversy. The publication of *The Doctor's Case Against the Pill* by feminist journalist Barbara Seaman (1969) turned the public's attention to the pill's side effects. Although the book was not well received in some circles, it eventually influenced U.S. Senator Gaylord Nelson to convene Senate hearings on the safety of the pill. Despite the meetings being dominated by men, they ultimately became a platform for women to demand that those taking the pill be informed of all the drug's potential dangers and side effects. Excluded from the hearings at the beginning, women

fought and earned their right to testify during the meetings.

Watkins (1998) notes that problems associated with data interpretation and risk-benefit analysis in the case of hormonal contraceptives made the controversy more complex. Weighing the pill's risks and benefits has never been an easy task. Even those who agreed that the pill posed serious health risks to women were not sure how to weigh them against the benefits. As mentioned earlier, the pill emerged in a social context where the overpopulation scare was a very real cultural phenomenon. Moreover, abortions were illegal at the time. Many women were willing to go to great lengths to ensure they did not get pregnant. Within medical circles, pregnancy was pathologized as the pill was referred to as "oral contraceptive therapy," with doctors implying that healthy women need to be treated of a condition (Watkins, 1998). This view of pregnancy as risky continues to this day even though the social and cultural context in which women choose to take the pill has changed (Lane, 1995).

In 1967, a study published in the *British Medical Journal* established a link between oral contraceptives and the risk of blood clots (thromboembolism). More FDA studies and the pill hearings of the late 1960s ensued. The link between the pill and serious health risks such as cancer and thromboembolism became evident. However, Planned Parenthood as well as pharmaceutical companies continued to stress the relative safety of the pill. Feminist health activists focused their efforts on getting the medical industry to share all the risk information with pill users. However, notions of informed consent at the time were either nonexistent or highly paternalistic. Doctors were reluctant to share VTE information they believed would make patients behave irrationally and stop taking the pill altogether. The debate over the pill's risks was also a power struggle over scientific information and who should have access to it. Women used this issue to demonstrate how disenfranchised they are within the medical establishment.

The main outcome of the pill controversy was an increased focus on informed consent. The FDA called for a package insert outlining some of the pill's risks. Initially, this insert was only available

to doctors. Then it became available to patients on request. By and large, the onus was on the patient to get informed, if a doctor was unwilling or unable to provide information. When the insert became widely circulated and available to all the women who were using the pill, health activists noted that not all the side effects discussed during the hearings were included (Marks, 2001). Precise statistics were also omitted. A notable problem was that the FDA left the drug manufacturers to decide what would go on the package insert. Pharmaceutical companies included only some of the more serious risks, but by no means all, especially not more minor concerns such as headaches, nausea, breakthrough bleeding, depression and vision problems.

In later formulations of the pill, however, the hormone dosage was reduced in an effort to minimize risks. For example, in the 70s and 80s, both doses of estrogen and progestin were lowered and multi-phasic pills were introduced (different estrogen and/or progestin formulations over the course of a woman's cycle). This was meant to lessen side effects, such as mood swings, nausea, and breakthrough bleeding. However, the functioning mechanism for pregnancy prevention (preventing ovulation and implantation) and relative health risks remained the same. Since then, we have seen changes to the synthetic progestins used in the combination pill. This particular component of the pill can take many forms with slightly different effects, and has allowed companies to differentiate themselves by advertising their pills on the basis of their ancillary progestin-based benefits, even though the overall formulation of the drug is not radically different, as it is still mostly estrogen-based. Scholars (Mamo and Fosket, 2009; Van Kammen and Oudshoorn, 2002; Watkins, 2012) have noted that in the absence of any major contraceptive breakthroughs in the past 30 years, companies have tweaked old versions of the pill and, through clever marketing, have turned it into a lifestyle drug with purported quality of life benefits beyond just the ability to have sexual intercourse without worrying about pregnancy. The newer marketed side benefits (acne treatment, pre-menstrual dysphoric disorder (PMDD) treatment, suppression of periods) add new considerations for the risk-benefit evaluation of

hormonal contraceptives. Watkins (2012, p. 1462) argues that the focus on ancillary benefits indicates that “marketing decisions, rather than scientific innovations, have guided the development and positioning of contraceptive products in recent years.”

Although in the past the main advertised function of birth control was pregnancy prevention, during the 1990s and 2000s, this discourse changed. The third generation of pills introduced in the 1990s was marketed to doctors in Canada and both consumers and doctors in the U.S. on the basis of ancillary benefits. For example, one of the more popular brands, Ortho-Trycylen-Lo, was clinically approved and advertised both as a contraceptive and as an acne treatment. The incorporation of ancillary treatments in clinical trials and advertising signals a shift on how we view and conceptualize the pill (Watkins, 2012). This thesis takes this shift into consideration, as it is also central to the way in which newer brands of pills have been tested and advertised. In addition, the mid-1990s were marked by another pill controversy, this time in the U.K. Here, as a result of concerns regarding the VTE risks associated with the third generation of pills (containing desogestrel or gestogene as the main progestin component), doctors were advised by regulatory bodies to alert their patients about these risks. What ensued is the '1995 pill scare,' where a significant number of British women either stopped taking the pills in question or switched to different brands. Some sources (e.g., Barnett and Breakwell, 2010) indicate that, as a result, the number of unwanted pregnancies and abortions rose in the U.K. the following year. The controversy also showed the impact that media can have in the amplification of a controversy (Allison et al., 1997).

The fourth and most recent generation of pills gave rise to the drospirenone controversy. Drospirenone (a type of synthetic progestin most often used in combination with ethinyl estradiol – the pill's estrogen component) is a hormonal compound that has been used in the latest generation of oral contraceptives (released in both Canada and the U.S. in the mid to late 2000s). Its composition is mainly characterized by its anti-androgenic properties and its purported treatment of acne and PMDD –

ancillary benefits that have been heavily marketed to potential consumers. The most popular pills that contain drospirenone are Yaz and Yasmin, both manufactured by Bayer. Controversy ensued following informal reports in the media that several young healthy women died as a consequence of blood clots caused by these contraceptives. Governmental agencies began to assess the risk of VTE as it relates to drospirenone. Wu et al. (2013), in a systematic review of epidemiological studies on this issue, concluded that dropsirenone indicates higher health-related risks. The authors compared those who took the new generation of pills to both those with no hormonal contraceptive use and levonorgestrel-containing contraceptive use, with levonorgestrel being the hormone used in the second generation of hormonal contraceptive technologies. On the other hand, despite this evidence, Health Canada and the FDA stressed the relative safety of drospirenone, even though some uncertainty remains as to what the exact risk increase might be.

In addition to medical and regulatory discussions of risk, the assessment of new contraceptive pills has also been contested through legal means. There are currently several class action lawsuits in Canada and the U.S. from groups of women who have been negatively affected by Yaz and Yasmin. Lawyers claim that Bayer has not only failed to adequately inform patients of increased health risks, but has also chosen not to investigate these risks thoroughly in clinical trials. The Yaz/Yasmin controversy highlights debates about risk measurement and the regulation of drugs – themes that are central to this thesis. Simultaneously, and partly as a result of the lawsuits, patient groups have been visible online through legal forums where women discuss negative side effects they experienced while taking Yaz or Yasmin. Women's health advocates have also been more vocal about the dangers of the pill recently in light of the Yaz/Yasmin reports (Grigg-Spall, 2013). Using the backdrop of historical risk assessment issues as well as recent trends in the development and marketing of contraceptives such as Yaz and Yasmin, this study investigates how risk is assessed by different groups through advocacy as well as legal and medical means.

LITERATURE REVIEW

Risk and Technology

Social scientific approaches to understanding “risk” are, in part, a response to the need to analyze technological innovations (Zinn, 2008). This work emphasizes the social context in which risk is produced and perceived, as opposed to debating techno-scientific measurements of risk. Before the emergence of social scientific perspectives on risk, theories were limited to the techno-scientific perspective. Debates in fields such as economics and engineering were centred on issues of identification, calculation, the level of risk seriousness, and the accuracy of scientific measurements and predictive models (Zinn, 2008). This perspective tends to be sceptical of the public's ability to perceive the 'real' magnitude of risks. Thus, it has been traditionally assumed that (only) science can measure the real risks, while human perception leads to distorted views. In contrast to sociological perspectives on risk, the techno-scientific approach does not ask questions about the ways in which conceptualizations of risk might be socially constructed. Instead, it draws a sharp distinction between 'objective' and 'subjective' risk: risk as measured by science and risk as perceived by laypersons, respectively (Lupton, 2013). Scholars working in a sociocultural tradition, however, seek to conceptualize risk as it is understood by actors in social and cultural settings. Similarly, the goal of my research is not to make claims regarding the scientific accuracy of contraceptive risk measurement and assessment, but rather to explore the social processes through which risks are negotiated, presented to the public, constructed as acceptable or unacceptable, and generally understood by stakeholders. In analyzing issues of risk as they relate to oral contraceptive pills, I will draw on three main theories of risk developed by social scientists: the 'risk society' or reflexive modernization theory pioneered by Ulrich Beck (1992), the 'cultural' or sociocultural theory originally developed by Mary Douglas (1983, 1986), and the governmentality framework. Using these theories as well as case studies on risk and

technology, I analyze how contraceptive risks are systemically produced and scientifically understood, but also how social perceptions of risk differ across contexts.

The 'risk society' perspective is one of the early theories to draw attention to the complexity of modern risks and inspire further work focused on analyzing technological dangers. This perspective highlights two sociological concepts: reflexive modernization and risk (Beck, 1992). Reflexive modernization refers to a set of new hazards produced by scientific and industrial development. These potential dangers cannot be estimated or contained in advance and because they are systemic, no individuals can be held accountable for the risks thus created. Rather, the produced risks are amorphous and ever present. According to Beck (1992), modernity must become critical of itself (reflexive) and of science, through techniques of rationalization and radicalization. More specifically, he is critical of the authority of technical experts to define agendas and risk discourses (Beck, 2012). The risk society framework emphasizes the individual condition of ambivalence, which is a result of the complexity and uncertainties inherent in societal and technological knowledge. While in the past hazards were more evident to the senses (they could be smelt or touched, for example), now major risks escape sensory perception. For example, food chemicals are hard to perceive. As such, these risks are made 'real' by scientific knowledge rather than by daily experience (Lupton, 2013). This is also true of the risks posed by hormonal contraceptives. Although individuals have come forward with experiences of adverse side effects, calculating risk is an activity relegated to the scientific realm. Additionally, risk information is imparted by regulatory bodies and pharmaceutical companies, with little input from patients.

Although they do not follow Beck's framework specifically, a number of studies have highlighted the risks posed by modern technologies and their consequences (Perrow, 1999; Vaughn, 1996). A prime example of the creation of high risks by complex technical and organizational systems is the Challenger Launch disaster, as analyzed by Diane Vaughan (1996). A sociological analysis of NASA organizational culture reveals that “the cause of disaster was a mistake embedded in the banality

of organizational life and facilitated by an environment of scarcity and competition" as well as an "uncertain technology, incrementalism," and a complex structure (Vaughan 1996, p. 45). Potential dangers can thus be normalized and incorporated into an organization's culture. Consequently, disaster becomes a result of incrementalism: small decisions within various parts of an organization that contribute to the production of a disaster over time. Such an analysis contradicts the view that disaster can simply be attributed to one major technical failure, as was the case following the Challenger incident. Risk is socially organized and systematically produced by social structures, rather than by technology or individual actions (Vaughan, 1996). An important parallel can be drawn here between studies of technological risk production and controversial oral contraceptives Yaz and Yasmin. At the time they were released on the market, the drugs' VTE risks were unknown. However, the potential risk increase was normalized through debate and ensuing indecision by North American regulatory bodies. Studies on the normalization of risk can thus inform the analysis of similar processes operating in the case of oral contraceptives.

In thinking about risks as they become entangled with technological systems, other scholars have focused on studying the dangers and consequences of risky technologies (Collins and Pinch, 1998; Nelkin, 1984; Perrow, 1999). Nelkin (1984) notes that scientific and technological controversies and ensuing protests are not necessarily a revolt against science but against the power relationships associated with technology and citizens' inability to shape decisions that affect them directly. A feature of modern technological systems and models of expertise is that laypeople are distrusted by professionals and generally unable to control the risks placed upon them by such complex systems. Consistent with this view, contraceptive users have been portrayed historically as non-compliant and prone to irrational fears (Watkins, 1998), while contraceptive development itself has been fraught with questions over who holds the authority to determine 'correct' risk/benefit ratios.

The sociocultural perspective on risk originates in the work of Mary Douglas (1986) and her

espousal of cultural theory. While cultural theory does not specifically question technical procedures for the measurement of risk, it does criticize the depoliticization of risk issues encouraged by techno-scientific approaches. Douglas (1986) has been critical of the way in which institutions use risk discourses to influence human behaviour and to reinforce norms. She argues that such discourses are underlined by cultural norms and interests as opposed to being simply reflection of techo-scientific measurement. The sociocultural perspective focuses on the social and cultural construction of risk: how we understand what is "risky" and what is not and which risks are selected and presented to the public. At the same time, it critiques the assumption that individuals are rational agents making decisions based on rational calculations. According to cultural theory, the distinction between objective and subjective risks is a false one, as risks can only be perceived through a cultural lens. The role that social and cultural influences (e.g. media visibility of risks, public controversy, personal beliefs, etc) play in individual risk perceptions has been ignored by some experts who tend to focus solely on scientific measurements of risk (Douglas, 1986).

In the sociocultural tradition, scholars have documented the ways in which risk discourses construct reality and influence individual perceptions in both medical and non-medical arenas (e.g., Fortun, 2004; Langston, 2008; Schmid, 2004; Timmermans and Leiter, 2000). Fortun (2004) places the communication of risk in historical and sociological perspective by focusing on information systems as instruments of power. She shows how mediums of communication have radically transformed the environmental field since the 1980s, making information, including risk information, more accessible for individuals affected. With more information available to the public, environmental dangers have been continually downplayed by the media and governments (Langston, 2008). An example is the lack of strict regulations around the use of endocrine disruptors in food and in manufacturing (Langston, 2008). While some risks are downplayed, others can be emphasized in order to mobilize populations. Such is the case of post-Chernobyl discourses that have been deployed strategically to gain authority,

solicit change and reconfigure relationships between the state, experts, and the lay public (Petryna, 2013; Schmid, 2004; Wynne, 1992). Ultimately, the deployment of risk discourses has the power to 'transform' a technology from a risky one to a safe one and vice-versa (Gabe, 1995). For example, Timmermans and Leiter (2000), looking at the historic case of thalidomide, show that the compound achieved a 'symbolic make-over' in the eyes of the public over the course of a few decades: attention shifted from the risk of foetal birth defects in babies of women who were treated with thalidomide in the 1960s to the drug's potential as a treatment for certain cancers.

The governmentality framework, critical of how risks are constructed and deployed by the state and medical establishments, is a useful perspective to inform analysis alongside other risk theories, as it better incorporates social inequalities in investigations of risk. Foucault's concept of a new style of governance in modernity has been prominent in the development of governmentality frameworks. Foucault (1984, p 102) emphasizes an “ensemble formed by the institutions, procedures, analyses and reflections, the calculations and tactics that allow the exercises of this very specific albeit complex form of power.” It is this ensemble that emphasizes certain risks for the public and thus creates a 'need' for management, either by institutions or individuals (Carter, 1995; Lupton, 2013; Williams et al., 1995; Zinn, 2008). Although there is no unified approach in studies of governmentality, authors influenced by this theory talk about the ways in which individuals are subjected to subtle forms of power deployed through risk discourses (Zinn, 2008). The governance system works through the production of the 'at-risk' self and the public's perceived need for self-examination. In this way, responsibility for managing risks is diffused throughout the social body (Faulkner, 2009; Petersen, 1997). This is evident, for example, in Faulkner's (2012) study of a prostate screening test in the U.K. that created additional anxieties for patients through prevention discourses. In this case, wide advertising of the test along with routinization caused increased public perception of risks. Genetic risk and surveillance, in particular, have caught the attention of scholars (Gibbon, 2006; Kerr and

Cunningham-Barley, 2000; Novas and Rose, 2000). Although they acknowledge the creation of the 'at-risk' individual, Novas and Rose (2000) claim that risk induces new relations and reinvents personhood at the genetic level by transforming patient-expert relationships – relationships that can benefit from new conceptualizations of risk. Conversely, others (Gibbon, 2006; Kerr and Cunningham-Barley, 2000) argue that reductionism and determinism continue to dominate risk science, while surveillance practices are still powerful. In addition, scholars (Klawiter, 2010; Murphy, 2010; Shim, 2014; Wynne, 1996) have noted that lay knowledge is currently undermined by institutions involved in the study of risk.

Various feminist and qualitative approaches have been used to understand risk as it relates to medicine and the experiences of women (e.g., Brown, 2015; Ettorre, 2012; Finucane et al., 2010; Gifford, 1986; Henwood et al., 2008; Klawiter, 2010; Martin, 2010; Mishra and Graham, 2011; Shim, 2000; Stevens, 2016). Out of these, several have explored how female bodies are constructed as sites of risk (Brown, 2015; Fosket, 2004; Klawiter, 2010; Martin, 2010; Stevens, 2016). Technologies can facilitate such processes in various ways through: the development and standardization of assessment tools (Fosket, 2004), preventative drugs (Brown, 2014; Fosket, 2004), biomedical knowledge production (Shim, 2000), and expert advice (Stevens, 2016). By studying the standardization of breast cancer assessment tools, Fosket (2004) underlines how certain risk models become prominent and widely used despite significant concerns regarding their accuracy and validity. The development of medical assessment tools can construct healthy women as 'at-risk' due to modern discourses that pathologize risk itself (Fosket, 2004). In the case of contraceptives, women are seen as constantly in danger of getting pregnant (Brown, 2015). As a result, professionals endeavour to control fertility risks through the prescription of highly effective contraceptives. Regarding the measurement of medical risk, scholars have noted tensions between biomedical knowledge production and lay perception of risk (Shim, 2000; Stevens, 2016). Through a critical analysis of the factors that go into epidemiological risk

assessments, Shim (2014) stresses that risk measurement in the epidemiology of heart disease, is something that is socially mediated and influenced by structural inequalities. As such, the way in which experts perceive risks and their effects on large populations can be in contradiction with the lived experience of those affected by diseases.

Technology, Contraception, and Risk

Technologies designed specifically for women, such as the contraceptive pill, become entangled with gendered norms (Bray, 2007). There are many studies of technology that have been inspired by constructionist approaches, but only a small number deal with gendered artifacts. However, Bray (2007, p. 37) notes that “one of the fundamental ways in which gender is expressed in any society is through technology.” Feminist scholars studying technoscience often use the term 'coproduction' to designate the dialectical shaping of gender and technology. The concept is intended to highlight a performative and processual character that characterizes both gender and technology (Bray, 2007). Its use is helpful when trying to avoid the analytical and political dangers of essentializing either identity or technology (Faulkner, 2009). Cowan (1983), for example, in her analysis of gender and technology, shows how, despite the proliferation of household technologies, women have devoted just as much time to household chores in recent times as they have during colonial times. Cowan (1983) also places considerable emphasis on the intersection between consumers and technologies in a way that embeds artifacts into consumption networks. There is an interesting parallel between this example and hormonal contraceptives. Such technologies and their development are also influenced by commercialization and industry interests: they are not only designed for pregnancy prevention, but also as a product that must be sold and thus appeal to users. To further emphasize the dialectical relationship between technology and identity, scholars have argued that gender can be constitutive of what is recognized as technology (Bowker and Star, 1999). This has been evident in the case of information technology, where competence is intertwined with ideas about gender and ability. Normative ideas

about gender can become embedded within an artifact before users even start engaging with it. Assumptions about users influence the production of technologies and their assessment. The work of Oudshoorn and Pinch (2003) emphasizes the role of users, their uptake of technologies or resistance to them, as well as ideas individuals themselves that are reflected in technologies. This framework has been especially useful to feminist scholars of technology who have sought to understand the role of women in technological change as well as the ways in which certain contraceptive technologies have reinforced gender inequalities.

Although risk is not always the focus of their enquiry, scholars have looked at several scientific and technological debates surrounding contraception. Technologies investigated include the contraceptive implant Norplant (Watkins, 2010, 2011), the IUD (Takeshita, 2004, 2012), the male condom (Tone, 2002), the female condom (Kaler, 2004), the Dalkon shield (Grant, 1992), and male contraceptives (Oudshoorn, 1999, 2004). Such studies have stressed both the multiple meanings that technologies can take as well as the input of different stakeholders into shaping these meanings. Diverse discourses have been used to convince potential users to adopt new contraceptive technologies. For example, the first IUDs were coupled with the promise of increased sexual freedom (Takeshita, 2004), while the female condom was 'sold' as a technology of empowerment for women (Kaler, 2004). After the initial hype, however, some contraceptive technologies fail to materialize their promises. Such is the case of Norplant, an implant with a modest uptake (Watkins, 2010) and the Dalkon shield, an IUD which was withdrawn after causing incidents of pelvic inflammatory disease (Grant, 1992). What becomes evident from historical studies of contraception is that such technologies need to embed themselves in legitimizing cultural discourses, whether they are gendered discourses (Oudshoorn, 2004), population discourses (Kaler, 2004), or more recently, consumerist discourses (Watkins, 2011). Oral contraception has also been susceptible to various legitimizing discourses over the course of history: from its initial covert presentation as a menstrual problems treatment for married women to

population control device to modern lifestyle drug.

The pill as related to gender and discourses about women users has received significant attention from scholars (e.g., Fennel, 2011; Littlejohn, 2013; Mamo and Fosket, 2009; Ortiz-Gomez and Ignaciuk, 2015; Tone, 2006; Vitale, 2005; Watkins, 1998, 2012; Wigginton et al., 2015). While some have focused on the gendered meanings of side effects and marketing (Fennel, 2011; Littlejohn, 2013; Mamo and Fosket, 2009; Tone, 2006; Watkins, 2012), others have discussed how the pill was received in different contexts, such as Japan (Vitale, 2005) and Spain (Ortiz-Gomez and Ignaciuk, 2015). However, less attention has been paid to the risk evaluation of oral contraceptives, in particular. Some have noted that early on during clinical studies on oral contraceptives, the degree of health risks considered acceptable for women was compared to the risks that would be posed to them by an unplanned pregnancy (Lane, 1995; Van Kammen, 2000). Therefore, right at the outset, women's bodies were perceived as a site of potential reproductive risks against which unpleasant side effects were being measured (Marks, 2000). According to scholars (Hanbury and Eastham, 2016; Oudshoorn, 2004; Van Kammen and Oudshoorn, 2002; Watkins, 1998), the concept of risk is deeply related to how ideas about gender are incorporated into hormonal contraceptive technologies. On the other hand, authors have noted that, generally, men's bodies are not conceptualized a site of risk (Oudshoorn, 2004). In a risk assessment that focuses on the dangers of childbearing and unsafe abortion, “the possibility of health risks for men falls outside of the equation” (Van Kammen and Oudshoorn, 2002, p. 440). In her study of male hormonal contraception research and development, Oudshoorn (2003) explores how the lack of expertise, material resources, and industrial involvement have stalled the development of a male pill, but also how gendered norms resist the feasibility of such a technology. In addition to living in a culture where the male reproductive system is under less scrutiny and institutional surveillance than the female body, a new contraceptive technology has to change gendered discourses on family planning (Oudshoorn, 2003). It is often assumed that men would not have any interest in being responsible for

family planning or controlling their fertility (Oudshoorn, 2003, Chapter 6). Also, research on risks posed by hormonal compounds for men have centred on sexual function - a concern directly influenced by hegemonic constructions of masculinity as potent and virile (Oudshoorn, 2003, Chapter 5). However, for women, no such concerns existed initially. For example, loss of libido was a side effect that was not even discussed in clinical studies until the mid-late 1990s, 40 years after the pill appeared on the market (Van Kammen and Oudshoorn, 2002). In addition, Van Kammen and Oudshoorn (2002) have noted that medical professionals tend to conflate efficacy with safety. Since hormonal contraceptives have a higher efficacy rate, they are presented as a more desirable method than condoms, for example. However, the fact that condoms pose no health risks is not emphasized as a benefit. Side effects (or lack thereof) are brushed under the guise of increased efficacy.

Social dimensions, such as notions about the female body and the perceived gendered appeal of lifestyle benefits, contribute to perceptions of risk factors associated with these technologies (Mamo and Fosket, 2009). To stress the cultural environment in which women make contraceptive choices, authors (Fennel, 2011; Hanbury and Eastham, 2016; Mamo and Fosket, 2009; Watkins, 2012) have discussed the marketing of pills – an aspect that can further affect risk perceptions. In a qualitative study of diverse women's experiences with the pill, Littlejohn (2013) stresses the importance that gendered appearance expectations play into users' decisions regarding contraception. Risk perceptions are especially susceptible to the marketing of such products, which, now more than ever, promotes their ancillary benefits rather than pregnancy prevention as a pill’s primary selling point (Watkins, 2012). Furthermore, the touted lifestyle benefits are gendered, as well – aimed towards correcting physical features (e.g., acne, hirsutism) that have been constructed as problematic by cultural norms of feminine beauty. Aside from side effects such as weight gain, nausea, headaches, and the likes, hormones increase the risk of blood clots, heart attacks, and cervical cancer severely when compared to women who are not users of hormonal contraceptives. The non-threatening side effects that might often

interfere with a woman's daily functioning are often considered negligible in light of the more severe effects. Even when risk assessment started to shift toward attempts to balance the risks with the benefits, women's bodies have still been seen as being a relatively acceptable site of risk. Generally, scholars note that the lay assessments of the severity of non-threatening side effects coming from women have not been taken seriously enough, especially in comparison to those of men (Marks, 1999; Van Kammen and Oudshoorn, 2002; Watkins, 1998).

Previous work has established that cultural factors and gendered norms, especially, play an important role in shaping opinions about the risks of contraceptives and risky technologies more generally. Individual risk perception depends on many factors, including one's characteristics and positionality. Evaluating risk itself is a process with different outcomes depending on one's gender and race (Finucane et al., 2010), where women and people of colour are more likely to view technologies as risky. In addition, women have been found to be more pessimistic than men about technologies and dangers that are societal in nature, such as commercial nuclear power and CFCs (Cutter et al., 1992). Studies have also shown that individuals perceive risks differently based on their source: natural or human-made (Brun, 1992; Keogh, 2005). Consequently, they tend to be less critical of risks that are seen as having a natural source (Keogh, 2005). This is an important distinction to be made because oral contraceptives can be seen as a human intervention onto a perceived natural body with natural reproductive functions. Social and cultural influences (e.g. media visibility of risks, public controversy, personal beliefs, etc.) play an important role in individual risk perceptions (Douglas and Wildavsky, 1983; Douglas, 1986). In the case of contraceptive controversies, there is some evidence that media coverage amplifies user perception of risk (Allison et al., 1997; Bartnett and Breakwell, 2003; Flamiano, 2013). The 1995 U.K. pill scare, where a number of women stopped taking the drug in light of new risk information, has been used by scholars to show the dramatic impact that the media can have on contraceptive practices (Allison et al., 1997; Bartnett and Breakwell, 2003). There is currently

little doubt that the marketing and research practices of pharmaceutical companies impact professional and consumer practices. The role of pharma in shaping medicine, markets, and consumer perspectives has been highlighted by several scholars (Abraham, 2008; Busfield, 2006; Fisher and Ronald, 2010; Fishman, 2004; Fox et al., 2006; Greene and Watkins, 2015; Loe, 2001; Watkins, 2002; Williams et al., 2008), with most being critical of companies' involvement in the development of new products and risk communication practices. While Greene and Watkins (2015) make the case that drug package inserts are not an adequate way to convey risk information to consumers, Abraham (2008) argues more broadly that sociologists should renounce neutrality and be critical of neo-liberal drug markets. To stress political aspects of drug markets, authors highlight how pharmaceuticals can become entangled with the creation of new disorders (Fishman, 2004), normative conceptions of gender and sexuality (Fishman and Mamo, 2002; Loe, 2001), as well as new connections between the public and private sector (Fishman, 2004; Williams et al., 2008). Most importantly, as this thesis also stresses, pharma companies are “involved in scientific 'fact making' in the clinical trials of drugs designed to assess their safety and effectiveness” (Busfield, 2006, p. 241).

Work informed by public health perspectives has provided some information on contraceptives users and risk, usually through survey and structured interview data collection. However, such studies are focused on strategies for improving usage of the pill. As such, they tend to highlight the accuracy of professional views over those of users. Nonetheless, this literature is useful for highlighting larger trends in how women perceive the risks of hormonal contraceptives. A number of authors have highlighted some of the concerns that users have with hormonal contraception (Emmett and Ferguson, 1999; Harrington et al., 2015; Nelson and Rezvan, 2012; Peiper and Gutman, 1993; Sihvo et al., 1998). It is well known that women experience side effects while on the pill and this affects their willingness to continue with hormonal contraception. As a consequence, some studies aim to show that women are not always informed about all the risks and benefits that oral contraceptives offer. For example, Peipert

and Gutman (1993) have found that approximately 40% of women surveyed believed there are substantial risks to OC use, while the majority were not aware of health benefits such as decreased risks of endometrial and ovarian cancer. Similarly, Nelson and Rezvan (2012) found that hormonal contraception is generally perceived as riskier than pregnancy. This highlights a key difference between lay and expert risk-assessments: while health professionals emphasize pregnancy as posing more risks, users are more likely to perceive OCs as risky instead. While experts tend not to make distinctions between the source of risks (natural vs. human-made), users do, as highlighted above. However, this is generally an aspect that has received less attention in studies of user perception on the risks of contraception. On the other hand, there have been some attempts to better understand women's experience with side effects, such as mood swings, headaches, nausea, spotting, and loss of libido. For example, Harrington et al. (2015) as well as Sihvo at al. (1998) highlight women's concerns regarding these particular side effects. These concerns affect risk perceptions as well as compliance with an oral contraceptive regimen. Additional factors that affect compliance include efficacy, attitudes of male partners, relationship status, and misinformation about pregnancy risks (Reed et al., 2014). Women who are less concerned about efficacy and in a stable relationship with a partner who is willing to take responsibility for contraception are less likely to use the pill (Reed et al., 2014). Whether or not a woman has taken an oral contraceptive before can also affect risk perception: those who have not taken a pill in the past are more likely to perceive it as risky (Emmett and Ferguson, 1999). However, what such studies have in common is an assumption that health professionals have a more accurate view of risks and that women users should adopt these views. In this thesis, I seek to explore patient assessments without suggesting they should be perceived as erroneous. Rather, user concerns reflect a different positionality, as sociological approaches to risk have shown. For both professional and lay views, this thesis emphasizes the cultural context in which contraceptive risk assessments are performed.

RESEARCH DESIGN

Research Questions

The overarching aim of this thesis is to investigate the risk/benefit assessment of new and controversial pills Yaz and Yasmin through an in-depth analysis of stakeholder perspectives and regulatory processes. I have formulated my specific questions in light of the need to better understand how the risks of oral hormonal contraceptive technologies are developed, negotiated, and perceived. The research presented in the three articles that comprise this thesis was guided by several related research questions:

1. How are the risks and benefits of drospirenone-containing pills evaluated in the Canadian context by different stakeholders and what risk models emerge as a result?
2. How are levels of acceptable risks associated with Yaz and Yasmin determined and negotiated?
3. What cultural factors play a role in risk evaluations of these controversial pills?
4. How do professional and lay perspectives differ and what do these differences lend to the debates about the pill's safety?

I define 'acceptable risk' as the maximum cumulative health risk that medical and regulatory experts will allow for a contraceptive pill to enter and stay on the market and available to consumers. 'Unacceptable risk' is the risk threshold that would prompt regulatory bodies to pull a drug off the market or prevent its approval. For women users, however, I define 'acceptable risk' as the maximum health risk they are knowingly willing to assume when taking an oral contraceptive.

Methodological Framework

To analyze controversial contraceptives Yaz and Yasmin, this research draws on work from the Social Construction of Technology (SCOT) and the approach to the study of technology that it outlines. SCOT scholars seek to analyze the social contexts in which technologies or "artifacts" emerge. Sociologists working in this tradition consider technological controversies to be fertile ground for the

study of social processes that reveal themselves in such contexts. SCOT scholars have used the metaphor of the “seamless web” to designate the interconnections between technology and society (Bijker et al., 1987) and to emphasize the social environment as a point of departure for the study of technology (Pinch and Bijker, 1987). They argue that the social groups that are involved in the development of an artifact play a critical role in defining and solving the problems that arise during this process. Outlining the assumptions of the SCOT approach, Bijker and Law (1994) stress that: 1) technology has no developmental logic; 2) conflict and/or difference give rise to technologies; and 3) the consequences of technologies are emergent phenomena and thus cannot be fully anticipated. When problems that arise during technological development have been solved, 'closure' has been reached (Bijker and Pinch, 1987), meaning that social groups either see the problem as solved or they redefine it and solve it via a different route. Closure is not always final, however, as social groups can reinterpret the technology. This is a consequence of interpretative flexibility – a technological artifact having different meanings for different groups. This flexibility is especially relevant to the pill – an artifact which has been linked to several challenges to its safety and has been given different meanings over the course of history (e.g, menstrual regulator, fertility control device, lifestyle drug, etc.). SCOT scholars have looked at controversies as a prime example of how social forces shape the technologies that users adopt.

This study takes a similar approach in that it seeks to understand larger risk/benefit assessment processes through the study of the drospirenone controversy and its actors. Venturini (2010) identifies several reasons why scholars of science and technology should study controversies: 1) controversies involve a variety of actors and viewpoints; 2) controversies reveal the social in one of its most dynamic forms; 3) controversies are resistant to simplifications and reductionism; 5) controversies involve challenges to things and ideas that were taken for granted. In order to study scientific controversies, emphasis is placed on looking at discourses/statements, cited literatures, actors, as well as their

embeddedness in larger networks and structures.

However, in order to account for inequalities in contraceptive risk assessment (e.g., pharma involvement and gendered risk conceptualizations) already emphasized by other scholars, I employ a more critical, and thus slightly modified SCOT approach to my study. SCOT has traditionally looked at technology through an agency-centered approach that tends to de-emphasize systemic limitations. However, as Klein and Kleinmann (2002) argue, it is also important to look at structure and the constraints it might place on the development of artifacts. In the present case, for example, a priori norms and assumptions partly govern the development of contraceptive technologies. SCOT maintains that technology is the result of interaction among distinct social groups, typically through consensus that is reached via negotiation (Pinch and Bijker, 1987). Nonetheless, systemic power inequalities might also be considered simoultaneously (Klein and Kleinmann, 2002).

To address the limitations of SCOT and to incorporate previous work that stresses inequalities in the development and risk assessment of contraceptives, I use critical discourse analysis (CDA) as the lens of analysis. Fairclough (2013) distinguishes between 'critical' and 'descriptive' goals in discourse analysis. He stresses that adopting critical goals means elucidating taken-for-granted background knowledge or "naturalizations," while making "clear social determinations and effects of discourse which are characteristically opaque to participants" as "these concerns are absent in currently predominant 'descriptive' work on discourse" (Fairclough, 2013, p.31). Furthermore, "the critical approach has its theoretical underpinnings in views of the relationship between 'micro' events (including verbal events) and 'macro' structures which see the latter as both the conditions for and the products of the former, and which therefore reject rigid barriers between the study of the 'micro' (of which the study of discourse is a part) and the study of the macro" (Fairclough, 2013, p.31). I use CDA not only to find common risk discourses in my data, but also to identify neglected areas and assumptions that need further unpacking. This study explores what are some of the potential

connections between historical risk assessments of hormonal contraceptives and the professional response to the Yaz/Yasmin controversy. As such, I focus on an analysis that encompasses "dialectical relations between discourse and other objects, elements or moments, as well as analysis of the 'internal relations' of discourse" (Fairclough, 2013, p. 4). In addition, CDA is a useful tool to study discourses while also paying attention to the ways in which it can reproduce social and political inequalities. As stressed above, this study takes the position that the development and evaluation of contraception occurs in a sociopolitical context in which certain actors have more power to define dominant risk discourses.

Empirical Data

In order to fulfil the objectives of this research project, I employed a variety of qualitative data collection and analytic methods. The purpose of the questions above is to shed light on the social meaning ascribed to risk evaluation models of hormonal contraceptives. To achieve this, I interrogate social processes and mechanisms through which risks are produced and evaluated – phenomena that can best be looked at through careful analysis of relevant documents and stakeholder risk discourses. Data for the thesis consist of key medical, epidemiological, and legal documents as well as in-depth interviews with 43 stakeholders, both lay and professional. Data collection spanned 20 months from August 2015 to March 2017. Prior to data collection, the study received ethics approval from the Institutional Review Board of McGill University.

Content Analysis

First, I conducted a content analysis of documents that pertain to the research and development of drospirenone-containing contraceptives. These include: 1) North American regulatory and professional press releases and official responses to the drospirenone controversy, 2) product monographs for contraceptive pills containing drospirenone, 3) transcripts of regulatory meetings in which risks of Yaz and Yasmin were debated, 4) SOGC and Health Canada contraception guidelines, 5)

all published epidemiological studies of the VTE risks of drospirenone, 6) all legal documents generated by Canadian class action lawsuit proceedings against Bayer. In total, these documents amounted to approximately 1800 pages of text. Below, I provide details about the documents and how they were collected.

As part of official responses, I analyzed professional associations and regulatory bodies' responses in North America to the amplification of the drospirenone controversy in the media between 2010 and 2015. I specifically looked at documents from the FDA, Health Canada, The American Congress of Obstetricians and Gynaecologists (ACOG), and The Society of Obstetricians and Gynaecologists of Canada (SOGC). Although my research is focused on the Canadian context, some FDA and ACOG documents were consulted. Throughout my research, I found the Canadian and U.S. contexts to be very similar – an aspect that was also stressed by professional interviewees who talked about a North American context as opposed to a Canadian one. In addition, several Canadian experts interviewed cited FDA decisions in their conceptualizations of risk. As such, I found it fruitful to look at U.S. regulatory and professional data alongside Canadian data. However, this thesis makes no claims about U.S. patient or clinician practices. Some FDA and ACOG documents are included because they represent expertise that does play a role in Canadian stakeholders' views, as stressed by them. Regulatory data specifically (advisory meeting transcripts and official statements) from the FDA were included in the sample also due to the fact that they discuss data from international studies that have played a role in the Canadian controversy and beyond. Furthermore, many stakeholders are not confined to a specific country, as experts reside in several different countries. Most importantly, there are further similarities and connections to the Canadian context to justify the inclusion of regulatory U.S. data: 1) clinicians interviewed talked about the North American context as being overall different from the European one, 2) most Canadian patients interviewed expressed being exposed to U.S. ads for Yaz and Yasmin, 3) Canadian legal cases cite information from the FDA, and 4) Health Canada and the

FDA have been releasing very similar official statements and risk information to consumers.

Epidemiological studies on drospirenone and product monographs can be found on PubMed and Health Canada databases, respectively. There have been just over 20 studies published (including meta-analyses) that deal specifically with drospirenone and VTE risks. I also looked at expert debates in epidemiological journals, as some studies received critiques in editorial sections. Canadian contraceptive guidelines were retrieved from Health Canada and SOGC databases. These documents also provided the names and contact information for Canadian clinicians who are involved in writing practice guidelines. In addition, documents filed by lawyers for Yaz and Yasmin class action lawsuits can be found on legal databases for public view. These include detailed charges and an outline of the risks that are under discussion. Canadian class action lawsuits in against Bayer, the makers of Yaz and Yasmin, have been underway in Ontario since 2014, while Quebec and Saskatchewan have only recently had their class actions certified by judges. Despite proceedings moving very slowly, the initial stages have generated several documents released by plaintiffs and Bayer outlining charges and official positions regarding risks taken by both sides. I analyzed existing legal documents in order to interrogate how acceptable risk is negotiated between pharmaceutical companies and consumers through the use of socio-legal discourses and to explore potential intersections between legal and medical arenas.

In-depth Interviews

I conducted 43 in-depth interviews with key stakeholders, including regulatory representatives, epidemiologists who have conducted studies on drospirenone and VTE risks, Canadian medical doctors involved in writing contraceptive guidelines, as well as affected Yaz and Yasmin users residing in Canada.

A total of 19 medical, epidemiological, and regulatory experts were interviewed as part of this study. I identified epidemiologists that have been involved in measuring the VTE risks of drospirenone-

containing pills by performing author searches on various databases. The most prominent ones were identified on the basis of their publishing record and citation frequency in the guidelines and regulatory documents described above. Those whose studies were cited by Canadian professional associations or health regulatory bodies and have published at least one article on the risks of drospirenone-containing pills were contacted for an interview via email. Out of 28 authors contacted, 10 agreed to be interviewed for this study. Four out of the 10 interviewees had industry ties, while four of the 10 authors were both clinicians and researchers (six were epidemiologists only), thus offering a variety of perspectives, informed by clinical practice or not. In addition, individuals working for Health Canada and the FDA who are involved in contraceptive drug regulation and risk assessment were contacted through government websites and by phone. Regulatory officials were more reluctant than other groups to participate in the study. However, by the end of the study, I secured one interview with a Health Canada official and one with an expert from the FDA. I also contacted medical doctors who have developed Canadian clinical practice guidelines related to drospirenone and VTE risks. Potential participants were identified from documents published by SOGC. Out of 17 authors contacted via email, seven agreed to be interviewed for this study. Individuals in this group were involved to different degrees in both research and clinical practice. With the exception of two experts, all interviews with professionals were conducted over the phone, as most live outside Quebec and some in other countries.

Additionally, 24 users were recruited from groups that have discussed the risks of new oral contraceptives online. Participants (women over 18 years old who have used drospirenone-containing pills for at least two months and residing in Canada) heard about the study through online websites and forums for Yaz and Yasmin users. After receiving approval from administrators, I posted recruitment ads on various Facebook groups and website forums where women have shared their experiences with Yaz and/or Yasmin. The forums that are aimed towards creating a sharing space for those who have been negatively affected by these pills are managed either by law firms involved in Yaz/Yasmin

litigation or by oral contraceptive users whose health has been affected by the use of drospirenone-containing pills. One of the most visible Canadian forums is run by one of the Ontario law firms involved in litigation (McKenzie Lake). It appears on Facebook under the name Take Your Body Back. Here many women and families affected by these drugs have shared their experiences with adverse side effects and even the loss of women close to them. Other forums where the study was advertised include survivor groups on Facebook, yasminandyaz.blogspot.ca, yazsurvivorcenter.wordpress.com as well as reddit.com, one of the most popular forums on the Internet, with thousands of participants, and particular "threads" (i.e., subreddits) that discuss contraceptive options and experiences. Interviewees are women that have been vocal about the risks of drospirenone online and through involvement in lawsuits - key stakeholders in the Yaz/Yasmin controversy. In total, 24 interviews were conducted with affected users. This sample is not random and generalizations cannot be made based on it. However, it represents a fairly diverse population in terms of age groups and and geographical locations within Canada. Interviewees' place of residence varied across six Canadian provinces: Ontario, Alberta, Quebec, Prince Edward Island, New Brunswick, and British Columbia. The women's ages ranged between 21 and 56, with median age being 27. There were no major socioeconomic disparities among respondents with most being from a middle class background based on their residence, occupation and income. 22 were white, while only two were women of colour (self-identified as Middle Eastern and South East Asian respectively). Due to their location outside the Montreal area, in-person interviews were not feasible. As such, all patient interviews were conducted over the phone.

I developed two main interview guides: one geared towards women who have taken Yaz or Yasmin and the other one geared towards medical experts who have been involved in the scientific assessment of risks associated with drospirenone-containing pills (see Appendices A and B). Although slightly different sets of questions were developed for users and experts, both interview guides focused on asking participants how they perceive the risks and benefits of the latest generation of hormonal

contraceptives. Specifically, I asked questions on which risks and benefits they consider important and how significant they perceive the risks to be and why. Data were analyzed for common themes that emerged from both patient and expert interviews. I aimed to examine if the following have an effect on risk analyses: notions about contraceptive efficacy and failure, attitudes towards potential outcomes of contraceptive failure (abortion and unintended pregnancy), as well as the trend of marketing the ancillary benefits oral contraceptives. I also paid close attention to any other reasons that affect evaluations.

Data Analysis

Analysis of documents and interview data proceeded along a continual process that involved literature review, coding, and memo writing. I entered all data into MAXQDA, a software package for organizing and analyzing qualitative data. I then coded all of the documents and interviews both deductively, using themes derived from the literature, and inductively for emergent themes. Transcribed materials from in-depth interviews were analyzed using the principles of grounded theory. I used this method alongside critical discourse analysis (CDA) to study the data. Grounded theory was primarily used to guide the process of analysis, from coding to developing larger themes. CDA, however, facilitated applying a critical lens to the codes and themes that emerged from using the principles of grounded theory.

Grounded theory seeks to identify the social processes and conditions that underlie phenomena. This method was especially suited to this study because the processes studied have not been fully articulated, and comparisons between data from multiple sources were an important part of the study. According to grounded theory principles, some of the themes/codes may be influenced by pre-existing theories. However, this method also allows for new themes to emerge. After my initial literature review, I proceeded to examine the data line by line and code both by paying attention to pre-existing concepts and by looking at new emerging ones. This process was followed by grouping codes together to find

common categories. In addition, I kept notes for each of the categories identified in order to lay out specific observations and insights. Further elucidation of the relationship between these categories occurred through writing and consultation with the literature. Once larger themes emerged, my next step was to link them to the existing literature in order to better understand how the findings relate to previous work and how they might further knowledge on contraception and risk. Each article uses relevant data to contribute to specific sets of literature.

First and foremost, the data were coded and analyzed to highlight differences and similarities between the risk perceptions of different stakeholders. I paid close attention to: 1) risks and benefits mentioned, 2) risks used as comparison points, 3) opinions on risk data, 4) opinions about weighing risks/benefits, 5) risk communication, 6) opinions on regulatory processes, 7) comparisons between contraceptive methods. Furthermore, I identified codes that were not necessarily informed by research questions, but emerged organically (e.g., the role of pharmaceutical companies, patient injury, contention regarding benefits). Data from expert interviews were corroborated with data from the content analysis of regulatory documents to see if opinions converge or if experts express different positions in different venues. Similarly, patient and expert data were also examined for similarities and differences. I used critical discourse analysis to identify areas and assumptions that needed to be further unpacked. This study explores some of the connections between problematic historical risk assessments of hormonal contraceptives and the Yaz/Yasmin controversy. As such, in light of the previous literature outlining issues affecting patients, I decided to pay critical attention to ideas and practices that might impact women users.

OVERVIEW OF THE THREE ARTICLES

Each article contributes to slightly different yet related bodies of literature. Some overlap of materials across the articles is necessary in order for each of them to be comprehensible on its own. However, each manuscript approaches the Yaz/Yasmin controversy from a different angle in order to

reveal key issues related to contraceptive risk assessment.

In Chapter 2, I examine how North American regulatory bodies and professional associations have responded to the Yaz/Yasmin controversy. Following an investigation into the health risks of drospirenone, professional stakeholders concluded that the potentially increased risks do not mandate pulling the new pills off the market. By looking at official statements and press releases, I analyze how risk information about drospirenone-containing pills has been presented to the public and what strategies have been used to assure users of the contraceptives' safety. More specifically, I ask how do professionals put contraceptive risks into context for users? Which risks are prevalent in their discourses? Which risks are absent? How do regulatory bodies assure users of the safety of drospirenone-containing pills? Prevalent risk models used by professionals are emphasized and examined through the use of critical discourse analysis methods. One of my main findings is that risks related to pregnancy and the postpartum period are heavily emphasized in professional discourses. At the same time, other risks and side effects associated with hormonal contraception, more generally, are downplayed. In addition, I found that there were no risk comparisons between different contraceptive methods. I argue that professionals' emphasis on risks associated with pregnancy is underlined by normative beliefs about women's bodies and sexuality. This article contributes to studies that show how the risk assessment of contraception is gendered. More broadly, it also contributes to the literature addressing issues related to gender in the development and assessment of technology. This paper has been published in *Social Science and Medicine* in August 2016 (see Geampana, 2016).

In Chapter 3, I look at lay stakeholders' experiences and views on the new generation of contraceptive pills. More specifically, I analyze how affected women view the risks of Yaz and Yasmin. Drawing on data from in-depth interviews with Canadian contraceptive users, I look at the ways in which affected consumers understand the risks of hormonal contraception and advocate for changes in risk communication and drug regulation. My first finding is that interviewees do not think they

received adequate risk information to make an informed decision when choosing a contraceptive method. Women also felt, as a consequence, that they were not prepared to identify VTE symptoms. In contrast to professional risk discourses, users do not think that pregnancy risks are a useful comparison point for placing the risks of hormonal contraception in context. I found that patient views were generally underscored by a critique of professional risk/benefit assessment. This paper contributes to the qualitative literature on user attitudes towards the risks of hormonal contraceptives. In addition, it addresses an understanding gap that exists in survey data of user views, as it provides a more in-depth explanation of women's perception of risk. As affected patients' experiences with hormonal contraception have been under-explored, I seek to extend discussions of contraceptive risk assessment to lay stakeholder groups. An earlier version of this paper was presented at the American Sociological Association meeting in Montreal in August 2017.

In Chapter 4, I explore how information about contraceptive risk is debated by stakeholders and how diverging opinions are reflected in risk/benefit assessments. I specifically ask how uncertainty is managed systemically and to whom responsibility for risk management is assigned. This paper draws on all in-depth interviews with stakeholders as well as content analysis of legal, medical, and regulatory documents. My overarching argument is that contraceptive risk assessment is characterized by a diffusion of responsibility for risk management, with detrimental consequences for users who are left to make sense of risk information on their own. Firstly, I underline how experts disagree on the uniqueness of the drugs' benefits. I then show how epidemiological data is highly contested, thus affecting risk/benefit weighing for stakeholders. Finally, the paper stresses the issue of responsibility for risk communication in light of expert disagreement and systemic diffusion of responsibility. This research has found that it is the users that are encouraged to make sense of risk information individually, while professionals disagree on risk measurement without making a clear decision regarding the drug's risk/benefit balance. This paper extends an organizational risk perspective to the

study of contraceptive risk assessment. In showing how risk management is left to the individual, it contributes to studies of risk and its distribution in modern societies. An earlier version of this paper was presented at the 4S (Society for Social Studies of Science) meeting in Boston in August 2017.

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CHAPTER 2

PREGNANCY IS MORE DANGEROUS THAN THE PILL: A CRITICAL ANALYSIS OF PROFESSIONAL RESPONSES TO THE YAZ/YASMIN CONTROVERSY

ABSTRACT

The fourth and most recent generation of hormones used in oral contraceptives has stirred a significant amount of debate regarding the safety of these compounds. Drospirenone, a new type of synthetic hormone used in popular oral contraceptives Yaz and Yasmin, has been found by epidemiologists to increase the risk of blood clots when compared to the previous generations of pills. North American regulatory bodies have investigated the health risks of drospirenone and concluded that the increased risks do not require pulling the new contraceptive technology off the market. Instead, the FDA and Health Canada along with several medical associations have actively managed the Yaz/Yasmin controversy through official statements and press releases between 2010 and 2014. This study provides an analysis of these documents and how risk information about drospirenone-containing pills has been presented to the public. The analysis addresses a gap in our knowledge about cultural factors that impact contraceptive risk assessment. Prevalent risk models used by professionals are highlighted and examined through the use of critical discourse analysis methods. More specifically, this paper highlights the main strategies used to put drospirenone risks into perspective and classify it as safe. I argue that while risks related to pregnancy and the postpartum period are overly-emphasized, other risks are downplayed through a selection process underscored by normative beliefs about women's

bodies and sexuality. Future research needs to address consumer perspectives and bridge the gap between lay and scientific risk/benefit assessment of oral contraceptives.

KEYWORDS: North America; hormonal contraception; the pill; Yaz; Yasmin; drospirenone; risk assessment.

INTRODUCTION

Drospirenone (most often used in combination with ethinyl estradiol) is a hormonal compound that has been used in the latest generation of oral hormonal contraceptives (released in both Canada and the U.S. in the 2000s). Its use is mainly motivated by its properties in combating moderate acne – a beneficial side-effect that has been heavily marketed to potential consumers in ad campaigns. The most popular pills that contain drospirenone are brand names Yaz and Yasmin. The scientific/medical controversy ensued following informal reports in the media of the deaths of young healthy women due to severe blood clots caused by these contraceptives as well as epidemiological studies suggesting increased risk. The pill was widely painted in both the U.S. and Canadian media as 'deadly' with news outlets focusing on the number of deaths associated with the use of Yaz and Yasmin – tens in Canada and hundreds in the U.S. Thousands more have claimed damages in class lawsuits against Bayer across North America. The drugs have been linked to at least 23 deaths in Canada and over 100 in the U.S. as well as thousands of injuries worldwide (CBC, 2013). Governmental agencies such as Health Canada and the FDA commissioned studies which could assess whether the risk of blood clots or venous thromboembolism (VTE) increases with the new generation of pills containing drospirenone. More epidemiological studies seemed to indicate that drospirenone increases this risk when compared to the risk posed by the previous generation of hormonal contraceptives (Lidegaard et al., 2011). The controversial headlines and news reports continued as more and more inconclusive and conflicting studies were reporting their findings. However, in the late 2000s evidence seemed to suggest that drospirenone does indeed pose a higher risk of VTE than the previous hormonal compounds used in contraceptives. The exact increase varies between different studies: it has been found to be between 1.5 to 7 times increase in risk of VTE when drospirenone is compared to previously-used compounds (Wu et al., 2013). Following such reports, as well as the intensification of public disapproval, regulatory agencies and medical associations responded to concerns about risk through public statements and

discussions. This study investigates these responses and offers a critical analysis of risk/benefit assessments that professionals have used to evaluate popular, but controversial contraceptives Yaz and Yasmin.

Hormonal Contraceptives and Risk: a Long Debated Issue

The history of hormonal contraceptives has been riddled with discussions of safety and risk threshold acceptability. Several historians (Briggs, 2002; Marks, 2001; May, 2010; Tone, 2001, 2012; Watkins, 1998, 2007, 2012) have outlined the social context in which such discussions took place beginning with the story of Gregory Pincus, the famous 'father' of the pill, and the team of scientists and doctors that started developing the contraceptive compound. While initial trials proved the pill's efficacy, they did not prove its long-term safety. Doctor Edris Rice-Wray, a faculty member of the Puerto Rico Medical School and medical director of the Puerto Rico Family Planning Association informed Pincus that 17% of the women in the study complained of nausea, dizziness, headaches, stomach pain and vomiting and that a 10-milligram dose of Enovid (Searle's brand name for the first pill formulation) would be unacceptable (Watkins, 1998). Pincus and his associate John Rock quickly dismissed these concerns as psychosomatic. Confident in the efficacy of the pill, Rock and Pincus pushed for its approval for market sale.

A couple of years after the FDA approved the pill, discussion emerged within the closed circle of the agency and pharmaceutical companies that the pill posed more serious side effects than previously thought. There were several reports of blood clots, strokes as well as possible links to cancer. As early as 1962, Searle received reports of 132 cases of blood clots in pill users (Watkins, 1998). Eleven of the cases resulted in death. Searle maintained that there was no conclusive proof that the pill caused those deaths.

The publication of *The Doctor's Case Against the Pill*, a controversial book by feminist journalist Barbara Seaman, brought awareness about the pill's potentially dangerous side effects to the

attention of the medical establishment, the government as well as the general public. Although the book was not well received in some circles, it eventually influenced U.S. Senator Gaylord Nelson to convene Senate hearings on the safety of the pill. Weighing the pill's risks and benefits was not an easy task. Even those who agreed that the pill posed serious health risks to women were not sure how to weigh them against the benefits. The pill emerged in a social context where the population scare was a very real cultural phenomenon. Moreover, abortions were illegal at the time, leading doctors and patients to view a potential pregnancy as the outcome that must be avoided at all costs. Historically, both in the U.S. and Canada, abortion has been a contentious issue. Contraception was officially illegal in both Canada and the U.S. until the late 1960s, while abortion was only decriminalized in 1988 in Canada and became legal in the U.S. in 1973 (McLaren and McLaren, 1997). As such, abortion was never discussed as an alternative to pregnancy following a contraceptive failure. This remained the case even after abortion became safe and legal.

In 1967, a study published in the *British Medical Journal* finally established a link between oral contraceptives and the risk of blood clots (thromboembolism). This amplified the controversy at the time. More FDA studies and the pill hearings of the late 1960s ensued. The link between the pill and serious health risks such as cancer and thromboembolism became evident. However, Planned Parenthood and pharmaceutical companies continued to stress the relative safety of the pill. Feminist activists focused their efforts on getting the medical industry to share all the risk facts with pill users.

In later formulations the synthetic estrogen dosage was reduced. This is one of the reasons why the pill is widely perceived as getting progressively safer. However, what has received less attention are the changing hormonal compounds of the combination pill (estrogen and progestin). In its synthetic form, progestin can take many forms. In addition, over the past 20 years, the pill has become a lifestyle drug with added “quality of life benefits.” Following the 70s and the pill hearings, the pharmaceutical companies focused less on new methods and formulations and instead have tweaked older versions of

the pill and marketed them on the basis of their ancillary benefits. The functioning mechanism and relative health risks remained the same. For example, one popular brand, Ortho-Trycylen-Lo, was advertised as an acne treatment. The fourth and most recent generation of pills involves the drospirenone controversy discussed here.

LITERATURE REVIEW

Risk as a Social Construct

Sociological approaches to risk are a response to the need to analyze technological innovations (Beck, 1992; Lupton, 2013; Zinn, 2008). In analyzing issues of risk as they relate to oral contraceptive pills, I will draw on the sociocultural approach originally developed by Mary Douglas (1983, 1986). Douglas (1992) emphasizes the cultural and political dimensions of the concept of risk in public policy. She argues that an analysis of risk has to include cultural biases and that risk can be generally understood as a social construct (Douglas, 1992). Different groups of individuals look at different risk types and characteristics as a consequence of their specific social position, their part in organizations, and the organizations' role in the wider political culture (Gabe, 1995; Lupton, 2013). Medical professionals, as a result of their positionality, might be removed from the layperson's perspective on health-related risks. While lay knowledge of risk has been emphasized in some instances (Gabe, 1995; Lupton, 2013; Zinn, 2008), this study focuses on expert knowledge and its cultural embedding into gendered norms. From a conventional medical view, risk analysis can be said to involve “the scientific elucidation of damage mechanisms from different natural or technical processes, and the quantification of probabilities and consequences” (Williams et al., 1995, p.120). However, alternative notions of risk can and do exist (Franklin, 1998; Williams et al., 1995). These notions stem from the fact that scientific evaluations rarely take into consideration the social context in which risks occur. They also do not take into account how social norms might influence a process that is deemed scientific and objective.

While Douglas's cultural theory does not specifically question technical procedures for the

measurement of risk, it does criticize the depoliticization of risk issues. Douglas (1986) has been critical of the way in which institutions use risk discourses to control human behaviour uncertainty and to reinforce norms. The sociocultural perspective focuses on the ways in which risks are selected and presented to the public. As such, it critiques the scientific assumption that individuals are rational agents making decisions based on rational calculations. Decisions regarding what data should be presented to the public have been instrumental in risk perceptions of hormonal contraceptives, for example.

In the sociocultural tradition, scholars have documented the ways in which risk discourses construct reality and influence individual perceptions (Fortun, 2004; Fosket, 2004; Langston, 2008; Schmid, 2004; Timmermans and Leiter, 2000). Some risks have been continually downplayed by the media and governments. One example is the lack of strict regulations around the use of endocrine disruptors (Langston, 2008). However, risks can also be emphasized in order to mobilize populations. Such is the case of post-Chernobyl discourses that have been deployed strategically to gain authority, solicit change and reconfigure relationships between the state, experts, and the lay public (Petryna, 2013; Schmid, 2004; Wynne, 1992). Timmermans and Leiter (2000), in their study of the rehabilitation of thalidomide, discuss how the attention shift from thalidomide's risk of fetal birth defects to the risk associated with the female reproductive behaviour (through the collaboration of doctors, pharmacists, and patients) achieved a 'symbolic make-over' of a drug known in the 60s for causing severe birth defects in babies of women who were treated with it. Ultimately, the deployment of risk discourses has the power to 'transform' a technology from a risky one to a safe one or vice-versa. I draw on these concepts as well as feminist perspectives on science to look at professional risk discourses in the wake of the Yaz/Yasmin controversy.

Few social science scholars have looked critically at the current social and cultural risk evaluation of oral contraceptives and none of them in a North American context specifically. Some

have noted that early on during clinical studies on oral contraceptives, the degree of health risks considered acceptable for women was compared to the risks that would be posed to them by an unplanned pregnancy (Van Kammen, 2002). Therefore, right at the outset, women's bodies were perceived as a site of potential reproductive risks against which unpleasant side effects were being measured (Clarke, 2000; Marks, 2000). On the other hand, authors have noted that men's bodies are not conceptualized a site of risk (Briggs, 2002; Oudshoorn, 2003). Scholars have noted how risk assessment in contraceptives was not only an assessment of chemical compound changes within the body. Rather, the evaluation reflects vastly different concerns regarding the well-being of each sex and what is important to take into consideration for each one (Marks, 2000; May, 2010; Oudshoorn, 2003; Van Kammen, 2002). In her study of male hormonal contraception research and development, Oudshoorn (2003) explores how the lack of expertise, material resources, and industrial involvement have stalled the development of a male pill, but also how gendered norms resist the feasibility of such a technology. In addition to living in a culture where the male reproductive system is under less scrutiny and institutional surveillance than the female body, a new contraceptive technology has to change gendered discourses on family planning (Oudshoorn, 2003). It is often assumed that men would not have any interest in being responsible for family planning or controlling their fertility (Oudshoorn, 2003, Chapter 6). Also, research on risks posed by hormonal compounds for men have centred on sexual function – a concern directly influenced by hegemonic constructions of masculinity as potent and virile (Oudshoorn, 2003, Chapter 5). Women's gendered selves in contraception development, on the other hand, are constructed in relation to body images and appearance, as this study will further illustrate. Recent studies (Brown, 2015; Hanbury and Eastham, 2016) suggest that not only is women's sexual health associated with a high risk of STIs and unwanted pregnancies, the responsibility for managing this risk falls on women's shoulders, especially according to professional discourses. More generally, scholars have argued that, during trials, scientists often make political choices on what is

considered important and what is not in terms of risk assessment (Latour, 1987). It is these social and political choices that need further exploration, especially in the North American context, where contraceptive class action lawsuits are becoming more and more frequent, indicating a complex environment for consumer choices.

METHODOLOGY

This study looks at relevant professional associations and regulatory bodies' responses in North America to the amplification of the drospirenone controversy in the media between 2010 and 2014. Between these years, the media has been vocal about the potential death threat posed by popular contraceptives Yaz and Yasmin. The stories of young healthy women dying due to blood clots caused by drospirenone have made headlines at major news outlets both in the U.S. and Canada. Magazines also had feature-length articles on the dangers of the newest contraceptive compounds developed. I specifically look at documents from the FDA, Health Canada, The American Congress of Obstetricians and Gynaecologists (ACOG), and The Society of Obstetricians and Gynaecologists of Canada (SOGC), focusing on their statements, public documents, and press releases that followed the amplification of the drospirenone controversy. Both the U.S. and Canada have been included here due to the similarities between professional risk management strategies to the Yaz/Yasmin controversy in these two countries.

My sample includes all documents containing information about drospirenone contraceptives released by these organizations and available online (usually on their websites) either in the form of official guidelines, press releases or articles. This search retrieved a total of 23 documents that pertain to these associations' involvement with evaluating and regulating drospirenone-containing oral contraceptives (see Fig. 1 for sample details). While this is not a very large body of documents, it represents very dense data that are a result of months and sometimes years of organizational efforts to assess and respond to the Yaz/Yasmin controversy.

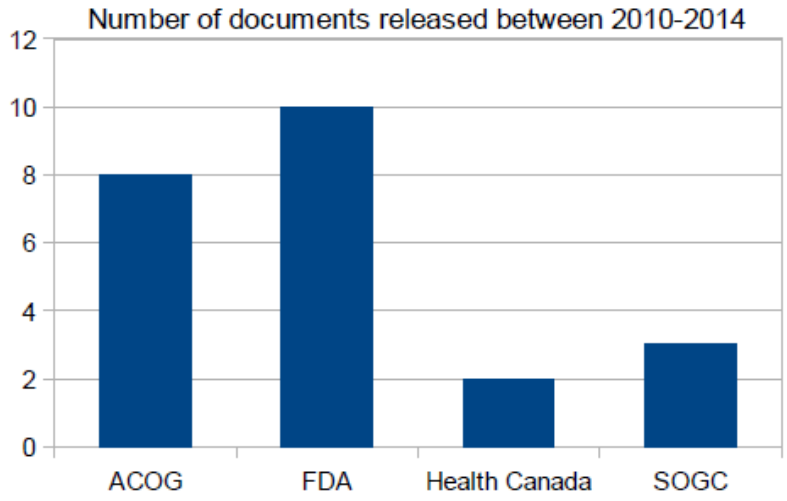

Figure 1

These data capture all official responses from ACOG, the FDA, Health Canada, and SOGC without leaving out any pertinent documents from these organizations. Analyzing written documents from the aforementioned associations accurately summarize official professional responses in North America for several reasons: 1) The FDA, Health Canada, ACOG and SOGC are the main organizations that influence decisions on whether or not to pull a new generation of contraceptives off the market. As such, they are the most important non-corporate decision-makers in the market regulation of contraceptives in North America. 2) The public defers to these organizations for relevant health information related to contraceptives. ACOG and SOGC regularly publish contraceptive guidelines that are then used by reproductive health care providers and patients. 3) In addition, ACOG and SOGC membership comprises of medical doctors who are the main prescribers of oral contraception. Their opinion on the risks and benefits of drospirenone-containing pills will likely be influenced by these organizations' official stance. It is also likely to be conveyed directly to women who express interest in hormonal contraception. 4) Documents such as the ones analyzed in this study have input from many

scientists, medical professionals and regulatory body officials. For example, guidelines by ACOG and SOGC sometimes have 15 or more physicians involved in their development. The FDA and Health Canada review drug safety and efficacy with the help of tens of different professionals including physicians, statisticians, chemists, pharmacologists, and other scientists. 5) Position statements on drospirenone-containing contraceptives are made after careful consideration of epidemiological studies. Whether or not organizations choose to see study results as valid or not, they do respond to the evidence presented by epidemiologists. As such, their positions are a result of lengthy data reviews, which suggests that official statements are weighty representations of professional views.

Using critical discourse analysis (CDA) as the main method of investigation, this study looks at how the risk information about Yaz and Yasmin is conveyed to the public in North American organizations' official documents and statements. I use CDA not only to find the most common themes and risk discourses in these documents, but also to identify neglected areas and assumptions that need further unpacking. This study also explores what are some of the potential connections between historical risk assessments of hormonal contraceptives and the professional response to the Yaz/Yasmin controversy. As such, I focus on an analysis that encompasses “dialectical relations between discourse and other objects, elements or moments, as well as analysis of the ‘internal relations’ of discourse” (Fairclough, 2010, p. 4). More specifically, the questions that inform my critical analysis are: 1) What kinds of risks and benefits are taken into consideration? 2) What is deemed as acceptable risk for women users of Yaz and Yasmin? 3) What risk comparisons are prevalent in professional statements? and 4) What elements are absent from risk benefit assessments? I define 'acceptable risk' as the maximum cumulative health risk that medical and regulatory experts will allow for a contraceptive pill that is on the market and available to consumers. 'Unacceptable risk' is the risk threshold that would prompt regulatory bodies to pull a drug off the market or prevent its approval.

FINDINGS

Questioning Data Quality

All organizations have developed their responses in light of epidemiological data available. Descriptions of studies are presented in most documents, sometimes with comments about the quality and validity of data. Both the FDA and Health Canada acknowledge potential increased risks as seen in their post-market approval enquiries into these risks and subsequent statements. For example, Health Canada (2011) states that "the review determined that drospirenone-containing birth control pills may be associated with a risk of blood clots that is 1.5 to 3 times higher than other birth control pills," while the FDA (2012), more vaguely, says that "drospirenone-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills." While assuring the public that all data showing VTE risk increases has been given careful consideration, critiques of epidemiological data validity do occur when studies with negative results are discussed:

> The studies also did not account for important patient characteristics (known and unknown) that may influence prescribing and that likely affect the risk of blood clots. For these reasons, it is unclear whether the increased risk seen for blood clots in some of the epidemiologic studies is actually due to drospirenone-containing birth control pills. (FDA, 2012)

> Two reports suggesting an increased risk of venous thromboembolism with drospirenone-containing oral contraceptives have significant methodological flaws that render their conclusions suspect. It seems likely that residual confounding could have distorted both the results and the conclusions of these reports. (SOGC, 2010)

> These studies had several methodological limitations, such as potential misclassification of venous thromboembolism and the duration of use of the OCs, inadequate control of confounding variables, and potential information and detection biases. (ACOG, 2012)

This is a recurring strategy used to reinforce the safety of drospirenone. However, a more poignant one is engaging in risk comparisons for the purpose of putting drospirenone's health risks into perspective.

Pregnancy and Postpartum Risks

Whether or not they are critical of epidemiological studies, organizations have spent more time discussing the relative safety of drospirenone despite agreeing that a risk increase is likely. A woman's risk of a fatal blood clot while pregnant has been one of the main comparisons that doctors and regulatory bodies have been drawing upon, in the documents analyzed here and more generally in the media, to assure consumers that the new generation of contraceptive pills is safe. This is a theme that cuts across both countries as well as all medical associations. Pregnancy and postpartum risks are invoked over and over again whenever risk measurement is discussed:

> To put the risk of developing a blood clot from a birth control pill into perspective: The risk of blood clots is higher when using any birth control pills than not using them, but still remains lower than the risk of developing blood clots in pregnancy and in the postpartum period (FDA, 2012).

> To keep the risks of VTE for pill users in perspective, it is important to remember that the risk of a VTE in pregnancy may reach 29/10,000 and in the peripartum period has been reported to be as high as 300-400/10,000. As one of the most widely used and effective contraceptive methods, the pill reduces rates of unplanned pregnancies and actually decreases the overall rate of VTE in the population in comparison to populations without access to effective contraception (SOGC, 2013).

> The risk of venous thromboembolism is increased among OC users (3–9/10,000 woman-years) compared with nonusers who are not pregnant and not taking hormones (1–5/10,000 woman-years), and some data have suggested that the use of drospirenone-containing OC pills has a higher risk (10.22/10,000) than the use of other progestin-containing OCs. However this risk is still very low and is much lower than the risk of thromboembolism during pregnancy (approximately 5–20/10,000 woman-years) and the postpartum period (40–65/10,000 woman-years) (ACOG, 2012).

All organizations use this comparison to stress the relative safety of contraceptives when compared to pregnancy and the postpartum period (both of which pose a higher risk of VTE). The alternative to hormonal contraceptives, according to professionals, is a potential pregnancy that comes with associated health risks. Pregnancy-associated risks have also been stressed more widely by OB/GYNs in the media when confronted with allegations that drospirenone-containing pills are not safe. For

example, in a manner that explicitly emphasizes pregnancy as a site of risk, ACOG published a report in 2013 called "Half of Women Unaware that Pregnancy Is More Dangerous Than Contraception." Here an OB/GYN states:

> "The risks of pregnancy, deemed such a natural and healthy process by society, get overshadowed by the highly publicized reports of contraceptive-related complications," Dr. Becker said. "If women continue to receive more influence on their contraceptive choices from media than their health care providers, we will never make progress at lowering unplanned pregnancy rates." (ACOG, 2013)

What is downplayed in these statements is the comparison between drospirenone-containing pills and the previous generation of pills – this being the comparison that sparked the Yaz/Yasmin controversy in the first place. When the discourse of pregnancy risks gains momentum, drospirenone-containing pills tend to be perceived and presented as safer by those reporting their risks.

This research has found that, overall, the discourse of pregnancy risks is the one that features most prominently across professional statements released with regards to the safety of dropspirenone-containing contraceptive pills. At least 17 of the 23 documents analyzed include a discussion of pregnancy-related health risk as compared to hormonal contraceptives. The risk of developing a blood clot during the postpartum period has also been emphasized explicitly. An example from the FDA (2012) can be observed below in Figure 2 below:

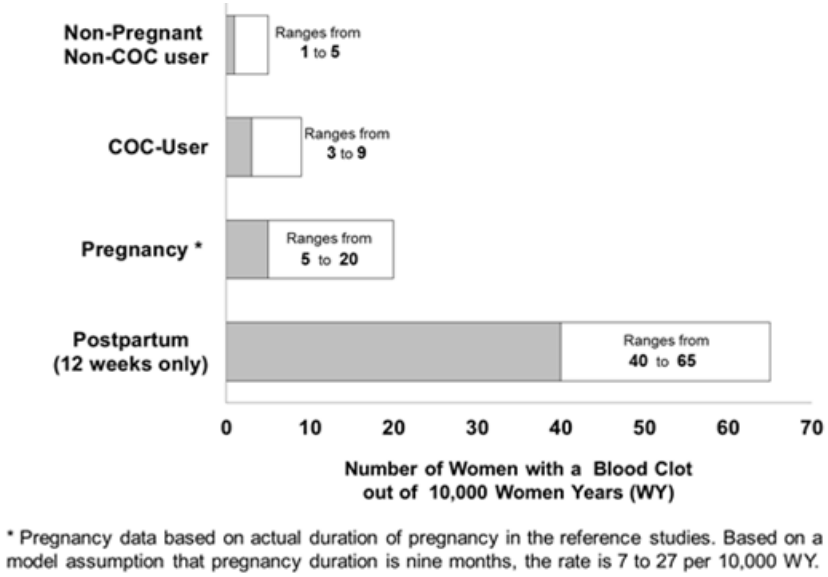

Fig. 2: Likelihood of Developing a Blood Clot

COC = combination oral contraceptives or birth control pills

*Source: http://www.fda.gov/Drugs/DrugSafety/ucm299305.htm (FDA, 2012)

Visual representations of risk have been deployed for the purpose of putting the health risks of all contraceptive pills into perspective following the Yaz/Yasmin 'pill scare'. Choosing not to have the risks posed by different generations of pills represented allows for pregnancy risks to become the main point of reference. This comparison creates a discourse where women's bodies are constantly at risk whether from getting pregnant, pregnancy itself, or the risks associated with the postpartum period. It conveys a gendered message about bodies and risk and portrays the female body as constantly at risk due to its fertility (Gross and Pattinson, 2007).

Efficacy as Safety

In addition, consistent with the critiques of other scholars that have looked at discourses surrounding contraceptive risk evaluations in developing countries (Van Kammen and Oudshoorn, 2002), this study found that in the case of the drospirenone controversy, medical professionals tend to

equate efficacy with safety whenever the benefits of hormonal contraceptives are discussed. For example:

> Fear and confusion resulting from media coverage of rare events […] has the potential to create far greater harm as inadvertent pregnancies are generally the result of panic stopping of COCs and these pregnancies themselves carry greater risks for VTE (SOGC, 2013).
>
> Modern OCs offer excellent contraceptive efficacy, and adherence is good because of their many non-contraceptive benefits. The occurrence of serious risks such as VTE, including pulmonary embolism, are rare with contemporary OCs (SOGC, 2010).

Higher efficacy is emphasized because it lowers the chance of a woman getting pregnant. However, the underlying assumption is that the pregnancy will be carried to term. As such, based on the risk evaluations presented by medical professionals, a woman has two options: being a user of hormonal contraception or becoming pregnant. Since hormonal contraceptives have a higher efficacy rate, they are presented as a more desirable method than condoms or other barrier methods. Hormonal contraception is represented as an excellent choice for any fertile woman.

In the documents analyzed, I have found no discussion of risk/benefit comparison across types of contraceptives. The health-related concerns surrounding hormones are not then contrasted to the lack of such concerns in the case of barrier methods, but rather to all the risks that are associated with women's bodies and childbearing. The fact that condoms have no health-related side effects is not emphasized as a benefit, for example. Side effects of hormonal contraceptives are seen as insignificant when compared to the benefit of high efficacy. Aside from potential side effects such as weight gain, nausea, migraines, loss of libido, hormones can also increase the risk of heart attacks and cervical cancer when compared to women who are not users of hormonal contraceptives. This is not mentioned, however, in any of the statements analyzed. The non-threatening side effects that might interfere with a woman's daily functioning are often considered negligible in light of the more severe effects (Mamo and Fosket, 2009), hence discussions are focused mainly on efficacy and fatal health risks.

The emphasis on pregnancy risks and the pill's efficacy echoes past population and fertility control discourses. One can deduct from the professional responses to the drospirenone controversy that clinicians and scientists use gendered risk/benefit assessment models very similar to the ones used in the 1960s when the social and cultural climate was significantly different. At the time of its market approval, the pill was hailed as a wonder drug that could rid the world of overpopulation problems. Moreover, as abortion was not legal anywhere in North America, many women wanted to ensure that they will not get pregnant as that could mean having either an unwanted child or an illegal abortion. Needless to say, neither option was a desirable outcome. Attitudes towards sexuality and responsibility for contraception also contributed to the hype surrounding the pill. At the time, social and cultural norms did not dictate that contraception should be a shared burden within a couple. Although some men would participate in fertility limiting practices (withdrawal, condoms, vasectomies), the ultimate responsibility and burden was placed on women's shoulders, as they were most often the victims of the unwanted consequences (Fennel, 2011; May, 2010; Watkins, 1998). Women at the time rarely had access to safe abortions, as this procedure was illegal in both Canada and the U.S. As such, comparing pregnancy or unsafe abortion risks with the risks posed by contraceptives was a logical and necessary endeavour. While abortion risks were significantly higher in the past due to unsafe procedures, the mortality risk associated with legal abortions today is less than 0.6 per 100,000 procedures (Raymond and Grimes, 2012). This is a lesser risk when compared to that posed by hormonal contraceptives. Women in North America today are faced with different options in a different cultural climate. Although the social and medical context has changed, risk evaluations have not. Although not all, most women now have access to safe abortions. The emphasis on the primacy, efficacy and safety of the pill is reminiscent of gendered fertility control discourses from the past.

Informed Patient Choice

The discourse of informed patient choice is often invoked in professional statements. An

underlying assumption is that women users will make a decision based on a techno-scientific risk benefit analysis. However, scholars (Douglas, 1986, 1992; Douglas and Wildavsky, 1983) have shown that lay views on risk differ significantly from the technical rational risk calculations that scientific experts engage in. Individual choice is often invoked along with the dangers of pregnancy. For example, Health Canada (2013) stresses that "blood clots are a rare but well known side effect associated with all birth control pills. The risks of blood clots are higher with pregnancy and childbirth than with oral contraceptives," but "women with questions or concerns about their birth control pill should talk to their healthcare professional." Similarly, ACOG (2012) concludes that "decisions regarding the choice of OC should be left to clinicians and their patients." The discourse of informed choice underlies the safety discourse. As such, once presented with scientific information about risks, it is a woman's responsibility to make her own decisions. The fact that women might consider side benefits as more important than the health risk increase is never acknowledged in professional risk assessments analyzed here. Most importantly, the following questions is never asked: Is assuming a greater risk of blood clots worth the added benefits? This poses a problem because users as well as health professionals are not offered guidance on how to weigh a health risk increase against the promise of acne and PMDD treatment. There is an assumption that a woman chooses birth control primarily for contraceptive purposes and that the added benefits are a bonus, when in fact consumers might consider the benefits before they look more closely at the drospirenone VTE risk. For example:

> Modern OCs are well tolerated (serious side effects are rare), and adherence to prescribed regimens is generally excellent. As a result, *OC users are able to prevent pregnancy and the considerable risks associated with being pregnant while enjoying the non-contraceptive benefits of hormonal contraception.* [emphasis added] (SOGC, 2010).

> Hormonal contraceptives are effective in treating menstruation - related disorders such as dysmenorrhea and heavy menstrual bleeding, *as well as preventing unplanned pregnancies* [emphasis added], according to a new Practice Bulletin issued today by The American College of Obstetricians and Gynecologists (ACOG) and published in the January 2010 issue of *Obstetrics & Gynecology*. (ACOG, 2009).

Professional risk benefit analyses tend to focus on efficacy and pregnancy prevention as the main benefits and then mention added benefits as a perk. However, it is not clear if consumers choosing drospirenone-containing pills make decisions first considering the health risk increase, given the way in which Yaz and Yasmin's side benefits have been emphasized in Bayer's ad campaigns and potentially to doctors as well. For example, Bayer was sanctioned in 2008 for running misleading ads about Yaz. The company minimized risks according to professionals who signalled issues to the FDA:

> The audio communication of serious risk disclosures during the "major statement" is minimized by distracting visuals, numerous scene changes, and other competing modalities such as the background music which combine to interfere with the presentation of the risk information. (FDA, 2008)

Bayer also overstated the efficacy of the drug in treating acne, PMS, and PMDD:

> The totality of the audio and visual claims and presentations misleadingly suggests that treatment with YAZ will allow women to say "good-bye" to their symptoms completely. For example, the TV Ad's theme song "Good-Bye to you" plays in the background as energetic, euphoric: playful women release balloons into the air displaying certain symptoms (e.g., irritability, moodiness, feeling anxious, bloating, fatigue, muscle aches, headaches, increased appetite, and acne). The balloons then float up and away from the women misleadingly suggesting that these women are saying, "goodbye" to their symptoms and are now symptom-free, when such an elimination of symptoms has not been demonstrated by substantial evidence or substantial clinical experience. (FDA, 2008)

The beneficial side-effects of the new hormonal compounds have been aggressively pitched to women in a gendered manner emphasizing appearance and periods as an inconvenience. This then might pose a problem when consumer choice and informed decisions are emphasized. These decisions are made in light of a consumer market that is increasingly complex and flooded by ads emphasizing added benefits at the expense of downplaying more serious health risks.

CONCLUSION

As the most recent development in safety debates about contraceptives, the Yaz/Yasmin controversy relates to historical conceptualizations of what acceptable risk is for users of contraceptive

pills. Women are expected by regulatory bodies and pharmaceutical companies to bear the risks of blood clots and other side effects such as loss of libido and migraines, but are encouraged to take control of their fertility (avoid pregnancy, abortion) and take advantage of appearance-related benefits. This is in stark contrast with the research and development of male contraceptives, where minimal risks and sexual function are emphasized instead (Oudshoorn, 2003).

One view that the pregnancy risk discourse perpetuates is that, for males, contraception does not have to be entangled with the idea of alleviating risks, since males do not experience pregnancy. As Oudshoorn (2003) has shown, the search for a male contraceptive is an arduous process often stalled by gendered beliefs about men and women and their respective roles in contraception. These findings further show how entangled conceptions of the female body are with risk acceptability. Adding to previous studies (Brown, 2015; Hanbury and Eastham, 2016; Oudshoorn, 2003; Van Kammen and Oudshoorn, 2002), this research shows the ways in which risk is related to gender and incorporated into new hormonal contraceptive technologies. Contraceptive options developed and tested on men have consistently had a lower acceptable risk threshold. In a risk assessment that focuses on the dangers of childbearing, “the possibility of health risks for men falls outside of the equation” (Van Kammen and Oudshoorn, 2002, p. 440). As the assessment of health risks and benefits in clinical trials shows, risky contraceptive technologies are perceived as more compatible with cultural constructions of the female body, while the norms governing our understanding of the male body tend to resist the interference of hormonal contraception in the 'normal' functioning of these bodies. Lane (1995) stresses that risk discourses about women's bodies are augmented by maternity rhetoric. As such, unfavourable events “are not only regarded as inevitable, but their timing is seen to be capricious and unpredictable. By deduction […] all women are subject to obstetric control and surveillance because all women are regarded as 'at risk'” (Lane, 1995). The message conveyed by the Yaz/Yasmin risk assessments analyzed here could have further implications for how the medical and scientific community

conceptualize risk and incorporate risk threshold acceptability in hormonal contraceptive research. Seeing women's bodies as a natural and inevitable site of risk lowers research and development expectations (Van Kammen and Oudshoorn, 2002).

In addition, there are important risks and benefits that professionals seem not to take into consideration, given women's tendency to go off the pill due to its less severe side effects (Black et al., 2009). Many women stop using hormonal contraceptives due to side effects such as depression, loss of libido, migraines, etc. One can assume that for women users, risk/benefit evaluation involves more than just efficacy and pregnancy prevention. However, concerns about sexual function, for example, are rarely discussed in the medical literature when evaluating the risks posed to women by hormonal contraceptives. Although loss of desire or nausea and headaches can have severe consequences on women's daily functioning, professional contraceptive risk/benefit assessment tends not to take these into consideration. Safety is usually defined as the relative absence of the threat of death which is a limited perspective when taking into consideration the concerns of women users. This study reveals a potentially large gap between the way in which benefits and risks of new contraceptive technologies are presented in the media and the way in which risks are presented to the public by professionals. Furthermore, the emphasis on the safety of drospirenone-containing pills fails to address the fact that recent research and development in this area has not produced a hormonal contraceptive that poses a smaller VTE risk when compared to the previous generation of pills.

Hormonal contraceptive technologies can have a great impact on the health and well-being of many women, as these type of contraceptives are widely used in the North American context. Studies (Jones, 2011) suggest that many women take the pill for reasons other than pregnancy prevention. As such, a risk assessment focused on pregnancy might not be adequate, especially for these users. With an eye to furthering discussions about hormones, contraception, women's bodies, and technological developments, this paper highlights a need to unpack problematic assumptions about gender and risk

that go into professional assessments of new hormonal contraceptives. As there is growing concern and consumer dissatisfaction with the new generation of hormones used in these technologies, more research is needed to identify problematic areas of risk assessment and differences between lay and professional assessment that can inform future scientific research and development as well as policy initiatives.

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PATIENT PERSPECTIVES ON CONTRACEPTIVE RISK

Chapter 2 provided an analysis of the strategies that regulatory bodies and professional associations use to reassure the public that drospirenone pills are safe. I have argued that, on one hand, VTE risks related to pregnancy and the postpartum period are overly-emphasized by professionals, while, on the other hand, drospirenone's potentially increased risks are downplayed. This paper stresses how this risk selection process is underscored by normative beliefs about women's bodies and sexuality. Comparing the risks of new contraceptive technologies to the VTE risks associated with pregnancy allows for increased risk thresholds for Yaz and Yasmin and, potentially, for future pills. It also reinforces cultural ideas about female bodies as inherently prone to risk due to their reproductive functions. Furthermore, there were additional discourses that professionals drew upon to emphasize the safety of Yaz and Yasmin. More specifically, they questioned the quality of the studies that found VTE risk increases in drospirenone and emphasized the importance of efficacy and informed consent. In this paper, I suggest that such approaches to weighing contraceptive risks and benefits do not take into consideration the complex choices that users have to make – choices that could potentially involve factors other than efficacy and fears of an unplanned pregnancy.

In the following chapter, I provide evidence that affected users conceptualize the risks of Yaz and Yasmin and pregnancy in ways that differ from expert assumptions presented in Chapter 2. Drawing on interviews with Canadian contraceptive users, I make the case that their understanding of risk needs to be analyzed through a sociocultural perspective. Chapter 3 emphasizes the changes in risk communication and drug regulation that interviewees advocate for. As a result of their experiences, affected patients can provide critical insights through which professionals can improve their approach to assessing contraceptives and providing risk information. Similar to the previous paper, Chapter 3

aims to reveal how stakeholder evaluations of risk are underscored by cultural views. However, Chapter 3 is also meant to complement Chapter 2 by focusing on patient perspectives – perspectives that can further understandings of the tension between lay and regulatory conceptualizations of risk.

CHAPTER 3

"ONE BLOOD CLOT IS ONE TOO MANY:" EXPLORING AFFECTED USERS' RISK PERCEPTIONS OF CONTROVERSIAL ORAL CONTRACEPTIVES

ABSTRACT

The purpose of this paper is to analyze women's negative experiences with the fourth generation of contraceptive pills, more specifically, affected users' views on the risks of controversial drugs Yaz and Yasmin. Drawing on in-depth interviews with 24 contraceptive users residing in Canada, I highlight how women who have experienced deleterious side effects understand the risks of hormonal contraception and advocate for changes in health risk communication and prescription drug regulation. Findings show that interviewees do not feel they received adequate risk information prior to being prescribed the drug nor do they think that pregnancy risks are useful for providing comparative risks to the risks associated with hormonal contraceptives. Furthermore, patient views were underlined by a general critique of professional risk/benefit assessment techniques and procedures. This study not only provides a detailed analysis of women's negative experiences while on the pill, but also shows how the modern complexities of health risk assessment extend to the realm of hormonal contraceptives.

KEYWORDS: contraceptive users; the pill; risk assessment; Canada; side effects

INTRODUCTION

A new controversy concerning the safety of the pill has emerged in recent years. Popular oral contraceptives Yaz and Yasmin, manufactured by Bayer, have been linked in the media to at least 23 deaths in Canada and over 100 in the U.S. as well as thousands of injuries worldwide (CBC, 2013). They have become controversial due to their potential increased risk of blood clots. While some studies have indicated that drospirenone, the new hormonal compound used in Yaz and Yasmin, increases the risk of blood clots when compared to other pills (Lidegaard et al., 2011; Wu et al., 2013), organizations such as the Society of Obstetricians and Gynecologists of Canada (SOGC) and Health Canada have stressed that the new pills are safe. As such, what constitutes significant risk has been a socially contested process.

Contraceptive development has been fraught for decades with debates and questions over who holds the authority to determine 'accurate' risk assessments. Although the risk of blood clots was acknowledged decades ago in the earlier generations of oral contraceptives (Watkins, 1998), controversies about the relationship between the pill and venous thromboembolism (VTE) risks persist and remain unresolved. In a systematic review of these historic debates, Lackie and Fairchild (2016, p. 297) note that “scientific and public attention to thromboembolism and the pill has had dramatic consequences,” where the focus on VTE risk has changed norms on informed consent and regulatory processes. In the case of Yaz and Yasmin, professional bodies such as Health Canada and SOGC determined the safety of drospirenone by comparing its alleged risks to other more severe women’s health risks. For example, professionals have publicly stressed that drospirenone is safe especially when compared to pregnancy and postpartum VTE risks (Geampana, 2016). This is a quantitative comparison that has been employed extensively in drug approval and in the contraceptive literature. However, it is problematic for a variety of reasons. First, it assumes that women's choices are limited to two options: the pill or pregnancy. Moreover, it reinforces a view of women's bodies as inherently

always at risk due to their reproductive functions, and finally, it does not consider whether or not such a comparison is accepted by and useful to the users themselves.

The history of the pill is riddled with tensions between professional and patient perspectives on risk. During the initial clinical trials conducted in the 1950s, patient concerns about side effects (e.g., nausea, headaches, vision problems) were dismissed by Gregory Pincus and John Rock as psychosomatic (Briggs, 2002). Consequently, the pill was approved for market sale without extensive knowledge of the prevalence of side effects, especially the more severe ones such as VTE and cancer. Once the link between estrogen and the incidence of blood clots became known to regulatory agencies and pharmaceutical companies in the 1960s, this information remained hidden from patients (Watkins, 1998). Even doctors were reluctant to share risk information with women because of fears that patients would act “irrationally” and suddenly discontinue their birth control. User activists had to engage in extensive protests to participate in risk debates dominated by male professionals. The result of these struggles was FDA's package insert requirement, first available only for doctors and later in the 1970s to patients as well. While professionals have been concerned about the quality of the VTE risk data available, affected patient advocates and their families have stressed personal suffering in past debates (Junod and Marks, 2002; Marks, 1999). However, professional discourses have often portrayed patients as non-compliant, uninformed, and prone to irrational fears (Watkins, 1998). Strikingly, the users interviewed for this study still echo the feeling that women's perspectives are not always fully considered by professionals. Currently, we have very little in-depth knowledge about the women who have experienced severe side effects while on the pill. We know even less about how they view contraceptive risks or the type of risk information they received before experiencing adverse side effects.

A 2009 survey on Canadian women's contraceptive practices shows that 44% of those who are sexually active use oral contraceptives as their main method of birth control (Black et al., 2009). In

Canada, regulatory approval of new contraceptive methods takes longer than in the U.S. and the U.K. (Troskie et al., 2016). Drospirenone-containing pills are no exception. Therefore, the Yaz/Yasmin controversy is a slightly more recent phenomenon in Canada, with class action lawsuits against Bayer moving at a slow pace. Nonetheless, much like the rest of North America, the pill is still one of the most popular forms of contraception. There is little data showing how the Yaz/Yasmin controversy has affected Canadian women's experiences with contraceptives. The media has suggested that the number of prescriptions for these drugs and the pill more generally have dropped following the controversy (McKnight, 2016), which indicates that affected users' advocacy and media presence has had a significant impact. Although the women interviewed represent a very particular group of contraceptive users, this paper takes the position that, as key stakeholders in the drospirenone debate, their views merit a more in-depth analysis and unpacking than what the existing literature has provided so far. This research specifically asks: 1) How are the risks of Yaz and Yasmin interpreted and evaluated by users who have been vocal about the risks of drospirenone?; 2) How do affected women put these risks in context?; and 3) What changes do they advocate for as a result of their experiences? Although the drospirenone debate is a significant episode in the recent history of oral contraception, scholars have not yet explored how this particular controversy might evidence ongoing debates about the risks of the pill. This paper looks in-depth at the affected patient perspective in order to better understand how lay advocates conceptualize risk and call for changes in the pharmaceutical and regulatory system.

LITERATURE REVIEW

Previous Approaches to Risk and User Assessment of Contraception

This paper incorporates concepts from the sociology of risk as well as critical perspectives on risk perception and contraception. Thinking critically about risks as they become entangled in controversies, scholars have focused on studying the dangers and consequences of risky technologies (Collins and Pinch, 1998; Nelkin, 1984; Williams et al., 1995). Nelkin (1984) notes that scientific and

technological controversies and ensuing protests are not necessarily a revolt against science but against the power relationships associated with technology and citizens' inability to shape decisions that affect them directly. Similarly, the women interviewed here are critical of the medical establishment and regulatory bodies' decisions in light of the risk uncertainty surrounding drospirenone. Laypeople's rationality, however, has been generally distrusted by experts and consequently, they have been deemed unable to understand and control the risks placed upon them by modern complex technological systems (Beck, 1992). Coming from a different yet compatible perspective, the "sociocultural" perspective on risk first posited by Mary Douglas (1986, 1992) critiques the widely-held assumption in fields such as experimental science and economics that individuals are rational agents making decisions based on rational risk calculations. Official professional discourses generally imply the performance of a technical-rational risk assessment on the part of the user - a calculated weighing of costs and benefits that is focused on numerical risk probabilities (Beck, 1992; Douglas, 1986; Wildavsky and Dake, 1990). However, Douglas (1986) critiques the assumption that either institutions or individuals engage in a purely 'rational' cost/benefit analysis to weigh risks. Rather, the magnitude of risks is influenced by factors such as the media and personal beliefs. Even professionals, institutions, and governments make cultural choices as to how risks should be presented (Douglas, 1992). Consequently, critical scholarship (e.g., Douglas, 1986; Wildavsky and Dake, 1990) takes the position that the distinction between objective and subjective risk assessment is a false one, as risks can always only be perceived through cultural and sociopolitical lenses. More specifically, Douglas (1986) stresses that the role that social and cultural influences (e.g.. media visibility of risks, public controversy, personal beliefs, etc.) play in individual risk perceptions has been ignored by experts who tend to focus solely on scientific and external measurements of risk. In addition, she has been critical of the way in which institutions use risk discourses to influence human behaviour and to reinforce norms (Douglas, 1986). According to sociocultural conceptualizations of risk, lay views should not be seen as incorrect, but rather included

into risk assessments and analyzed in the context of users' experiences.

Previous research has established that cultural factors and gendered norms, especially, play an important role in shaping opinions about the risks of contraceptives and risky technologies more generally. Individual risk perception depends on many factors. For example, women have been found to be more pessimistic than men about technologies and dangers that are societal in nature, such as commercial nuclear power and CFCs (Cutter et al., 1992). Studies have shown that individuals perceive risks differently based on their source: natural or human-made (Brun, 1992; Keogh, 2005), being generally less critical of risks that are seen as having a natural source (Keogh, 2005). In the case of contraceptive controversies, there is some evidence that negative media coverage amplifies user perceptions of their risk (Allison et al., 1997; Bartnett and Breakwell, 2003; Flamiano, 2013). Regarding professional risk assessment, scholars have stressed that medical and regulatory contraceptive assessments portray pregnancy as risky through cultural mechanisms that deem the female body as inherently more prone to risk (Brown, 2015; Marks, 2000; Oudshoorn, 1999; Van Kammen and Oudshoorn, 2002).

Risk perceptions might be especially susceptible to the marketing of the pill, which now more than ever promotes the pill's ancillary benefits rather than pregnancy prevention as its primary selling point (Watkins, 2012). Importantly, the touted lifestyle benefits are gendered, as well – aimed towards "correcting" physical features (e.g., acne, hirsutism) construed as problematic by cultural norms of feminine beauty. Drospirenone has been marketed heavily on the basis of such benefits. To stress the cultural environment in which women make contraceptive choices, scholars (e.g., Fennel, 2011; Hanbury and Eastham, 2016; Mamo and Fosket, 2009; Watkins, 2012) have discussed the gendered marketing and use of pills – an aspect that can affect risk perceptions. In a qualitative study of diverse women's experiences with the pill, Littlejohn (2013) stresses the importance that gendered appearance expectations play into users' decisions regarding contraception. Social dimensions, such as notions

about the female body and the perceived gendered appeal of lifestyle benefits, contribute greatly to perceptions of risk factors associated with these technologies (Mamo and Fosket, 2009). While ancillary benefits and negative side effects are important factors to women users, health professionals tend to disregard such concerns. Scholars note that women's lay assessments of the severity of non-life-threatening side effects (e.g., weight gain, nausea, headaches) have not been taken seriously enough, especially in comparison to those of men (Oudshoorn, 1999; Oudshoorn, 2003; Van Kammen and Oudshoorn, 2002).

Research informed by public health perspectives has provided more empirical information on contraceptives users and risk, usually through survey and structured interview data collection. These studies are generally focused on strategies for improving compliance and usage of the pill. As such, they tend to highlight the accuracy of professional views over those of users. Nonetheless, this literature is useful for highlighting larger trends in how women perceive the risks of hormonal contraceptives. A number of authors have analyzed some of the concerns that users have with hormonal contraception (Emmett and Ferguson, 1999; Harrington et al., 2015; Nelson and Rezvan, 2012; Peiper and Gutman, 1993; Sihvo et al., 1998). For example, Peipert and Gutman (1993) have found that approximately 40% of women surveyed believed there are substantial risks to OC use, while the majority were not aware of health benefits such as decreased risks of endometrial and ovarian cancer. Similarly, Nelson and Rezvan (2012) found that hormonal contraception is generally perceived as riskier than pregnancy. This highlights a key difference between lay and expert risk-assessments: while health professionals emphasize pregnancy as posing more risks, users are likely to perceive OCs as riskier. Harrington et al. (2015) as well as Sihvo at al. (1998) highlight women's concerns regarding side effects of contraception. These concerns affect risk perceptions as well as compliance with an oral contraceptive regimen. Additional factors that affect compliance include efficacy, attitudes of male partners, relationship status, misinformation about pregnancy risks (Reed et al., 2014), as well as

whether or not women have taken an oral contraceptive before, with those who have not being more likely to perceive it as higher risk (Emmett and Ferguson, 1999). However, what such studies have in common is an assumption that health professionals have a more accurate view of risks and that women users should adopt these views. Here, I seek to explore lay assessments without suggesting they should be perceived as erroneous. Rather, user concerns reflect a different positionality, as risk sociologists have shown. Critical of professional distinctions between objective and subjective risks, authors (e.g., Douglas, 1986; Wildavsky and Dake, 1990) stress that risks are perceived through a cultural lens influenced by various factors such as social norms, visibility of risks, and personal beliefs – factors that are often overlooked by professionals.

Using sociocultural approaches to risk, this paper aims to bridge the gap between critical qualitative studies on the assessment of contraceptives and the limited knowledge we have on user perception of the risks of the pill. We know from previous work that cultural factors such as the perceived source of risks, gender, marketing, and the media can influence the way individuals conceptualize risks. On the other hand, the health literature has suggested that women perceive pregnancy as less risky than the pill; they are not aware of the health benefits of OCs; and their compliance with the drug's regimen depends on how the perceived severity of side effects, their relationship status, as well as general knowledge about the pill and pregnancy. In light of the knowledge available, this paper has three aims: 1) to analyze how lay advocates think about the risks of drospirenone in order to understand this controversy in the context of ongoing debates about the pill, 2) to extend critical analyses of contraceptive risk to the experience of lay stakeholders, and 3) to provide a more in-depth understanding of women's negative views of the pill that goes beyond survey approaches informed by professional views.

METHODOLOGY

The interviewees for this study were recruited from online groups discussing the risks of new oral contraceptives. I found the groups through Google, Facebook, and Reddit searches. The study was advertised to potential participants (women over 18 years old who have used drospirenone-containing pills for at least two months and reside in Canada) through online websites and forums for Yaz and Yasmin users. The forums, aimed towards creating a sharing space for those who have been negatively affected by Yaz and Yasmin, are managed either by law firms involved in Yaz-Yasmin litigation or by oral contraceptive users whose health has been affected by the use of drospirenone-containing pills. Here, many women and family members affected by these drugs have shared their experiences with adverse side effects and even the loss of women close to them. The user forums and groups include Take Your Body Back, Yaz & Yasmin Settlement Forum, Yaz and Yasmin Victim Support Group (all of which are Facebook groups), yasminandyaz.blogspot.ca as well as yazsurvivorcenter.wordpress.com. After gaining permission to post recruitment ads, I advertised the study to potential participants. Users on these forums are predominantly women who have experienced negative side effects while on Yaz or Yasmin. Another forum where participants were recruited from is reddit.com, one of the most popular forums on the Internet, with thousands of participants, and particular “threads” (i.e., subreddits) that discuss contraceptive options and experiences. In total, 24 interviews were conducted with users between December 2015 and October 2016. Interview duration ranged between 40 and 100 minutes. This sample is not random, but rather purposive, and generalizations cannot be made based on it. However, it represents a fairly diverse population in terms of age groups and geographical locations within Canada. Interviewees' place of residence varied across 6 Canadian provinces: Ontario, Alberta, Quebec, Prince Edward Island, New Brunswick, and British Columbia. The women's ages ranged between 21 and 56, with median age being 27. There were no major socio-economic disparities between respondents with most being from a middle class background based on their residence,

occupation and circumstances. Twenty-two were white, while only 2 were women of colour (self-identified as Middle Eastern and South East Asian respectively). None of the respondents expressed being religious or morally conflicted about taking a contraceptive pill. As such, I did not consider religiosity as a factor that contributed to interviewees' attitudes towards the pill.

Due to their location outside the Montreal area, in-person interviews were not feasible; all interviews were conducted over the phone. The interview guide was focused on asking participants how they perceive the risks and benefits of the latest generation of hormonal contraceptives. Specifically, I asked questions on which risks and benefits they consider important and how significant they perceive the risks to be. Transcribed materials from in-depth interviews were analyzed using the principles of grounded theory. Grounded theory seeks to identify the social processes and conditions that underlie phenomena. This method is especially suited to this study because the processes studied have not been fully articulated, and comparisons between data from multiple sources are an important part of the study. I entered all data into MAXQDA, a software package for organizing and analyzing qualitative data. Standard procedures for analyzing qualitative data were employed. Specific codes were developed using both deductive and inductive strategies. These codes were developed after the data was transcribed and organized. Connections were made between different themes. According to grounded theory principles, some of the themes/codes may be influenced by pre-existing theories. However, this method also allows for new themes to emerge.

Interview data were analyzed to highlight differences and similarities between the risk perceptions of women users. Patients were asked a number of questions related to their perceptions and opinions about the risks posed by the new generation of hormonal contraceptives. As outlined in the objectives of this study, I aimed to examine if the following have an effect on risk analyses: notions about contraceptive efficacy and failure, attitudes towards potential outcomes of contraceptive failure (abortion and unintended pregnancy), as well as the trend of marketing the ancillary benefits oral

contraceptives. I also paid close attention to any other reasons that affect evaluations.

FINDINGS

All respondents experienced adverse effects while on drospirenone pills, ranging from more minor side effects such as headaches and nausea to potentially fatal events such as deep vein thrombosis (DVT), pulmonary embolism and stroke. Given the particularities of the sampling method, the study is only meant to explore the experiences of users who have had negative side effects. This group does not constitute a representative sample and it is not the purpose of this paper to suggest that there are any certainties and generalities regarding the risks of Yaz and Yasmin or the experiences of the women taking them. However, most of the women interviewed seek to influence public opinion through involvement in Canadian lawsuits, their online and media presence, as well as word of mouth. It is the position of this paper that, as key stakeholders in the Yaz/Yasmin controversy, their views on risk are important to understand as they have the potential to influence others' opinions on the risks of contraception and the impending lawsuits and legal availability of Yaz and Yasmin in the future. My research has found that most users defined the drugs they took as risky only *after* experiencing adverse effects. Interviewees were vocal about the negative effects of Yaz and Yasmin and the impact these contraceptives have had on their lives. Very few of them expressed being concerned about potential health risks when they started taking drospirenone-containing oral contraceptives.

Prior Risk Information as Inadequate

Most interviewees felt they did not receive appropriate risk information prior to starting their new oral contraceptive. As mentioned above, they did not express being concerned about drospirenone initially. Factors that contributed to user perception of this new pill as safe were reliance on doctors' opinions and the marketing context that marketed these pills as “better” than others. Interviewees expressed that their doctor's recommendation was what made them confident about drospirenone-containing pills Yaz and Yasmin. For most, it was their family physician who suggested one of these

pills, while for a few it was their OB/GYN. Women also stressed that they trusted their doctors to make the right decision for them:

> You have faith that your doctor knows what they're prescribing, right? I did...You know, if they're gonna prescribe stuff like Yaz and Yasmin then they should know what's going on, I thought. (User 2)

> I think I was really naïve. And I was young, too. So, my doctor's telling me, like, "Here's a pill." My doctor is giving me a pill, so, she has a medical degree and whatever, so I'm trusting her. So I didn't... Yeah, I didn't really have any worries, really, 'cause, yeah, no, didn't. And now I do. Now I do after it all happened. (User 7)

> I think sometimes we mostly will take the advice from our doctors and the pharmacist. And if they aren't pushing and advocating the risks of it, that's where you're gonna get it, the most advice, than going through and reading the small little pamphlet side effects and whatever it is. So it needs to come from the physicians. (User 21)

As seen above, the general user perception was that, if a doctor recommends a pill, he/she must believe that it is safe for the patient. Thus, we see the manifestation of what Beck (2012) described as a deference to experts regarding modern risks. The doctor-patient exchange was not described as egalitarian by the women interviewed. Doctors' recommendations were not further discussed or challenged. This is despite the fact that, according to interviewees, health professionals' prescription choice of drospirenone-containing pills was mainly influenced by their perceived novelty and marketing allure. A great amount of trust was placed by respondents in medical professionals. The very few women who had any doubts about taking this particular contraceptive had their fears put at ease by their physician. Even then, interviewees deferred to professionals when making decisions about a particular brand of contraceptive pill. In turn, the women felt assured by doctors that drospirenone-containing pills are safe and will meet their needs.

At the beginning of their regimen, most users saw the new contraceptive pill as not very different from previous generations of pills. Several users expressed that because they had already tried other brands without experiencing major adverse effects, they felt that Yaz/Yasmin must also be safe for them. Patients and doctors alike constructed drospirenone-containing pills as similar to other brands

regarding their safety and risk of blood clots despite the fact that they contain a different chemical compound. Interestingly, Yaz and Yasmin were conceptualized simultaneously enough alike other OCs that doctors could rely on their safety and patients would feel comfortable taking them, yet different enough to warrant prescribing them over other more well-established generic pills. Yaz and Yasmin were constructed as just another contraceptive pill, albeit a newer, more exciting one. When asked about what doctors told them regarding hormonal contraceptives and drospirenone in particular, women said:

> The only thing that she said at the time was the same thing that they said about the birth control pills I took previously...that when you get a little bit older, your chances of a blood clot are higher, but that there was nothing unusual about it, basically. It was no different than anything else that I had taken before. So I wasn't overly concerned about it because I had been on birth control pills before. (User 5)
>
> She didn't tell me much. So it was mainly this pill is better than the other ones. It would be a good idea to get on it and that's pretty much it. (User 13)
>
> I believe it was basically the run of the mill break down, “don't smoke because it increases the risk of whatever.” Because before she prescribes anything she'll ask you, "Okay, do you smoke? Do you drink? Do you have other medications for obvious reasons?" And then, from there she said, "Okay, good. Good that you don't smoke." But she didn't do a run down to say, "Well, there's more risk associated with this as opposed to another one." (User 8)

There was an assumption that because women do not present typical risk factors such as smoking and because they have taken oral contraceptives before, there is no need to go over potential risks. Regardless of whether someone has or has not taken a contraceptive pill before, the overwhelming sense at the beginning of the regimen was that drospirenone is safe and additionally, that it had an edge over older pills because it also promised to treat acne, bloating and other symptoms associated with premenstrual dysphoric disorder (PMDD).

In most cases, drospirenone-containing pills were recommended by doctors themselves as the OC to try. Only one of the women recounted asking for a specific pill when discussing options with

their physicians. Some, however, recall feeling confident about being prescribed these particular pills after seeing ads in the media that emphasized Yaz's ancillary benefits:

> Well, I just kind of took what my doctor said, I trusted my doctor. So she put me on it, But then I saw it on a commercial, so I felt more confident taking it, I think, definitely. And I was like, "Oh that's my birth control." So I felt confident, I felt safe on it. (User 19)

> I remember there was huge campaign ads for it, commercials, the girls jumping hitting the coloured balloons and how it was gonna solve my complexion problem and it was gonna help me with my weight and blah, blah, blah and I thought, you know what if I'm gonna use something, why not something that's gonna do all this stuff? So I started it, and then, probably about a month later I started feeling tired, very tired and just no energy. (User 9)

This shows the effect that advertising contraceptives to consumers can have. Acne treatment was considered by most a nice bonus to have. Only two interviewees were looking to treat acne specifically when they sought a pill prescription from their doctor. Some stressed that acne can be treated through other means as well. However, the marketed ancillary benefits gave Yaz and Yasmin an edge over other options. Users stressed that their doctors showed enthusiasm about the advertised acne and PMDD treatments, considering drospirenone pills to be an improvement over the previous generation of progestins. Thus, new pills were painted in a positive light by doctors to their patients as doctors seemed to echo Bayer’s marketing materials touting the pill’s non-contraceptive benefits. And women expressed confidence in professional recommendations.

With regards to the risks posed by hormonal contraceptives, doctors rarely discussed such concerns at length. At most, some physicians recommended that women read the pill insert found in every pack of oral contraceptives. However, interviewees did not think that inserts are an adequate means for conveying risk information. Users express dissatisfaction with font size on inserts and a layout that does not encourage careful scrutiny. They explained why they think that package inserts are not an adequate solution to convey risks associated with contraceptive pills:

> Because people might, it is still being sold, and your doctor's still giving it to you, so people trust their doctors and they might see this sheet, and they might be like, "Oh," but then, they go and ask their doctor, and their doctor reinforces the fact that they gave it to them, right? So, you put a lot of trust in your doctor, and so, yeah, I don't think... If I saw that sheet, I'd be like, "Oh, okay, I might look into it a little bit more," but I'd probably still take it just 'cause my doctor gave it to me. (User 1)

> I can only speak for myself, but it's what happened to me. The experience that I had with it. It's not worth... Yes, in the pamphlet they say, that there is a risk of possible blood clot. But I would have appreciated being told from my doctor, instead of reading it and discussing it further with her. And her being more informed, and willing to inform. (User 14)

Although the need for users to become more informed through their own efforts was underlined by some, the majority of women expressed dissatisfaction with the lack of information from doctors, Health Canada, and pharmaceutical companies. Patient discontent is reminiscent of historical debates about package labelling for estrogens. Watkins (2002) notes that the availability and content of pill inserts was a contentious issue in the 1970s when concerns about the risks associated with estrogen became more pressing. Initially, the publishing of a pamphlet by manufacturers became a requirement, but the content and the way it was distributed (by doctors or pharmacists on request) had been influenced by professionals as well as pharmaceutical companies (Watkins, 2002). Women advocates argued that this is not enough. Although now every user receives an insert with risk information in their pill package, questions remain regarding the adequacy and relevance of its content.

Pregnancy and Other Contraceptive Methods: Placing Risks in Context

Lay people and professionals alike put technological risks in context by comparing them to other risks or risks posed by similar technologies. In the case of drospirenone, interviewees discussed both pregnancy and other contraceptive methods, including non-hormonal ones, as posing less or very different kinds of risks. I asked users about their opinions on the relative safety of drospirenone pills when compared to the risks of blood clots during pregnancy – a comparison that has been relied upon by professional associations and regulatory bodies in North America in order to assure consumers of

the low risk that Yaz and Yasmin pose. Interviewees questioned the use of this comparison, however. One woman stated that comparing OC risks to pregnancy risks is like looking at “apples and oranges.” Consistent with findings in larger populations (Nelson and Rezvan, 2012), women did not see pregnancy as risky. However, most often, given reason that women had for questioning the basis of the comparison is that they saw pregnancy as natural – something that women engage in and carry to term willingly. The pill, on the other hand, was seen as a foreign and unnatural external risk – something that most respondents perceived as riskier than a natural bodily process like pregnancy. Such qualitatively different assessments of types of risk depending on their perceived source (natural versus human-made) were prominent in interviewees' responses. For example, an interviewee who suffered a pulmonary embolism while on Yasmin said:

> I think comparing the pill to pregnancy is retarded [laughs] For a prescription drug, the risk should be minimal. Pregnancy is something that happens naturally and people want to be pregnant. It's unfair to say that pregnancy is dangerous in the same way that pills are. (User 17)

Two women further commented:

> I think that plays on your emotions a lot. And I think that people who don't wanna get pregnant, they don't not want to get pregnant because they're scared they're gonna get a blood clot when they're pregnant. They don't wanna get pregnant because they don't wanna have a baby. There is a lot of risks associated with being pregnant. Are we gonna pick and choose? Are we gonna compare this to a blood clot? I don't like that statement at all. [chuckle] It sounds like something a used car salesman would say. You know what I mean? It sounds slimy or something. It doesn't make me comfortable at all. (User 13)

> Pregnancy is a naturally occurring thing in your body. The birth control is not a natural occurring thing for your body. Yasmin, with that artificial hormone, that is not cohesive to your body. I disagree with it 100%. I had three pregnancies. Three children, I never had an issue at all. Never, never. So I disagree with that comparison about it. (User 10)

In contrast to public health approaches that tend to emphasize how pregnancy is riskier than contraceptive pills, interviewees did not think that this comparison is useful to them. They also did not find it to be reassuring for women, in general. However, the women in the sample did not necessarily

reject the pregnancy comparison because of a lack of information about pregnancy risks as other studies have suggested (ACOG, 2013; Nelson and Rezvan, 2012), but rather because they conceptualize pregnancy and the pill to be inherently conceptually and materially different and thus, their associated risks hard to compare. Although health professionals emphasize pregnancy prevention and the bonus of ancillary benefits as reasons why women should stick to the pill (ACOG, 2009; SOGC, 2013), the lived experiences of the users interviewed show that health and risk concerns about the pill can take primacy over fears of an unplanned pregnancy.

Contraceptive methods with lower efficacy rates than the pill were often appreciated by users for their lack of side effects. When comparing the risks and benefits of various options, interviewees saw non-hormonal options as having the benefit of not interfering with what they perceived as natural bodily processes. In addition, perception of the risk of having an unplanned pregnancy was different depending on individual circumstances. Users interviewed had to make complex choices when weighing risks of side effects and the efficacy of their chosen methods. In contrast to professional emphases on the primary importance of efficacy for evaluating hormonal contraception (ACOG, 2012; FDA, 2012; Health Canada, 2011; SOGC, 2010, 2013), the women interviewed revealed that their concerns about unplanned pregnancy had changed with their age and relationship status, with it not always being the primary consideration when choosing a contraception method. Women recall being much more worried about getting accidentally pregnant in their teens than in their mid-late 20s and onwards. For example, one interviewee reveals:

> At the time […] my biggest concern was not getting pregnant. However since 2011, I decided that the risks were not worth it anymore, especially since I developed a reaction. But I am more mature now, if I was still in my teens or early 20s I probably would still choose the risk. (User 4)

After experiencing side effects while on Yaz or Yasmin, respondents expressed willingness to trade the high efficacy of hormonal methods for less efficacious options such as condoms, withdrawal, and the

fertility awareness method, given their low risk of adverse side effects and women's changing tolerance for health risks. Women explained the advantages of these methods over the pill and why they would choose these now:

> We mostly use the pull out method, and I track my cycle and make sure not to have sex while I am ovulating. It's proven effective so far, but it's definitely not a method I would have used when I was younger. (User 12)

> 'Cause to me, now, I look at what you're putting in your body, right? To me, it sounds weird, but if a guy is just putting on a condom, he's not putting anything into his body and affecting everything that goes on inside of him, right? So to me, yeah, definitely, the condom would be better, obviously, both of them, it increases the chance of you not getting pregnant, but yeah, I'd say I'd definitely go over condom before pills. (User 16)

> I do think non-hormonal methods are better, in general, like consistent use of condoms, or maybe non-hormonal IUDs, or something, would be better than a pill, than a hormonal pill. (User 20)

Being in a long-term relationship also made women more comfortable with assuming a higher risk of unplanned pregnancy. Some even expressed that they have already discussed abortion with their partners as an option in the eventuality of a pregnancy. Thinking back on her experience with Yasmin, one woman said:

> Yasmin affected me in a non-life threatening way, and I gave it up as soon as I realized it was it that was giving me rashes. But I was 25 years old and in a long-term relationship and we were both okay if we'd accidentally gotten pregnant. (User 4)

Affected users choices' were often not driven by efficacy and they did not believe this should be the main factor to influence contraceptive choices. In their view, efficacy was sometimes not enough to offset the side effects that women could potentially experience on hormonal contraception. Moreover, interviewees did not see the pill as a drug that benefits their health, as it is sometimes presented in public discourses (Jones, 2011; Kaunitz, 1999). They rather see it as a necessary evil that helps women prevent pregnancy, but are only willing to take it only as long as the perceived health risks are not too high when compared to other methods of contraception.

Risk as Individual Experience: Tensions Between Population Frameworks and the Personal

During interviews, a tension emerged between thinking about risks in large populations as epidemiological data and thinking about risk as a personal experience. According to some of the interviewees, the at-risk profile painted by professionals served as what they now see as false reassurance that severe side effects will not happen to them. In addition, experiencing side effects when they did not fit the risk profile seemed to amplify the perceived gravity of the situation and risk of the drug. A number of women expressed that, prior to starting their regimen, their doctors were involved in differentiating between a group of patients that are likely to be safe on the pill and a group who are more likely to experience adverse effects. With regards to hormonal contraception use and its risk of VTE, the 'at risk' patient is commonly defined by medical professionals as over 35 and a smoker (FDA, 2012, Health Canada, 2013). A BMI that is too high is also often referred to as a risk factor. As most interviewees did not fit this profile, it initially served as reassurance that they would not experience adverse effects while on Yaz or Yasmin. Those who did experience life-threatening events as a result of pill use express shock and dismay that something like this could happen to women that are young (under 35), healthy and active:

> So then they did scans, and there was [sic] blood clots. And honestly, yeah, they did... They checked, they were like, "You're on this birth control." It was instant, they knew. 'Cause I was healthy, I was athletic, I was in the middle of doing soccer training camp, so that was the only, really, solution to it. (User 20)

> I was healthy, I was in good shape, I was taking care of myself so you always think that, well, that's not gonna happen to me. And they always advise people that smoke shouldn't be on it and vice versa. So, I said I'm not a smoker. So I really did not have worries. (User 5)

> I've never smoked a day in my life. I've never drank anything in my life. I'm a really healthy person. I've never had anything health-wise concern till that moment, till that drug. (User 14)

Consistent with a recent survey about the demographics of women who have experienced blood clots

while on the pill (Marrs, 2016), most respondents affected did not fit the risk profile described above either: most are young (under 35) and self-reported as healthy. Nonetheless, qualitative data cannot give one a picture of risk dynamics in large populations. What can be said, however, is that affected users have had a complex and largely fraught relationship with population risk data. On one hand, these data were reassuring to women in advance of going on a contraceptive pill, but consequently, experiencing side effects without fitting a risk profile exacerbated the magnitude of the risk in the users' eyes. Moreover, interviewees felt that their experiences are unjustly dismissed because of more scientific rational epidemiological approaches to risk that emphasize large populations and probabilities. All felt not enough is done to understand individual circumstances.

Women repeatedly stressed their personal experiences and their wish to be seen as more than a statistic, especially given the numerous ways in which illness has affected their lives. As mentioned above, all women interviewed suffered a range of side effects as a result of taking drospirenone-containing pills. These ranged from minor side effects such as nausea and rashes to DVT and pulmonary embolism. About two thirds of interviewees are involved as plaintiffs in Canadian class action lawsuits against Bayer. It is not the purpose of this study to make inferences about the risks of drospirenone. However, the lived experience of illness was a focal point for all women interviewed and as such, a picture of contraceptive risk as an embodied personal experience emerged – a conceptualization of risk that is hard to incorporate into public health approaches. Women expressed frustration with professionals talking about risk as a numerical value or a probability because they felt such views do not capture their experience. For interviewees who experienced adverse side effects while on Yaz or Yasmin, these events have had numerous ramifications beyond hospitalization:

> I suffered not only physically but mentally after my ordeal, mostly because of the conflict within myself, having to process the information given to me by my doctors. I interpreted almost dying from taking a pill to mean that I was going to have to avoid medications at all costs-to having to take up to 10 pills a day. The pharmaceutical company felt like the bad guy to me, and anxiety and depression took over my life for

> quite a while. I am just now starting to be able to lose the weight that I put on during my course of treatment...my sleep patterns are still a mess […] This has affected every aspect of my life and it's something that I'll continue to struggle with. (User 17)

> I called the hospital next morning and went in for an ultrasound only to be admitted and to have emergency surgery that Tuesday night. The surgeon who removed my gall bladder said it was the worst one he had ever seen in all his years as a general surgeon and the toxicology report came back that I should have been dead […] If I could afford to sue Bayer myself I would because taking a pill has ruined my life and in 7 and a half years I have had 5 major surgeries, can no longer work and I am not the person I was before. (User 8)

The fact that personal experience is important in influencing user risk assessment comes as no surprise. However, the picture painted by affected women tells a story of risk not as a single event in time (such as incidence of DVT, embolism, etc.), but as an experience that extends beyond one episode, with ramifications that expand to many areas of their life, including work, contraception, personal relations, and general health. One woman explains:

> It's not just like, "Oh, you took this pill, and you had these blood clots, and now you're better," it lasts. So yeah. You might hear it from other people too, hopefully, I don't know, but... Yeah, I don't think that this company realizes what they did to their customers. It's not just a one-time thing, it's continuous throughout their life, and then the people that have lost people to it, that's absolutely horrible […] it's just horrendous what this company's done to people. But, yeah. I guess it is what comes along with taking contraceptive, but this one in particular makes me angry. (User 10)

As stressed earlier, women did not feel they received adequate risk information prior to taking Yaz and Yasmin. Not being vigilant about VTE risks affected the severity of their negative experiences. Interviewees felt their illnesses were made worse because diagnosis was delayed, as neither patients nor their doctors considered the possibility of a blood clot at first. Early detection of blood clots is crucial, as they can travel to one's lungs and cause a fatal pulmonary embolism. However, most women who have experienced such a severe reaction recall being sent home repeatedly before being admitted to emergency rooms when their symptoms worsened.

Moving Forward: Speaking Out About the Risks

As a result of their negative experiences, interviewees were eager to provide insights into what they think could be improved in risk communication and official risk/benefit evaluations of drospirenone-containing pills. More than half of the women interviewed only found out about the controversy surrounding Yaz and Yasmin after they had come off of the pill and in some cases, after they had suffered serious injuries. When asked, interviewees said that they do not consider the tradeoff between ancillary benefits and a potential increase in health risks to be fair. Many stressed that had they known about the controversial nature of these pills and potential health risk increase when they began taking them, they would have reconsidered even in light of the added benefits that drospirenone-containing pills offered. Affected users were vocal about their negative opinions about Yaz and Yasmin:

> Do I feel that Yaz is unsafe, in my experience yes. If I had any indication that the medication I was taking would potentially kill me, I would have most certainly not taken it. I still feel that contraceptives as a whole are probably not the best option, but society tells us that it's the easy fix and we are definitely geared to believe it now. (User 2)

> If even one thing is gonna cause, or if a pill is gonna cause one person to die, and there's been more than one person. So if that's just gonna cause one person to die, why would you continue the risk? (User 17)

> Personally, I think the risks are not worth it and I think there's more research that needs to be done because one blood clot is one too many. To have it happen to one person, to have people actually dying from them; It's too many. So I think it should be taken off and looked at again. And there's something that needs to be changed obviously if it's causing these kinds of symptoms and situations in women. (User 24)

As contraceptive pills are not drugs used to treat an illness, women thought that the risks of hormonal contraception, and drospirenone especially, should be minimal. There was a general perception that any potential increase in the risk of blood clots is too much to take on for the purpose of pregnancy prevention and/or side benefits. At the very least, users thought that the risks of drospirenone should be the same as those of other oral contraceptives currently on the market, and if

they are not, Yaz and Yasmin should be taken off the market. Many interviewees advised friends and family members to change contraceptive methods if they were taking a drospirenone-containing pill. Regarding hormonal contraception more generally, women were more ambivalent, with some seeing all hormonal options as potentially too dangerous, while others thought that pills that were on the market before drospirenone have acceptable risks.

Affected users underline the need for more consumer awareness and information from doctors about the risks and benefits of different contraceptives. Not only do they wish they had known more about risks before taking Yaz and Yasmin, but moving forward, interviewees say that they are more considerate of the dangers that any prescription medication carries. Many expressed that they now make sure to research all drugs recommended by their doctors before actually taking them. They also note that they are more sceptical of the medical profession and do not always trust their doctors anymore to make the best decisions for them. Many transitioned from passive to active consumers in light of experiencing negative sight effects while on drospirenone. For example, users express being wary of putting any kind of medication into their bodies:

> I'm not naive to what I'm taking, even, I try not to take Tylenol as much as I used to. I'll try to endure a headache, or whatever. I don't pop pills as much as I used to. (User 9)

> I recognize that the use of synthetic hormones have an increased chance of blood clots, and knowing that now, I would've made the conscious decision to refrain from using any form of contraceptive. In the years since my illness, I have attempted to live a life free of prescription medication as best I can. (User 1)

Furthermore, interviewees felt that Health Canada should have pulled the pills off the market and that pharmaceutical companies should have done more clinical testing and should have been more forward about the potential risks associated with drospirenone. Health Canada has released statements acknowledging a potential risk increase, but provides a range (1.5 to 3) and as such, also admits that some uncertainty remains. Affected users see this uncertainty as reason enough to pull drospirenone

pills off the market, in light of other options they feel have been proven safer. This is despite the fact that the Yaz/Yasmin package insert now contains a warning regarding potential increased risks of DVT and blood clots when compared to previous generations of pills. As stressed earlier, women did not think that the format of the inserts is helpful for conveying risk information that is clear, easy to follow, and accurate.

They all suggested that more should be done by various groups, including companies, doctors, and regulatory bodies to make sure that women have all the information they need about hormonal contraceptives and drospirenone-containing pills in particular. Although they see Bayer as the main culprit for the Yaz/Yasmin controversy, they also stress that users should be provided with better risk information from their doctor and package inserts. Additionally, they mention the need for consumers to become more pro-active and informed themselves by researching risks as opposed to getting all their information from doctors.

CONCLUSION

This paper has provided an in-depth analysis of how affected women understand and conceptualize the risks of controversial contraceptives, Yaz and Yasmin. It also outlines the changes that users advocate for in light of their experiences. As key stakeholders in the Yaz/Yasmin controversy, affected users' views are important due to the weight they hold in legal action against Bayer and thus, the ongoing debate about the risks of the pill. Echoing Beck's (2012) suggestion that modern society is sometimes characterized by a general deference to the opinion of experts, most women relied on the recommendation of their doctor to make decisions about a contraceptive brand. Interviewees decided to research drug risks further only after suffering personal injuries. Only when the risks became tangible did they become real to consumers. However, through becoming more informed, affected users have also challenged the medical establishment as exemplified in interviewees' critical attitude towards drugs more generally.

As other scholars have stressed (Watkins, 2012), the “lifestyle” marketing of new contraceptive pills can be problematic because it over-emphasizes ancillary benefits while downplaying risks. Although the sample has limitations, this study provides some evidence that the way in which Yaz and Yasmin were marketed did influence provider recommendations and reassured women about their prescribed drugs. Despite the role that marketed ancillary benefits played in giving these pills an edge of novelty over others, affected users expressed they would not be willing to trade low health risks for extra benefits, in retrospect. Regarding risk information received before experiencing health issues, women did not feel that it was adequate. Users stress doctors' and pharmaceutical companies' responsibilities to inform consumers. Users did not think the information provided by these groups included all relevant knowledge on risks. Such views show that concerns about the pill that were discussed throughout the past decades are still relevant today. At the forefront of users' concerns is being able to provide *informed* consent when choosing a contraceptive. Interestingly, drug package inserts with risk information were introduced as a result of initial pill controversies and patient advocacy (Marks, 1999). However, many decades later, the women interviewed argue that they did not find the presentation of current information adequate or useful. Because they were not aware of rare but severe risks, interviewees felt they were not equipped to recognize their symptoms. Although further research is needed, findings might suggest that more attention needs to be paid to risk communication strategies. However, this should be looked at in a larger study that can encompass a more diverse population.

The user perspective on the drospirenone debates evidences ongoing tensions between lay and expert perspectives on risk. As mentioned above, historically, professionals have engaged in discussions about data accuracy and validity, while patient advocates tend to stress personal suffering instead (Junod and Marks, 2002; Marks, 1999). The views of the women interviewed show that dissatisfaction with professional approaches remains, as patients feel that their views are disregarded in

favour of epidemiological data. There is no doubt that these perspectives are hard, if not impossible, to reconcile. In addition, while professionals use pregnancy risks to provide context for dropirenone VTE risks (Geampana, 2016), affected users felt that this is not a useful comparison, as they perceived pregnancy to be a natural and therefore completely different kind of risk. This furthers work that stressed the importance of the perceived type of risk source (Brun, 1992; Keogh, 2005). It also expands on the quantitative risk assessment literature by explaining more in-depth why women might perceive pregnancy as less risky and also, some of the reasons why they might choose less effective contraceptive methods. As mentioned before, further studies with more diverse samples are needed to get a full picture of user contraceptive risk assessment. However, this research provides a starting point by bridging some of the gaps between data on user perspectives and critical qualitative studies of contraceptive technologies.

The findings also further ideas about the importance of cultural factors in user contraceptive risk assessment. In line with Douglas' (1986) line of thinking, this paper stresses that contraceptive risks are not evaluated in a vacuum governed by rationalization. As she points out, risk should not be conceptualized as objective or subjective, but rather through a cultural lens, given the repercussions for those who experience risk first-hand: as a result of their negative experiences, the women interviewed advocate for changes drug regulation and risk communication. Such views, when contrasted to professional discourses, reveal different patient conceptualizations of risks – understandings that are not necessarily focused on absolute risks, but rather on severity based on perceived source (natural vs. human-made). To further stress cultural influences on risk perception, the marketed side benefits influenced doctors' recommendations, according to users. At the same time, the risks presented and emphasized subsequently in the media served to reinforce women's convictions that, in the end, drospirenone-containing pills are not safe.

Respondents' assessment of new contraceptive pills reinforces the importance of sociocultural

factors in risk evaluations. It is crucial to move beyond distinctions between objective and subjective risks and instead, look at contraceptive risk perception in a social context to better understand patient experiences. Approaching risk from such an angle challenges us to think more critically and in-depth about the evaluation of contraceptives. A more nuanced understanding of user risk perception is needed to facilitate favourable health outcomes for women.

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ASSESSING AND MANAGING THE RISKS OF CONTRACEPTIVES

Chapters 2 and 3 looked at how the risks of drospirenone are conceptualized in official professional discourses and by lay stakeholders, respectively. These chapters emphasize how both expert and patient perspectives are influenced by cultural factors. While professionals have emphasized the risks of pregnancy, users stress that they do not find such a comparison useful for assessing the pill's risks. Affected patients perceive the VTE risks associated with pregnancy to be different in nature because they do not come from a human-made source. Consequently, patients critiqued professional evaluations of the risks of drospirenone. Furthermore, the findings presented in Chapter 3 show that patients do not think they received adequate risk information prior to being prescribed drospirenone-containing pills. Both Chapters 2 and 3 stress the tensions that exist between lay and professional perspectives. In light of this divergence, Chapter 4 aims to explain the processes through which Yaz and Yasmin were left on the market, despite lay stakeholders' concerns about the potentially increased risks that these pills pose. The goal of this paper is to go beyond official risk discourses and to explore in-depth how debates about the safety of drospirenone have manifested themselves in regulatory and epidemiological risk evaluations. Furthermore, it explores the ensuing consequences for the management of contraceptive risk. In Chapter 4, I argue that professional contraceptive risk assessment is characterized by disagreement and consequently, a diffusion of responsibility between stakeholders for managing risk. The consequence of such processes is that users are left to manage the drugs' potentially increased risks of VTE themselves. I identify three specific areas that are characterized by disagreement. Firstly, experts diverge on whether the drugs' benefits are indeed unique. Secondly, risk measurement in post-market surveillance data has also been a contentious issue within professional circles. Finally, there is little consensus on how to weigh risks and benefits and consequently, how to

establish acceptable risk thresholds for contraceptives approved for market sale. In light of such disagreements and the ensuing diffusion of responsibility with regards to the management of contraceptive risk, users are then encouraged to manage risk themselves.

CHAPTER 4

LEAVING PATIENTS TO DECIDE: THE DIFFUSION OF RESPONSIBILITY IN CONTRACEPTIVE RISK ASSESSMENT AND MANAGEMENT

ABSTRACT

Focusing on controversial birth control pills Yaz and Yasmin, this paper explores how debates about the safety of these drugs have materialized in risk evaluations and the management of contraceptive risk. Drawing on in-depth interviews with stakeholders and content analysis of legal, medical, and regulatory documents, I argue that professional contraceptive risk assessment is characterized by systemic uncertainty and doubt, resulting in increased responsibility for users to manage the drugs' potentially increased risks of venous thromboembolism (VTE) themselves. The paper identifies three key areas in the assessment process that are characterized by disagreement: the drugs' benefits, risk measurement in post-market surveillance data, as well as risk/benefit weighing. While professionals debate uncertainties both in epidemiological research and clinical practice, users are encouraged to manage risk individually. Such processes are underlined by a diffusion of responsibility with regards to the management of contraceptive risk.

KEYWORDS: contraceptives; risk assessment; ancillary benefits; risk measurement; drug regulation

INTRODUCTION

Disputes about the safety of the birth control pill have become prominent in recent years. Popular contraceptives Yaz and Yasmin, manufactured by Bayer, have been linked in the media to at least 23 deaths in Canada and over 100 in the United States as well as thousands of injuries worldwide, due to a potential increase in the risk of venous thromboembolism (VTE) and incidence of blood clots. The estimated VTE risk increase varies across studies from 1.5 to 7 times when drospirenone (the new hormonal compound used in Yaz and Yasmin) is compared to previously-used compounds (Wu et al., 2013). On the other hand, organizations such as the Society of Obstetricians and Gynaecologists of Canada (SOGC) and Health Canada have stressed that the new pills are safe, by comparing their risks to the VTE risks women are exposed to during pregnancy and the postpartum period. What constitutes "significant" risk has been contested by stakeholders in the case of the new generations of pills. To add to the complexity of the post-marketing drug evaluation process, Yaz and Yasmin's ancillary, non-contraceptive benefits - treatment of acne and premenstrual dysphoric disorder (PMDD) - have been heavily marketed to potential consumers. In light of these advertised benefits, questions arise whether these would be enough to offset the potentially increased risks and offer users a favourable risk/benefit ratio. However, as this paper will highlight, it is not clear if drospirenone's benefits are unique and actually reflect advertising claims. A problematic pharma marketing context coupled with stakeholder disagreement on risk measurement, and patients' negative experiences signal that current contraceptive risk/benefit assessment is an intricate undertaking that merits more attention from scholars. This paper uses the Yaz/Yasmin controversy to critically evaluate broader contraceptive risk assessment processes which have, so far, remained largely unexamined. Historically, the pill has been fraught with many debates about its safety. While some have documented the controversies (Marks, 2000; Marks, 2001; May, 2010; Watkins, 1998), we know little about how the meaning of acceptable risk is still contested and, more importantly, what consequences such processes have for users. Drawing on risk theories, I

argue that a diffusion of responsibility in risk assessment and management is endemic to the process of evaluating and regulating hormonal contraceptives. More specifically, this paper shows that professional stakeholders disagree on whether or not the benefits of Yaz and Yasmin are unique as well as contraceptive risk measurement and acceptable risk thresholds for pills on the market. This, in turn, has consequences for patients who are left to make sense of conflicting risk information.

LITERATURE REVIEW

The Proliferation, Diffusion, and Management of Modern Risks

In order to better understand the production, evaluation, and diffusion of contraceptive risks, this paper draws on sociological risk theories. My analysis stems from the sociological assumption that risk is socially organized and systematically produced by social structures, rather than by individual actions (Beck, 1992; Lupton, 2013; Perrow, 1999; Vaughan, 1996). The “risk society” framework, for example, conceptualizes modern systemic risks as amorphous and ever present – a consequence of the modern organization of scientific and technological systems. More specifically, where risks are concerned, Beck (1992) is critical of the authority of technical experts to define agendas and risk discourses. While he posits that previously hazards were more evident to the senses (they could be smelt or touched, for example), many types of risks now escape sensory perception. For example, food chemicals are hard to perceive. As such, these risks are made 'real' by scientific knowledge rather than by daily experience (Lupton, 2013). This is also true of the risks posed by hormonal contraceptives. Although some individuals have come forward with experiences of adverse side effects, calculating risk is an activity relegated to the medical and scientific realm. Furthermore, Perrow (1999) argues that high-risk technologies, such as nuclear power, chemicals and space aircrafts are currently multiplying, giving rise to systems that increase risks for operators, passengers, as well as innocent bystanders. Such systemic approaches are a useful lens for analyzing the structural proliferation and diffusion of risks as a result of complex regulatory decisions and the growth of pharmaceutical companies.

Aiding this conceptual theory are empirical scholars that study the systemic distribution of risks through highlighting the dangers posed by modern technological artifacts and their consequences (Perrow, 1999; Petryna, 2013; Vaughan, 1996). An example of the creation of high risks by complex technical and organizational systems is the Challenger Launch disaster, as analyzed by Vaughan (1996). To study the disaster, Vaughan examined NASA's organizational structure to uncover that "the cause of disaster was a mistake embedded in the banality of organizational life and facilitated by an environment of scarcity and competition" as well as an uncertain technology and a complex culture (Vaughan, 1996, p. 45).

Using insights from Science and Technology Studies' analyses of technologies embedded in risky systems, I make the case that drugs and other medical technologies might also be considered as artifacts that create an economy of risk through the diffusion of responsibility and uncertainty with regards to their more severe side effects. Although the literature on pharmaceutical markets does not specifically draw on risk theory, the role of "big pharma" and medical technologies in shaping medicine and consumer perspectives has been highlighted by scholars (e.g., Abraham, 2008; Busfield, 2006; Fisher and Ronald, 2010; Fishman, 2004; Fox et al., 2006; Greene and Watkins, 2015; Loe, 2001; Williams et al., 2008). There are several aspects of pharmaceutical technologies that warrant us to think of drugs as risky technologies. For example, Light (2010) emphasizes deficient approval processes, while Greene and Watkins (2015) make the case that drug package inserts are a flawed way to convey adequate risk information to consumers. In addition, some (Abraham, 2008; Busfield, 2006) see the neo-liberal logic that drives drug markets as detrimental to users. More importantly, pharma companies govern "scientific 'fact making' in the clinical trials of drugs," while downplaying potential risks (Busfield, 2006, p. 241). Moreover, risks also tend to be minimized because of the misleading ways in which drugs are advertised (Greene and Herzberg, 2010; Greene and Kesselheim, 2010). Bringing together theories of risk and work in medical sociology, I stress the need for better

understanding the diffusion of risks in the assessment of contraceptives.

While Beck's (1992) “risk society” theory is useful for looking at systemic risks, it does not account for the normative ways in which risks might be deployed by experts. In the case of contraceptive pills, unplanned pregnancy risks have been emphasized by professionals in gendered ways (Geampana, 2016; Van Kammen and Oudshoorn, 2002). As such, I also use insights from work on governmentality in medicine – work that is critical of how risks are constructed and used by state and medical institutions. Foucault's concept of a new style of governance in modernity has been particularly prominent in the development of work on governmentality. Foucault (1984) understands the risk apparatus as an “ensemble formed by the institutions, procedures, analyses and reflections, the calculations and tactics that allow the exercises of this very specific albeit complex form of power.” It is this ensemble that emphasizes specific risks for the public and thus creates a 'need' for management, either by institutions or individuals (Lupton, 2013; Zinn, 2008). For example, several studies have explored how female bodies are constructed as sites of risk (Brown, 2014; Fosket, 2004; Klawiter, 2010; Martin, 2010; Stevens, 2016). Technologies can facilitate such processes in various ways: through the development and standardization of medical assessment tools (Fosket, 2004), preventative drugs (Brown, 2014; Fosket, 2004), biomedical knowledge production (Shim, 2000), and expert advice (Stevens, 2016). Fosket (2004) underlines how certain risk models become prominent and standardized despite significant concerns regarding their accuracy and validity. Shim (2014) also stresses that risk, in the case of epidemiological evaluations of heart disease, is something that is socially mediated and influenced by structural inequalities. As such, the way in which experts perceive risks and their effects on large populations can contradict the lived experience of those affected by diseases. Similarly, this paper stresses tensions between the epidemiology of contraceptive VTE risks and individual patient perspectives on risk.

Risk in relation to hormonal contraception is specifically related to normative ideas about

gender, pregnancy, and women's bodies (Geampana, 2016; Oudshoorn, 2004; Van Kammen and Oudshoorn, 2002). Since the early clinical studies on oral contraceptives, the degree of health risks considered acceptable for women has been compared to the risks associated with unplanned pregnancy (Van Kammen, 2000; Watkins, 1998), with the assumption that pregnancy is the alternative to consider when taking a contraceptive. Oudsoorn (2002) explains that, in developing countries, the risk of hormonal contraceptives has also been evaluated against maternal mortality rates and as a consequence, these technologies have been widely perceived as able to curb these rates by preventing women from getting "accidentally" pregnant in the first place. Therefore, risks associated with the contraceptive pill have been construed as more tolerable when the alternative might be the reproductive risks (e.g. unplanned pregnancy, abortion) associated with women's bodies have been emphasized throughout the pill's history (Marks, 2000; Watkins, 1998). As a consequence, contraceptive evaluations reflect political concerns stemming from gendered conceptions of acceptable risks for each sex (Marks, 2000; May, 2010; Oudshoorn, 2004; Van Kammen, 2000). As risk assessment tends to focus on the dangers of pregnancy and unsafe abortion, the possibility of health risks for men is not incorporated in such evaluations (Van Kammen and Oudshoorn, 2002). In addition, women are still the ones mainly responsible for birth control (Brown, 2015; Littlejohn, 2013). Adding to the literature on gender and contraception through the use of sociological risk perspectives, this paper emphasizes the systemic diffusion and proliferation of contraceptive risks. It does so by highlighting expert disagreement on risks and benefits leading to indecision in regulatory processes, all to the detriment of users left to make sense of complex risk information on their own.

METHODOLOGY

This study employs qualitative data collected from a variety of sources. I conducted a content analysis of documents that pertain to the research and development of drospirenone-containing oral contraceptives. These data include official guidelines and press releases from regulatory bodies and

relevant professional associations, product monographs, regulatory advisory committee transcripts, epidemiological studies on the risks of drospirenone, as well as court trial documents from proceedings against Bayer, the makers of Yaz and Yasmin. Documents were collected from Health Canada and FDA's websites as well as public and legal databases. Following ethics approval from the McGill Research Ethics Board, I conducted 43 in-depth interviews with key stakeholders, including clinicians involved in developing contraceptive guidelines, epidemiologists who have studied drospirenone, regulatory experts, as well as contraceptive users. The sample includes 2 regulatory representatives (1 Canadian and 1 from the U.S.), 6 epidemiologists who have conducted studies on drospirenone), 4 researchers/clinicians (both authors of studies and health professionals), 7 Canadian clinicians/contraceptive guideline developers, and 24 contraceptive users (most of whom are involved in class action lawsuits). There is significant overlap in expertise as professionals are often involved in both research and clinical practice. Stakeholders constitute a purposive sample – they were recruited for their expertise either in risk evaluation, risk communication, or regulatory approval. Users were also recruited on the basis of their involvement in lawsuits against Bayer or advocacy against Yaz and Yasmin. All clinicians and users are from Canada. However, experts on drospirenone were not limited to the Canadian context. This is due to the fact that regulatory bodies consult data published by international researchers. As such, it would not make sense to limit the sample to Canadian epidemiologists. Regulatory data (advisory meeting transcripts and official statements) from the United States Food and Drug Administration were also included in the sample due to the fact that they discuss data from international studies. In addition, there are similarities and connections to the Canadian context: 1) clinicians interviewed talked about the North American context as being overall different from the European one, 2) most Canadian patients interviewed expressed being exposed to US ads for Yaz and Yasmin, 3) Canadian legal cases cite information from the FDA, and 4) Health Canada and the FDA have been releasing very similar official statements and risk information to consumers. However,

I discuss FDA practices not to draw conclusions about the U.S. system, but to be able to discuss how international experts that are also relevant to the Canadian context have debated the risks of drospirenone.

The questions that guided the data collection and analysis are: How are the risks and benefits of new hormonal contraceptive technologies evaluated by different stakeholders? Which risks and benefits are emphasized? What are the prevailing risk models used to evaluate new hormonal contraceptives? What individual/groups are seen as responsible for managing risk and why? Data collection occurred between August 2015 and March 2017. Documents and transcribed materials from in-depth interviews were analyzed using MAXQDA, a computer-assisted qualitative data analysis software. Guided by the principles of grounded theory, I identified both deductive and inductive themes. Using critical discourse analysis (CDC), I looked to find common themes and risk discourses in the data, but also aimed to identify neglected assumptions that might also warrant attention. This study also explores some of the potential connections between current risk assessments of hormonal contraceptives and the wider context in which they are developed and marketed.

FINDINGS

Debating the Benefits

One of the questions that arise in contraceptive risk/benefit assessments is whether or not the new technology offers additional benefits when compared to other options already available to consumers. Although oral contraceptives offer a variety of benefits (e.g. cycle regulation, decreased risk of certain cancers), it is generally accepted that these are the same across all combined pills. Therefore, my discussion will focus on the benefits that are intended to differentiate drospirenone from other pills. While the marketing of Yaz and Yasmin claimed initially that they are the best contraceptive pills on the market, this research has found that, although not all, many experts are inclined to think that there is nothing special about drospirenone's marketed ancillary benefits. This, in turn, is important

when considering how to balance the risks and benefits of these pills. Although drospirenone-containing contraceptives were first and foremost approved for pregnancy prevention, they were marketed and promoted for their ancillary benefits, most notably under the slogan "beyond birth control." In order to legally accomplish this, Bayer sought approval from regulatory bodies in both Canada and the U.S. to advertise the pills for acne and PMDD treatment, after conducting the required clinical trials demonstrating the pill's positive effects. The company tried to advertise the drug as a general PMS and acne treatment, but was fined by the FDA for overstating drospirenone's benefits in post-market release TV ads, as the compound is only approved to treat severe acne and the more severe form of PMS: PMDD. Nonetheless, the advertisements were seen by the target audience: women and their clinicians were drawn to these advertisements portraying young active women who claimed to have found a pill that goes "beyond birth control" and fights moodiness, bloating, and acne. In places like Canada, the U.K, and Australia, where direct-to-consumer advertising is illegal, marketing was directed at clinicians who were targeted by Bayer with pamphlets and free samples for patients, thus enabling the pills to make their way to consumers through gatekeeping prescribers. Canadian class action lawsuits claim that the benefits were overstated in Bayer's 2009 press statements where "similar to the advertising in the U.S. that the FDA took issue with, the Canadian press release also states that Yaz treats acne, but does not specify the *type of acne it is indicated to treat* (Ann Schwoob et al. vs. Bayer Inc. et al., 2010, emphasis not mine)." It is through such advertising that Yaz and Yasmin blurred the line between contraception and lifestyle drug – a phenomenon that scholars like Watkins (2012) and Mamo and Fosket (2009) have critiqued, emphasizing the phenomenon of advertising contraceptive pills based on their ancillary benefits.

The need to attract consumers and prescribers with ancillary benefits comes, in part, from a lack of significant breakthroughs in contraceptive innovation during the past few decades. To a large extent, the options women have today are very similar to the ones they had in the 1990s. Indeed, some of the

health professionals interviewed do see the new pills as the consequence of a stalled contraception pipeline, in a context where it is too expensive to come up with radically different methods. Hence, pharmaceutical companies look to boost sales through marketing techniques, altering their pill's compounds to target the non-contraceptive "benefits" of taking the pill. Such techniques can overstate a pill's benefits. A Canadian clinician and contraceptive guideline author explained what the oral contraceptive development process looks from her perspective and how pills are similar:

> They're always tinkering, they're always offering a new option to say, "We've got something better." And without exception, each time they come up with something that's a little bit better, so lighter periods, less moody, we're gonna make it better for you, the marketing is aimed at young women, and it's aimed at, "Are you feeling awful on your pill? Try ours, it's better." So what we see when we get a new hormone coming out and the other piece to understand is that the estrogen component of pills hasn't changed in 40 years, it's always been the same. (Professional 14)

Even when asked about drospirenone's benefits in particular, many experts emphasized 'sameness' across all oral contraceptives. The author of several published drospirenone studies stresses the role of marketing in the perception of the pills' distinctive benefits, while, in his opinion, these are not unique at all:

> There isn't really a pharmacological difference. From the beginning, I don't think there's any significant differences between hormonal contraceptives. This is true regarding the benefits as well as the risks. I believe that the so-called advantages of some hormonal contraceptives are just enormously magnified through the marketing of the pharma companies. (Professional 5, clinician/epidemiologist)

As emphasized above, sameness may also imply that the risks are not different either. However, the issue of risk measurement will be tackled into more detail below. Most importantly, for discussing drospirenone's benefits, the emphasis on similarity suggests that there are no added benefits when compared to other pills. Despite the heavy marketing of the ancillary benefits of Yaz and Yasmin, the expert community does not seem to agree whether they are actually unique or significant enough to differentiate drospirenone-containing pills from other oral contraceptives. Some researchers are

adamant that the pharmacological differences between contraceptive pills are minimal, while others are more inclined to believe that the purported anti-androgenic effects of drospirenone can be especially beneficial for some women, thus setting Yaz and Yasmin apart. Those who are most familiar with clinical trial approval data were more likely to be sceptical about ancillary benefits. Conversely, those who are more involved in clinical practice stressed that some patients might benefit from additional benefits. At the same time, some express simply not knowing, despite all their knowledge. Interestingly, stakeholders that emphasize sameness to other compounds stress that there are many other pills on the market that can combat acne; the difference between these and the drospirenone ones being that the manufacturers of previous pills did not seek label approval for side benefits, as this requires the submission of additional clinical trial data. As such, some see Bayer's advertised ancillary treatments simply as a marketing move that masks similarity:

> All combined contraceptives can combat acne. The only difference is that some have a labelled indication and some have not. But all of them...there's only very minor differences in the progesterone...I know the randomized clinical trials on acne quite well. I know that the differences are really minor...the primary active principle is the same. (Professional 15, clinician/epidemiologist)

> If someone comes with acne I would first prescribe another pill before considering Yaz or Yasmin. You know, it depends if drug companies bother to do a study. And if they haven't invested the money, there is no evidence. But there's no premium benefits in comparison to cheaper pills. My feeling is that drug companies, to make women feel less anxious about blood clots, they really push these side benefits in terms of advantages, which are advantages to some women. But there's no clear evidence that they're better than other pills. (Professional 12, clinician/researcher)

Others acknowledged that they are uncertain about the benefits of drospirenone:

> I have read that in clinical trials or in studies, there is no significant difference between any of the oral contraceptives with respect to the acne and the pre-menstrual syndrome and all these kinds of things. So, I'm not convinced that there is a difference. I know that Yaz was basically marketed as being better. I don't know if that's true or not. (Professional 3, epidemiologist)

> Now where it gets a little more difficult is among oral contraceptives, if one is riskier

> than the other, do its relative benefits outweigh its relative risks? And that's less clear. I don't think we really know for sure. (Professional 9, epidemiologist)

As mentioned above, clinicians were more likely to see potential value in the new hormonal compound. For example, one OB/GYN involved in drafting Canadian contraceptive guidelines said:

> Well, I will be honest with you, the negative press...it's been really discouraging to me. Because I think that Yaz, I think the product that has drospirenone in it, is a good product for a couple of reasons. One of them being that the progestin that's in it is very anti-androgenic, meaning, it's good for people who have a lot of acne and things like that. So, somebody comes to me and they need contraception but one of the side-effects that they would really benefit from would be an improvement in their acne, I might preferentially think of prescribing that one. (Professional 7)

Most importantly, the uncertainty regarding drospirenone's unique benefits is an aspect that is rarely openly conveyed to the public. This research has found that such debates are generally confined to expert groups. Consequently, there are no measures to inform patients or clinicians who are not up-to-date on epidemiological data that drospirenone's marketing may be misleading with regard to its uniqueness. This could potentially leave users and clinicians to get information about the pills' benefits solely from pharmaceutical companies, TV ads, or the pamphlets provided by Bayer. Patient stakeholders interviewed expressed that the allure of the new pills definitely played a role in their choice, despite the fact they were not looking for an acne treatment:

> Just birth control. I wasn't expecting anything else from it. Like I said, I never had cramps or any PMS symptoms. I didn't have a need for anything else. Being told that, "Yeah, sure, it will help with acne maybe," that was a bonus, but I wasn't expecting it to. But it's probably why my doctor recommended it. (User 14)

> No. No, the main thing was for me not to get pregnant, and then these were... So, I knew I had to go on something and then this one had, supposedly, these added benefits. And that's what geared me towards it. (User 19)

Despite the initial marketing appeal and the influence it had on prescription practices, it is debatable whether or not drospirenone has additional benefits when compared to other contraceptive compounds. This research has found that, overall, for both patient and experts, the ancillary benefits of Yaz and Yasmin are not very salient in current benefit assessments. Few decision-making stakeholders seem to

be as enthusiastic about acne and PMDD treatment as Bayer's ads. In addition, affected patients have been adamant that any additional ancillary benefits would not be enough to offset the potential increase in VTE risks. Given the uncertainty around whether these pills might be better than others, it is unclear if the purported additional benefits can or should balance out a potential increase in VTE risks. What is certain is that the significance of the advertised non-contraceptive benefits of drospirenone has been questioned by stakeholders. As I will later discuss, not having a clear picture of the added benefits affects the weighing of risks against benefits.

Uncertainty in Risk Measurement

The epidemiological studies discussed in the wake of the Yaz/Yasmin controversy are all part of the post-market surveillance data collected to assess VTE risks. While trials need to establish some degree of safety, outcomes like VTE are too rare to have conclusive data prior to a contraceptive going on the market. As such, risk debates about drospirenone are centred on data collected after its initial approval. An important aspect to note about these data, before delving into expert critiques, is pharmaceutical companies' involvement in its collection. Not only does Bayer collect post-market surveillance data through additional studies, but if a significant number of adverse effects are reported by consumers, it is usually the manufacturer's responsibility to conduct research commissioned by regulatory bodies, with some exceptions. The largest post-market approval dataset collected on drospirenone and VTE risks was funded by Bayer. This has led to scepticism of Bayer's findings that drospirenone's risks are similar to those of other contraceptive pills among some experts who testified in regulatory advisory committees. It is not customary for regulatory agencies to collect post-market approval data, but in the case of drospirenone, the FDA has conducted a post-market surveillance study of its own, in addition to those funded by Bayer. Health Canada, on the other hand, has drawn upon international and privately funded studies that have also been discussed by the FDA in their assessment of drospirenone. In this case as in most other cases, regulatory bodies are largely dependent on data

collected by pharmaceutical companies. Interviewees talked about the role of companies in the production and dissemination of data as currently entrenched in the way new contraceptives are being developed:

> Well, that would be fine if the government would give tons of money to scientific teams in university grounds to do that type of research. And there is no research funds available for the development of contraceptives in Canada and in many places in the world. So given that the public sector does not fund or very few funding exists for this type of domain, it gives the pharmaceutical sector the whole freedom to take it. And there are some NGOs, non-governmental organizations, that do some research, namely, CONRAD and the Population Council in the US, but these two organizations are dedicated to populations in the developing world, so they are not the ones who will develop contraceptives for women in the western world at all […] And the way it works nowadays, it is so expensive to have a new drug, to do a new drug submission to Health Canada or FDA. There is no public sector able to afford that. (Professional 15, clinician/epidemiologist)

> It would be nice to have more choices. But I guess the system, as I've grown up in it and that I recognize, is that it's the pharmaceutical companies who have the money, the drive, the research expertise to do the developments that it takes to get a drug even to a point where they have a drug they can test. I guess they could farm that out to other research bodies or academic groups, but I'm not sure that they would invest their money in the same way if they did it that way. They want a product that they can sell. (Professional 8, clinician/guideline author)

As mentioned above, because initial approval data did not provide sufficient information on VTE risks, the focus of the Yaz/Yasmin controversy has been on post-market surveillance studies. There have been more than 20 studies published on the VTE risks of drospirenone since it was released on the market. The results of these studies range from finding that there was no risk increase of VTE to finding risk increases varying between 1.5 and 7 when compared to levonorgestrel (LNG) pills (second generation oral contraceptives). However, for regulatory purposes, the studies that have dominated post-marketing debates on VTE risk are the 10 that appear on a chart in Bayer's Yaz/Yasmin patient insert (see Figure 1). Because of their prominence in risk discussions, these studies will also be the focus of my analysis. Their data suggest that the risk increase for VTE can be anywhere between 1.5 and 3 (compared to other OC), hence these are the numbers that both the FDA and Health Canada have

provided in their official public statements. There are several methodological concerns that have dominated discussions of risk measurement, such as, for example, pharma involvement in research and the limited demographic information available on patients included in post-surveillance studies.

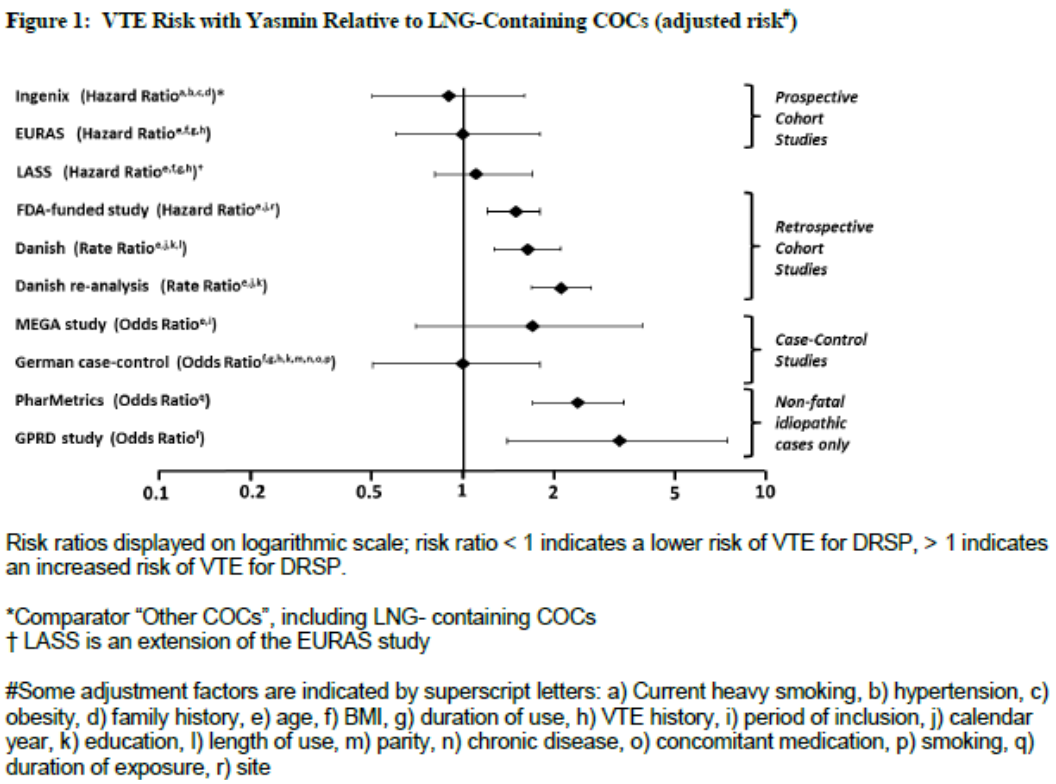

Figure 1: VTE risks as evaluated in epidemiological studies relative to LNG

All studies come with disadvantages, as experts have noted. In terms of research design, prospective cohort studies have been favoured. These are studies where large numbers of patients were recruited for the specific purpose of measuring VTE risks with drospirenone versus levonorgestrel. However, all three prospective studies available (Ingenix, EURAS, and LASS) were funded by Bayer and consequently, have been critiqued on this basis. For example, Dr. Diana Zuckerman, a Yale epidemiologist, noted during an FDA regulatory meeting:

> We all know that there's plenty of research showing that funding sources influence research findings. And there have been numerous articles in *JAMA* and many other medical journals showing the impact of funding and how that affects the fact that studies that are funded by a particular entity tend to show that their product is safer and more effective than other studies show. That doesn't mean that the researchers are intentionally misleading or misrepresenting the data; sometimes it's absolutely not conscious. People believe in the products that they're working on and studying, and they tend to accept the good findings and discount the negative findings. But sometimes, of course, research methodology is manipulated in order to maximize the likelihood that findings will be positive. And I just want to say that although I think the panel has not been given access to the Kessler report that was recently made available, it did have some very specific examples where Bayer was misleading and misrepresenting VTE findings.

Strikingly and unsurprisingly, the three studies funded by Bayer found the lowest risk increase overall. Therefore, although they are considered to have the advantage of a prospective research design, their findings have been called into question because of their funding source. The post-market retrospective studies include two done by Danish researchers using data from Danish patients and one conducted by the FDA. Retrospective studies have found higher risk increases (rates closer to 2), but have been critiqued for using data from patient databases that were not specifically designed for the purpose of measuring VTE outcomes. As opposed to recruiting participants and observing their outcomes while on drospirenone pills, retrospective studies take data already collected through national health databases and look for specific outcomes (in this case VTE) in these data. Scandinavian countries, in particular, are known to have detailed centralized records of patients and their health outcomes. For this reason, Danish researchers have been at the forefront of studies on women's outcomes on contraception, including a recent one that found higher rates of depression in women who are on the pill (Skovlund et al., 2016). Finally, the other studies discussed by experts include two case control studies and and two non-fatal idiopathic cases only studies. Case control studies compare groups with different outcomes (in this case VTE events vs. no VTE events) and measure odds ratios for these groups – a measure that is considered weaker than those of the prospective and retrospective studies. Idiopathic case studies, on the other hand, are limited to groups with negative outcomes and also measure odds ratios.

All researchers interviewed as well as those who have critiqued the drospirenone studies in journals and the media have stressed the inadequacies of the studies available and the limited information we have on patient characteristics and their medical histories. Many have argued that all post-market surveillance studies have failed to collect all the relevant information on patients that they have either recruited or whose data they retrieved from databases. Such critics stress that missing data from patients who participate in epidemiological trials or unknowns in the retrospective data from national databases have led to bias and confounding. Most notably, some epidemiologists are highly critical of the initial Scandinavian studies that found a VTE increase, as these studies used databases that did not have information on patient BMI and smoking/lifestyle. These factors are known within the professional community as indicators for a higher risk for VTE. One epidemiologist, for example, said about these studies:

> And there were a number of methodologic flaws in that study. In particular, the fact that it's database-driven in the first place, which had its own set of flaws in terms of having accurate information documented or not. But then, other things he didn't take into account were things like the facts that people have higher risk of VTE in the first 3 to 6 months after starting a new pill. (Professional 19)

With regards to individual database information, retrospective studies have also been critiqued for the way they measured individual outcomes. The validation of VTE diagnoses was shown to be inaccurate for some of the patients included in retrospective databases studies. For example, database inaccuracies suggested VTE events in patients that did not actually experience them. However, the research design of a retrospective study does not usually allow for individual follow-up and validation of a potentially inaccurate diagnosis in the database used. As such, there has been much speculation by professionals about confounding variables for individuals who were already considered at risk when they started the pill regimen and bias due to a lack of accurate information on VTE outcomes. Even in studies that have found just a slight or insignificant increase, experts have questioned the limited patient data available – a gap that is concerning when trying to control for individual risk factors in all the studies. This has

long been a topic of debate in regulatory advisory meetings that have looked at the epidemiological studies outlined above. Prospective studies have also been critiqued for not collecting all relevant information on participants. Additionally, some epidemiologists have pointed to the possibility of clinician prescribing practices as potentially skewing incidence rates. In advisory meetings, they noted that some health professionals prescribe contraceptive pills to older women who might be more at risk for blood clots (it is well known that there are higher VTE risks for women over 35). Thus, another question in the debate became whether prescription practices might skew incidence rates in all the studies where age has not been controlled for. This is not to say that epidemiologists blame clinicians for risk increases in the data. Rather, they underline the limitations that come with not knowing exactly to whom drospirenone has been prescribed.

More generally, contraceptive trials, by nature, pose additional epidemiological challenges because: 1) they cannot be randomized due to ethical reasons; 2) many women have used the pill at some point in their lives and previous use of the same or of a different brand is also likely to affect outcomes; however, not all studies control for this because of a lack of user information. Epidemiologists explain these limitations:

> Well, of course, the best study is a randomized control trial, but that's never going to be done. The product's on the market, so the best we can do now is look retrospectively at the data that's out there, so we have to look at case reports or adverse incident reports through some kind of [regulatory] bodies. We have to rely on what people report. There could be all kinds of DVTs, for example, that have happened that have never been reported with the drospirenone products or with others, so our limitations right away are the data that's available to us and then how you analyze the data that you have and there's always going to be limitations when you use an analysis, an approach or whatever. We just have to live with the limitations of whatever the study design is and the limitations of the data you have available to you. And I think that's why it gets confusing. (Professional 18)

> And in a lot of our databases we don't have lifetime history of use. We have use, we're able to go back sometimes one year, sometimes three years. But we're not able to go all the way back. And what some colleagues have previously shown is that, if you're not able to get first-time use, you need to be very careful because otherwise you can have bias by comparing first-time users of the newer generations, versus restarters of the

older generations. (Professional 9)

In light of these debates, many epidemiologists and researchers expressed simply not knowing what the risk is. However, only a minority expressed that the pills should be pulled off the market. Solutions given by interviewees for risk management often involved individuals deciding on their own whether or not to take drospirenone-containing pills. This was despite professionals not being sure themselves what the actual risk involved is or if there are tangible ancillary benefits to balance drospirenone's risk/benefit equation.

How to Weigh Risks and Benefits for Regulatory Purposes: Lack of Consensus

Although professional associations and regulatory bodies in Canada and the U.S. have used the higher VTE risks associated with pregnancy as the main comparison point to assure consumers that drospirenone is safe (Geampana, 2016), there has been no expert consensus on what the "acceptable" risk should be in the case of oral contraceptives on the market. Health Canada decided that a potential risk increase between 1.5 and 3 compared to the previous generation of oral contraceptives (containing levonorgestrel) is acceptable, especially when compared to pregnancy risks (pregnancy and the postpartum period are associated with a significantly higher risk of VTE). The regulatory body has warned patients that they "should be aware that stopping their birth control may result in unintended pregnancy" (Health Canada, 2011), while also expressing uncertainty regarding the exact risk increase. However, as I will detail below, experts have different priorities with regards to how the pill's risks and benefits should be weighed and placed in context for users. It is hard, if not impossible to agree on what the risk threshold *should* be for oral contraceptives on the market. While health professionals interviewed agree that pregnancy is a useful comparison in order to put the risks of drospirenone into perspective for users, the question of what the cutoff rate should be for market approval still looms large. On one hand, drospirenone is surrounded by enough uncertainty for professionals to suggest that it might pose higher risks than other oral contraceptives. On the other hand, these higher risks are still

low compared to pregnancy and postpartum VTE risks. Interviewees did express that the pregnancy comparison should not mean that all risks below this threshold should be acceptable, especially since there are safer oral contraceptives on the market. However, the cutoff risk rate for regulatory purposes is not agreed upon, as some experts tend to focus more on the comparison between different oral contraceptives, while others focus on the pregnancy prevention properties of the compound and consequently, compare drospirenone risks to pregnancy risks only. One researcher/clinician outlines the difficulties that professionals face when weighing risks and benefits:

> For the case of oral contraceptives, regulatory agencies and, really, we as a society, have decided that a certain amount of risk of thrombosis is acceptable relative to their ability to prevent unwanted pregnancy […] Now where it gets a little more difficult is among oral contraceptives, if one is riskier than the other, do its relative benefits outweigh its relative risks? And that's less clear […] It's one of the reasons, in terms of trying to weigh some of the benefits and risks, what's tough with it, is you're often comparing apples and oranges. (Professional 1)

Evident in both FDA and Health Canada approaches to risk/benefit weighing, some experts look at Yaz and Yasmin as stand-alone options, without considering what else is on the market (pills or other forms of contraception) and whether or not drospirenone pills have any additional benefits when compared to older generations of progestins. Others stress that the pills should not be on the market since some of the risks are unknown and the benefits are too similar to those of other contraceptive pills. For example, the variety of inconsistent opinions can be seen in the excerpt below, where FDA advisory committee experts respond to the following question: "Do you think that the benefits of drospirenone pills outweigh the risks?":

> "DR. HEWITT: I would echo that. Similar reasons I voted yes. The absolute risk was very low, and the risk associated with pregnancy was far greater.
> DR. HILLARD: I voted yes. Ditto.
> DR. STOVALL: And I voted no because I don't think in patients with thrombophilia and several other populations that it would be appropriate.
> MS. ARONSON: I voted no -- this is Aronson -- because of the confusion regarding studies, and the differences and the results of the FDA phase 1.
> DR. CLARKE: Clarke. Yes, because the overall benefit still outweighs the risks, even though I think there's a small increase in risk, a modest increase in absolute risk.

> DR. GILLIAM: Gilliam. I took a -- I voted yes. I took no vote to mean that it should be off the market, and I didn't think that was right, so I voted yes. (FDA Advisory Committee 2011)"

As no guidelines were given on which risks and benefits to consider – compared to what and for what indications - Dr. Hewitt focused on pregnancy risks, Dr. Clarke on the absolute risk increase, Dr. Stovall on vulnerable populations, Ms. Aronson on the data confusion, while Dr. Gilliam took the question to mean whether or not the pills should be off the market. This shows the variety of perspectives on the weighing of risks and benefits and the lack of coordinated effort to establish common relevant comparison points.

Only a minority of experts testifying in the 2011 FDA advisory committee stressed that added risks should prompt regulatory bodies to pull Yaz and Yasmin off the market; these experts thought the pills had no significant added benefits when compared to other hormonal contraceptives and only offered increased risks. The women users who have suffered injuries, however, unanimously disagree with regulatory decisions to keep drospirenone pills on the market. Patient groups have criticized regulatory bodies for asking vague misleading questions during hearings and, in the case of Health Canada, for not being transparent about its decisions despite reaching a strikingly similar conclusion the to the FDA. In addition, some have stressed testifying experts' pharmaceutical industry ties.

Prominent in the debates on weighing the risks and benefits is also a discourse of individual choice, where consumers are assumed to benefit from having more options, regardless of what these options actually entail. Such discourses tend to be prevalent among those with industry ties and Bayer representatives. A number of experts present in advisory meetings stressed the added "choice" that drospirenone compounds offer as beneficial. The discourse of consumer choice has been deployed for mitigating the pills' risk factors: while different pills may have different risk/benefit profiles, these are all important to have on the market in order to maximize women's "choices." An emphasis on

individual choice reinforces the marketing of contraception as a lifestyle product, where the consumer is perceived to become empowered through their choices. Given that there are other highly effective contraceptive options on the market, clinicians and patients have debated whether or not drospirenone pills fill a market gap at all, in light of their uncertain benefits.

The process of placing risks into perspective is underscored by tensions between population-level risk numbers and the experiences of individuals who have had VTE experiences. Consequently, disagreement on what is acceptable risk in the case of drospirenone also stems from the difficulty stakeholders have in reconciling these perspectives. Those involved in the negotiation of regulatory decisions express the need to see a significant or noteworthy number of adverse effects at a population level. They are less concerned about individual cases and this is seen as a problem by patient advocates. Although affected users and some experts critical of pharma have spoken out at hearings and in the media, it seems improbable that the professional and scientific community takes such opinions into consideration, given that their discussions of risk tend to focus on population level numerical risk ratios. Users affected have challenged this approach both in the media and the interviews that I conducted. One woman who has suffered blood clots expressed frustration that personal experiences are not taken into consideration by experts and pharmaceutical companies:

> You have to humanize what the medication does to people and I guess for me I know the lawsuit and everything it's about justice. I don't want the money. I don't want anything. I want desperately for them to hear me, to hear me as human, as a person, as a mother, as a daughter, as a wife, me, this person that this has happened to and how many other women that it happened to, for them to see me. (User 23)

Another user expressed her dissatisfaction with pregnancy risks being used by professionals as a comparison point to place the risks of drospirenone in context:

> If you didn't take it, you might have a baby, but, yeah, it might be bad for a young 16-year-old to have a baby because she didn't take Yaz, but in the long run, you can either have a baby or you can die. So yeah, so that's my outlook on it, what do you want really? (User 7)

Personal professional opinions on weighing the risks and benefits of contraception range from those who are adamant that Yaz and Yasmin are great choices for women to those who think they should have been pulled off the market. This is evident in the way stakeholders weigh risks and benefits: without clear regulatory guidelines, this is often an individual decision based on each expert's priorities.

The Importance of Informed Consent

This paper makes the case that uncertainty about both risks and benefits contributed to drospirenone pills being kept on the market and the onus being placed onto users to make a "choice" about whether to take them. Without doubt, the lack of consensus on benefits, risks, and the weighing of these, is problematic for regulatory processes. Given that the pills are available, however, the next step is to ensure adequate risk communication for patients considering this option. The issues arising from this process are two-fold: 1) first, as already mentioned, risk management responsibility is assigned to patients and 2) there are no mechanisms in place to ensure that women do have all the adequate information to make a decision. The process of ensuring that accurate risk information reaches users is also characterized by a diffusion of responsibility. One of the main reasons for this is the multitude of actors involved in imparting risk information: pharmaceutical companies through inserts and promotional products, doctors during patient visits, as well as regulatory bodies through statements and press releases. Additionally, there is often little communication between these stakeholders regarding risk communication processes. As such, making sure that informed consent is achieved is an elusive process.

With regards to ensuring adequate risk communication, all health professionals interviewed agree that patients should be informed by their doctors about the potential VTE risk increase with Yaz and Yasmin. Nonetheless, some clinicians expressed that they personally do not believe that the risks of drospirenone differ significantly from the risks of other oral contraceptives. They maintained, however,

that they would still mention what studies have said about these particular pills. Informed consent, where a patient is given all of the information necessary in advance of making a decision about treatment is, a key component of health risk management, according to professional stakeholders. However, there is no centralized process in place to ensure that information reaches users. Even though regulatory guidelines may mention that user decisions should be made in consultation with their doctor, regulatory bodies do not manage the information that patients receive from their physicians. The VTE risk information that users get from doctors can vary and can sometimes be non-existent or superficial. Both affected users as well as guideline makers would like clinicians to mention VTE risks. However, in practice this is not always achieved, as most users interviewed have indicated.

Pharmaceutical companies are, to a greater degree (because of legal challenges), held accountable for providing users with the adequate information in pill inserts. Whether or not erroneously, regulatory statements assume that users make a calculated choice after carefully considering the risks outlined in product monographs. However, as was stressed in FDA regulatory meetings and especially by patients, inserts are often hardly legible, full of medical jargon, and list study results in long detailed lists that are hard to decipher. Additionally, from a legal perspective, it is Bayer that plaintiffs and their lawyers are holding responsible for users not having the necessary information in package inserts to allow them to make informed choices. Given the multitude of stakeholders involved in risk communication, responsibility can take different nuances depending on whether one looks at legal, medical or patient advocacy arguments. The result of competing and/or overlapping discourses on responsibility is that women are left to figure out the risks of contraception on their own. Although not all, a large burden of responsibility is placed on the user. This is especially true in light of the large quantity of inconclusive epidemiological data that patients might have to go through – data that even experts disagree on with regards to its bias, relevance, and adequacy of research design. The emphasis on informed consumer choices is a potential consequence of an inability

to deal with uncertainty systematically.

CONCLUSION

Drawing on sociological risk theories and critical work on contraceptive technologies, this paper argues that a diffusion of responsibility for risk management is endemic to the process of evaluating hormonal contraceptives. This is evident in several related contexts: the articulation of the drugs' benefits, the data used to measure risks, risk/benefit weighing, and responsibility for risk management. Bridging the gap between studies of pharmaceutical markets and risk theories, this study also shows how disagreement and uncertainty is systemically produced as a result of the complexity of drug risk assessment. As previous work has emphasized (Beck, 1992; Perrow, 1999), systemic risks are persistent yet amorphous and as a consequence, they are hard to detect and be managed by individuals. I here show that this is true of hormonal contraceptives and drugs, more generally. As stressed throughout the paper, contraceptive evaluation processes are not only characterized by disagreement and diffusion of responsibility, but also by pharma's influence in the collection of data on VTE risks. As such, the assessment of contraceptives cannot be separated from practices dictated by commercial interests.

Additionally, the Yaz/Yasmin controversy highlights how the construction of the 'at-risk' self emphasized in governmentality perspectives coexists with the systemic creation of new risks: on one hand, pregnancy risks are emphasized and magnified, while VTE risks are debated. In the case of drospirenone, individual management of risk information has been emphasized by professionals, despite conflicting messages that users might get. In light of the different views on what the exact risks of drospirenone are, patients are left with the responsibility to decide on their own if they should take these pills. Whether or not users have the adequate information to make decisions should be a concern for professional stakeholders. It has been difficult to ensure that efficient risk communication is achieved in the current context, given the diffusion of responsibility.

This paper also reveals the more complex risk negotiations that lie beyond official position statements released to the public by regulatory bodies. While some have argued that drospirenone pills were not an additional choice that women needed at the time they were released on the market, other have welcomed this new option. By studying areas of contention, one can draw attention to the ways in which risk/benefit ratios for contraceptives can be improved in the future, either through more public involvement in research or through better risk communication strategies. This study adds to critical perspectives on medicine and pharmaceutical technologies that seek to go beyond simply describing a network of stakeholders. As Abraham (2008, p. 869) notes, "bias manifests itself at the micro-social level of science-based pharmaceutical testing and regulatory decision making." I here show how this process takes place in the case of hormonal contraceptives by focusing on the recent Yaz/Yasmin controversy.

Furthermore, this research extends research on contraception by looking critically at systemically produced and managed risks – something that has seldom been discussed in relation to new hormonal contraceptives. As such, it bridges the gap between work that focuses on the construction of technologies themselves (Kaler, 2004; Oudshoorn, 2004; Takeshita, 2012; Watkins, 2010) and work that deals with their risks (Van Kammen and Oudshoorn, 2002), to show that the meanings of contraceptive technologies are co-produced in discussions of their risks. The analysis of this controversy is especially significant as it marks a slightly waning interest in the pill, while interest in long-acting reversible contraceptives (LARCs) like the IUD is increasing in North America. The drospirenone case highlights some of the issues that characterize not only users' experiences with the pill, but also the regulatory and scientific difficulties in ensuring a favourable risk/benefit drug ratio and the availability of adequate risk information for consumers.

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CHAPTER 5

CONCLUSION

The aim of this thesis was to analyze current debates about contraceptive risk as reflected in stakeholder debates and regulatory processes in Canada. The recent Yaz/Yasmin controversy provided a rich empirical opportunity for interrogating how experts and women consider their tolerance and acceptability of health risks associated with contraception. Several different yet interrelated research questions motivated my analysis. In the first article, I ask what are the prevalent risk models used to assure the public that drospirenone pills are safe and which risks and benefits are emphasized in professional statements. In the second, I ask how are the risks and benefits of Yaz and Yasmin evaluated by lay stakeholders and how might this assessment differ from professional discourses. In the third, I look at unresolved contraceptive risk and benefit measurement debates and ensuing consequences for users. The findings that I describe in each article have implications for our understanding of contraceptive risk in light of what the Yaz/Yasmin controversy has revealed about the evaluation process. I have argued that risk/benefit evaluations are influenced by sociocultural norms, including gendered conceptualizations of risk as well as tensions between lay and professional perspectives. Systemic uncertainty regarding risks creates a climate where responsibility is diffused and where patients have to manage risks using conflicting information.

RESEARCH SUMMARY AND SOCIOLOGICAL IMPLICATIONS

The first article examines the public discourses that were used by professionals to assure users that drospirenone is safe in the wake of the amplification of the Yaz/Yasmin controversy. Regulatory bodies and professional associations used several strategies to argue that new knowledge about the pill's health risks does not require pulling the new pills off the market. This was accomplished through

several strategies to frame the new risk knowledge. First, professional stakeholders argued that risk knowledge about VTE was uncertain and controversial, underlining methodological flaws in the studies that found increased VTE risks with drospirenone. Secondly, they emphasized their confidence that informed decisions can be made by patients in consultation with their doctors. However, this is contradictory: on one hand, professionals emphasize uncertainty, while, on the other hand, they assume that doctors and patients will be able to make sense of complex information that even epidemiologists do not agree on. Most importantly, experts talked at length about the higher VTE risks that women face during pregnancy and the postpartum period, implying that if patients do not use a highly effective contraceptive method like the pill, they may get pregnant and face even higher VTE risks. The logic that drospirenone's VTE risks are lower than pregnancy VTE risks kept the pill on the market and was supported in the statements and press releases analyzed. I argue that focusing on the risks of pregnancy, as opposed to the risks posed by other oral contraceptives or even non-hormonal contraceptives already on the market has important implications for the cultural acceptability of risk that is associated with female bodies and assumptions about the ways and reasons why we believe women should prevent pregnancies. This article stresses that the public discourses are guided by normative beliefs about women's bodies and sexuality. In doing so, it contributes to the body of scholarship that demonstrates how contraceptive risk assessment is gendered (e.g., Oudshoorn, 2003; Van Kammen and Oudshoorn, 2002). Building on feminist technoscience literatures, the article also addresses issues pertaining to gender in the development and assessment of technology. More specifically, it shows that assumptions about gender are an integral part of developing and assessing contraceptives and technologies more generally. Ideas about the acceptability of risk for women are embedded in the technology itself, thus highlighting political aspects pertaining to the evolution of artifacts.

In the second article, I explore how and why lay stakeholders argue that Canada's current regulatory and medical system has failed to protect them from what they perceive to be drospirenone's

harmful effects. I specifically look at the unique ways in which affected consumers understand the risks of hormonal contraception and those of Yaz and Yasmin in particular. In contrast to professional discourses analyzed in this thesis, users had a different conceptualization of reproductive risks that is not focused on absolute risks, but rather on assessing severity based on the source of risk: natural or human-made. Women did not consider pregnancy risks to be a fair comparison point for situating the risks of hormonal contraception, the reason being that pregnancy is perceived as a "natural" process, where the pill is technological, human-made, and voluntary. As a result of their negative experiences, interviewees advocate for changes in risk communication and drug regulation. A salient finding in my research is that affected users do not think they received adequate risk information from their doctors in order to make an informed decision regarding their contraceptive method. Women argued that a grave consequence was not being able to identify early VTE symptoms. Patient views generally ran contrary to official professional risk/benefit assessment conclusions. This paper contributes to the existing literature on user perception of the risks of hormonal contraception. More specifically, it adds a more in-depth explanation of women's views on the risks of pregnancy and the pill. It consequently points to the need to understand user risk not through a professional lens, but by analyzing the social and cultural positions of those exposed to risks. Furthermore, the findings stress the need for a better reconciliation of lay and professional views on risk. More generally, users' experiences highlight the consequences of risky technologies developed without input from those that experience risk first-hand.

The third article looks at stakeholder debates about risk measurement and the uniqueness of drospirenone's benefits. Here, I argue that users have to decipher risk information on their own as a result of expert disagreement on risk data quality and risk/benefit weighing. Despite the decision to keep Yaz and Yasmin on the market, experts do not agree on the exact numerical VTE risk associated with drospirenone. Nor do they agree on what the acceptable risk threshold for pills on the market *should* be. In this article, I explore how liability for risk management is diffused amongst stakeholders.

I argue that contraceptive risk assessment is characterized by a systemic diffusion of responsibility for risk evaluation, with detrimental consequences for patients who often become responsible for managing risk on their own, needing to draw conclusions from conflicting information. The paper emphasizes expert dissent on the uniqueness of the drospirenone's ancillary, non-contraceptive benefits and the magnitude of the health risks. Along with contested epidemiological data, such disagreements affect the risk/benefit weighing that stakeholders perform. Most importantly, I highlight the issue of effective risk communication and decision making in light of the unsettled questions that pervade regulatory decisions. Extending a sociological systemic risk approach to the study of contraceptive assessment, I show that medical technologies can also be seen as sources of risk diffusion. Through the emphasis on risk management performed by individuals, the study contributes to work that stresses the problematic distribution of risk in modern societies.

My research has several implications for our understanding of the risk/benefit assessment of hormonal contraceptives, the evaluation of future contraceptive options, and controversial drugs more generally. Firstly, it builds on previous studies that show the ways in which gendered norms govern the risk evaluation of oral contraceptives (Van Kammen and Oudshoorn, 2002; Oudshoorn, 2003; Brown, 2015; Hanbury and Eastham, 2016). The findings presented here further show how conceptions of the female body are still entangled with risk acceptability, despite growing calls for men to take more responsibility for contraception. I argue that professional decisions based on pregnancy risk discourses implicitly uphold the idea that, for men, acceptable contraceptive risks must always be lower than those borne by women. An implication of gendered risk discourses is that male contraception does not have to be designed to alleviate reproductive risks, since males do not experience pregnancy. Analyzing this issue through a sociocultural perspective signals the need for new models for conceptualizing risk. For example, a potential move forward would be for professionals to think about risk as a shared burden between members of a couple. Such an approach would highlight the decreased risks posed to women

when male contraceptives are developed: if additional options for men become available, these would have the advantage of a decreased risk burden for women – an aspect that, I suggest, should be taken into consideration by contraception researchers. Professional stakeholder perspectives revealed by the Yaz/Yasmin controversy could have future implications for how technology developers incorporate risk threshold acceptability in hormonal contraceptive research. The current focus on women's reproductive risks does not pressure pharmaceutical companies to conduct research into safer alternatives if new products are compared to the relatively high VTE risks posed by pregnancy. This thesis highlights processes through which potentially increased risks are allowed for new contraceptives on the market. In light of disagreement on risk/benefit weighing, clearer guidelines are needed to determine what acceptable risk should be for contraceptives on the market.

Additionally, this research highlights that there are risks and benefits not taken into consideration by professionals, given that women face complex choices beyond just whether to take the pill or become pregnant. An aspect that is masked by the excessive emphasis on efficacy, is users' experience of less severe side effects (Black et al., 2009) and how that might affect their willingness to stay on the pill. Given the different choices women have, risk/benefit evaluation for users is likely to involve more than efficacy and pregnancy prevention. Although my findings are limited to women who have experienced negative side effects while on Yaz or Yasmin, I have shown that interviewees' risk assessment is complex and must be better understood outside of medical paradigms that focus on techno-scientific measurement. For example, age, relationship status, and perceptions of the pill as a human-made risk were important factors in user risk evaluations. Most importantly, women did not feel that the risk information they received was adequate and emphasize doctors' and pharmaceutical companies' responsibility to inform consumers. Their experiences highlight the need for knowledge about potential adverse side effects and how to recognize VTE symptoms. User perspectives explored here emphasize ongoing tensions between lay and expert perspectives on risk. On one hand,

professionals have been more focused on discussing data accuracy and validity, while, on the other hand, patients stress personal injury (Junod and Marks, 2002; Marks, 1999). Professionals use pregnancy risks to provide context for dropirenone VTE risks (Geampana, 2016). However, affected users felt that this is not a useful comparison, as they perceived pregnancy to be a natural process. Therefore, the risks resulting from childbearing were considered different in nature from the human-made risks posed by drospirenone. The findings further work that emphasizes the importance of the perceived type of risk source (Brun, 1992; Keogh, 2005) and furthers survey studies through a more in-depth understanding of user risk perception. While this study shows that themes emerging from historical debates about the pill are still relevant to the Yaz/Yasmin controversy, it also highlights the ongoing need to better reconcile scientific and lay perspectives.

In light of the problematic marketing of new contraceptive pills (Watkins, 2012), this study provides some evidence that ads did influence prescriber recommendations in Canada when Yaz and Yasmin were released on the market. However, despite the role that marketing played in making these pills seem more alluring, affected users stressed they would not be willing to trade lower health risks for ancillary benefits. Most importantly, experts themselves do not agree if Yaz and Yasmin provide benefits that are unique. This is in stark contrast to the way the pills have been marketed to consumers and their providers. Professional disagreement about the benefits of drospirenone signals a problematic marketing context for new contraceptive pills, where users receive more information from ads and company pamphlets, rather than from medical experts who have looked at the evidence for ancillary treatments in clinical trial data.

This case study shows that responsibility for decision making and contraceptive risk management is diffused among stakeholders as a result of unresolved debates on what should be considered acceptable risk. In light of such structural processes revealed by the Yaz/Yasmin controversy, I argue that other potentially risky contraceptive innovations might be susceptible to

similar unresolved debates, with detrimental consequences for users. In this thesis, I have used sociological risk perspectives to emphasize that the drospirenone case (and medical technologies, more generally) can also be an example of technologies' amorphous yet ever present risks. More generally, by stressing how contraceptive risk assessment is influenced by cultural factors and processes, I have furthered STS research on understanding contraception as a medical technology, by bridging the gap between work that focuses on the social meaning and construction of such technologies (Kaler, 2004; Oudshoorn, 2004; Takeshita, 2012; Watkins, 2010) and work that deals with their risk assessment (Van Kammen and Oudshoorn, 2002). In doing so, I have shown that the meanings of contraceptive technologies are intertwined with, and constituted in part by, understandings of their risks. Because professional stakeholders have not reached a consensus on the benefits and risks of drospirenone, users have been left to decide on their own whether or not to choose these pills. A major implication of this finding is the need to ensure that efficient risk communication is achieved. This is not an easy task in light of the diffusion of responsibility in risk management decisions. This thesis highlights several areas where risk communication can be improved. Firstly, more attention needs to be paid to the adequacy of package inserts provided by pharmaceutical companies, specifically their language and accessibility. Secondly, it is not clear if patients receive satisfactory information from their doctors when choosing a contraceptive method. Finally, regulatory bodies could consider imparting risk data to the public in more comprehensive and user-friendly ways. Regardless of the strategies developed, whether or not patients have the adequate information to make decisions should be a primary concern for stakeholders.

LIMITATIONS

One of the biggest limitations of this research is that it cannot speak to perspectives on risk beyond those expressed by stakeholders. In analyzing lay and clinician perspectives, the findings open up questions regarding micro-level risk discussions that take place between patients and doctors. However, my data can only be used to make inferences about those involved in the Yaz/Yasmin debate

and regulatory decisions. These findings cannot be generalized to other groups. I sometimes suggest what some of the data might be indicating about wider population-level risk assessment processes, but such suggestions need to be further tested through empirical research on larger samples of users and care providers.

Another limitation of this research is the extent to which an outsider can have access to regulatory discussions and decision-making processes. My assumption going into this research was that stakeholders might express views that can diverge from public regulatory and professional discourse, to some extent. During the process of data collection, I aimed to study risk assessment beyond official discourses, but there are limitations to how much access one can gain to actual regulatory processes, especially in Canada. Gaining access to regulatory officials was difficult as they were more reluctant to discuss the controversy and even after agreeing to speak to me, preferred not to answer certain questions directly or reveal any uncertainties in their own thinking. For example, they were more likely than other participants to give a firm answer as to what acceptable risk should be in the case of contraceptives. Even though I gained access to two interviewees involved in regulatory decisions, observing regulatory discussions behind closed doors was not feasible. This is especially an issue in Canada where Health Canada is, to an extent, less transparent about regulatory processes when the safety of drugs is in question (Dhalla and Laupacis, 2008). I tried to address this shortcoming through careful analysis of documents and asking all professionals questions related to regulatory processes. Nonetheless, one can assume that there are debates that the public and even researchers do not have access to.

Another aspect of this case that could be perceived as a limitation is the context within which the data were produced. Given that the aim of the research is to gain insights into the current risk assessment of contraceptives, one might reasonably ask to what extent a case like the Yaz/Yasmin controversy is suited to accomplish this aim. This decision to study this case is predicated upon the

assumption that risk evaluations can be best observed by studying a controversy that can reveal diverging opinions that would not be as apparent otherwise. I argue that because the debate on drospirenone is ultimately about making decisions regarding acceptable risk thresholds, priority should be granted to understanding the debate within the medical and regulatory arena, rather than elsewhere. Legal arenas are of importance for this case, too. However, Canadian class action lawsuits against Bayer have been moving at a slow pace and as such, no stakeholder hearings have yet taken place nor have any final decisions been made. Although I have gathered all documents generated by class action lawsuits at the time I submitted my thesis, there will be additional legal data that will warrant careful scrutiny.

DIRECTIONS FOR FUTURE RESEARCH

As mentioned above, the findings cannot be generalized to larger populations of users and clinicians and how they perceive the risks of hormonal contraceptives. Given the scope of this thesis, my objective was not to collect data that would be representative to these groups as a whole. Rather, I was more interested in exploring the dynamics of the drospirenone case and what it might tell us about how the main stakeholders negotiate the meaning of acceptable risk. Nonetheless, the Yaz/Yasmin controversy opens up questions about prescription practices and women's perceptions of contraception more generally. One area for future research, therefore, would be to conduct a larger study on user risk assessment. A related area to explore would be to investigate the content and adequacy of risk information that patients receive from their care providers. This could be achieved through a study of consultation transcripts or, indirectly, through administering a survey to users asking them about information received from their doctors. In light of informed consent concerns raised in this thesis, I believe this type of data could point to better strategies that professionals can use to ensure adequate information is imparted to users. Additionally, a representative study on women's risk perceptions of different contraceptives could provide health professionals with much needed information on how users

make decisions. Such a study, however, should not make value judgements about patient views, but rather try to understand risk perceptions in their social context.

Gendered aspects of the risk evaluation of drospirenone lead to questions about the potential development of male contraceptives and how such options might be currently assessed. Oudshoorn (2003), for example, has highlighted how the lack of material resources and industrial involvement have stalled the development of a male pill. Gendered norms also contribute to resistance to such a technology. Researchers often assume that men would not have any interest in being responsible for family planning or engage with a technology that could potentially affect sexual function – a problem that often arises in clinical trials with men (Oudshoorn, 2003; Van Kammen and Oudshoorn, 2002). The question remains, however, what the risk thresholds used in male contraceptive research are and how they might contribute to the dearth of options available for men currently. A critical analysis of how these thresholds are debated and negotiated could facilitate the development of more equitable contraceptive options. The objective of such a study should be to explore how the risk assessment of new contraceptive technologies for men compares to that of technologies for women. Currently, there are a few promising options for men that are still in the early clinical trial phases. These include Vasalgel, a non-hormonal reversible gel that is injected in the vas deferens as well as hormonal pill options. However, progress is very slow. Consequently, social scientists should better understand the processes that stall research and how they might relate to perceptions of individual risks as well as risks associated unplanned pregnancy rates, if these are at all considered.

Finally, the Yaz/Yasmin controversy as well as new studies about depression, cancer, and suicide risks associated with the pill have intensified the public critique of hormonal contraceptives (Grigg-Spall, 2013; Skovlund et al., 2016). In recent years, we have seen a growing interest in long acting reversible contraceptives (LARCs) such as the implant and IUDs, both hormonal and non-hormonal. A new research endeavour would build on the knowledge that we have about pill risks and

investigate if such options might offer women a more favourable risk/benefit ratio. The objective of such a study would be to look at how and why LARCs have become more prominent recently and what type of risk assessments have been performed to evaluate such methods. This information should then be compared to what we know about pill risk assessment. In light of the questions raised in this thesis about the use of pregnancy risks in professional assessments, another fruitful avenue for research would be to investigate how LARCs are currently used in public health programs around the world for the purpose of curbing unplanned pregnancy rates. Future research should investigate how pregnancy risks are deployed in the case of contraceptives other than the pill.

CONCLUDING REMARKS

In this thesis, I have analyzed the dynamics of the Yaz/Yasmin risk controversy in order to understand the debates that are at the heart of contemporary risk/benefit assessments of contraceptives. The controversy has both renewed old concerns about the pill and, I believe, ushered in a new era where users and doctors alike are more critical of hormonal contraception. I hope this thesis can serve as a resource for those interested in learning more about the risk evaluation of the pill in Canada and beyond. Further, I have no doubt that the Yaz/Yasmin case will affect the development of future contraceptive options, as it has exposed the limitations of the current landscape and the need for improved methods for both women and men.

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APPENDIX A

Interview Guide - Patients

1. When did you start taking Yaz/Yasmin and for how long did you take it? Are you still taking it currently?
2. If you stopped taking it, what prompted you to do so?
3. Have you experienced any side-effects while on Yaz/Yasmin? If yes, what side effects?
4. Have you taken any other oral contraceptives before or after Yaz/Yasmin? If yes, which brand(s)?
5. What prompted you to start taking this particular contraceptive pill?
6. Did you see any ads or heard about this pill in the media prior to taking it?
7. What did your doctor tell you about the health risks associated with this pill when he/she prescribed it to you?
8. Did your doctor mention anything about particular risks associated with Yaz and Yasmin?
9. How did you perceive the risks presented to you by your doctor? Did you find them acceptable? Why or why not?
10. Were you aware of any other risks not presented to you by your doctor? If yes, what risks and where did you find out about them?
11. What were the health and/or side benefits that you were expecting to get from this pill?
12. What was the most important benefit of this oral contraceptive for you?
13. What do you think were the most concerning risks, if any?
14. Were you aware of the media controversy surrounding Yaz and Yasmin? If yes, did this have any impact on your decision to take the pill or not?
15. Did you do any additional research on the pill's health risks since you started taking it? If yes, which sources of information did you consult? If not, what sources of information would you consult?
16. Based on what you know currently, do you think that Yaz/Yasmin's benefits outweigh the risks? Why or why not?
17. What would make you believe that a pill's risks outweigh its benefits?
18. In your opinion, should an increase in health risks (as compared to previous oral contraceptives) prompt Health Canada to pull the pill off the market? Why or why not?
19. What do you look for in a contraceptive method?
20. What method are you currently using, if any?
21. Are you content with the range of contraceptive choices available for women in Canada currently? Why or why not?

APPENDIX B

Interview Guide – Professionals

1. Tell me about your involvement with evaluating the risk of drospirenone-containing pills.
2. What prompted the need for evaluating these contraceptives?
3. Have you been involved before with the evaluation of oral contraceptives? If yes, how?
4. What were the main conclusions of your study/evaluation?
5. Do you think that the risk of drospirenone-containing contraceptives represents a significant increase if compared to the previous generation of contraceptives? Why or why not?
6. What should be the maximum risk allowed for oral contraceptives on the market?
7. In determining this maximum risk, what should it be compared to and why?
8. The risks of contraceptives are often compared to the risks of pregnancy. Do you think this is a fair/useful comparison? Why or why not?
9. Why do you think abortion is not generally discussed as an alternative to pregnancy?
10. How important is efficacy in comparison to potential side effects?
11. Based on what you know currently, do you think that Yaz/Yasmin's benefits outweigh the risks? Why or why not?
12. How important are side benefits in comparison to health risks?
13. What would prompt you to believe that a pill's risks outweigh its benefits?
14. In your opinion, should an increase in health risks (as compared to previous oral contraceptives) prompt regulatory bodies to pull the pill off the market? Why or why not?
15. Are you content with the range of contraceptive choices available for women currently? Why or why not?

Additional questions for clinicians:
11. ii) What do you tell your patients about the health risks associated with contraceptive pills when you prescribe them?
11. iii) Do you mention anything about particular about risks associated with Yaz and Yasmin?
Additional questions for epidemiologists/researchers:
4. ii) What health risks did these studies measure?
4. iii) Can you explain in more detail how these risks are measured by epidemiologists?
4. iv) What are some of the disadvantages of these studies?

APPENDIX C

RESEARCH CONSENT FORM (USERS)

Title of Research: "Beyond birth control:" Yaz/Yasmin and the risk evaluation of oral contraceptives
Researcher: Alina Geampana, PhD Sociology Candidate, McGill University
Contact Information: McGill University, Department of Sociology, 855 Sherbrooke Street West, 712 Leacock Building, Montreal QC H3A 2T7 Tele: 514-238-9733 E-mail: alina.geampana@mail.mcgill.ca
Faculty Supervisor: Jennifer Fishman
Contact Information: McGill University, Biomedical Ethics Unit, 3647 Peel Street, Montreal QC H3A 1X1 Tele: 514-398-7403 E-mail: jennifer.fishman@mcgill.ca

Purpose of the Research:
The existing literature on the medical and scientific evaluation of oral contraceptives is relatively scarce. There is little understanding of the role that different parties play in measuring the health risks of hormonal contraceptives with new formulations such as Yaz and Yasmin. My aim is to investigate how the risks and benefits of these drugs are weighed against each other both by women users and health professionals in the Canadian context. This study is part of my dissertation project and could be potentially used for academic publications.

What is Involved in Participation:
Your participation involves a single interview of approximately 40 minutes to one (1) hour in duration. Interviews will be scheduled at a time that is convenient for you. Interviews will be done by telephone unless it is convenient for you to meet with the principal investigator in person.

The interview is composed of several open-ended questions,which you are asked to answer to the best of your ability. I am interested in your experiences with brand name contraceptives Yaz or Yasmin and how these have informed your views on the health impact and potential risks posed by oral contraceptives. I am also interested in your views on the current contraceptive options available to women in Canada.

Your participation is entirely voluntary. You may refuse to answer any particular question or end the interview at any time. The interview will be digitally recorded. The digital audio file as well as the written transcript will be stored in a password-protected personal computer only accessible by myself and my faculty supervisor. I will transcribe your interview and remove any identifiable information from the transcript. The transcript will be given a study number and will not be associated with your name. All interview material will be kept confidential through coding and storing.

The risks inherent in this study are low. It is possible that you may experience some strong feelings in talking about your past or current health problems and healthcare experiences. These feelings and experiences are very important for this study. Anything you reveal will not be associated with your name in any publications—a pseudonym will be used.

By signing this form, you are consenting to participate in the study.
You can choose to withdraw from this study at any time by contacting me (see Contact Information).

Consent:
I agree to be recorded □ YES □ NO
I agree for the interview material to be used in future related research □ YES □ NO

Participant's Signature: _____

Participant's Name (printed): _____

Date: _____

Researcher's Signature: _____

If you have any questions concerning the ethicality of this project, please contact Lynda McNeil (Research Ethics Officer, McGill University, James Administration Building, 845 Sherbrooke St. West, room 429, Montreal, Qc, H3A 2T5, Tel: 514-398-6831, Fax:514-398-4644, Email: lynda.mcneil@mcgill.ca)

APPENDIX D

RESEARCH CONSENT FORM (HEALTH PROFESSIONALS)

Title of Research: "Beyond birth control:" Yaz/Yasmin and the risk evaluation of oral contraceptives
Researcher: Alina Geampana, PhD Sociology Candidate, McGill University
Contact Information: McGill University, Department of Sociology, 855 Sherbrooke Street West, 712 Leacock Building, Montreal QC H3A 2T7 Tele: 514-238-9733 E-mail: alina.geampana@mail.mcgill.ca
Faculty Supervisor: Jennifer Fishman
Contact Information: McGill University, Biomedical Ethics Unit, 3647 Peel Street, Montreal QC H3A 1X1 Tele: 514-398-7403 E-mail: jennifer.fishman@mcgill.ca

Purpose of the Research:
The existing scholarly literature on the medical and regulatory evaluation of oral contraceptives is relatively scarce. There is little understanding of the role that different parties play in evaluating the risks of hormonal contraceptives with new formulations such as Yaz and Yasmin. My aim is to investigate how the risks and benefits of these drugs are weighed against each other both by women users and health professionals in the Canadian and North American context. This study is part of my dissertation project and could be potentially used for academic publications.

What is Involved in Participation:
Your participation involves a single interview of approximately 40 minutes to one (1) hour in duration. Interviews will be scheduled at a time that is convenient for you. Interviews will be done by telephone unless it is convenient for you to meet with the principal investigator in person.

The interview is composed of several open-ended questions which you are asked to answer to the best of your ability. I am interested in your experiences with evaluating the risks of drospirenone-containing pills (brand name contraceptives Yaz or Yasmin) and how these have informed your views on the health impact and potential risks posed by oral contraceptives. I am also interested in your views on the risks of current contraceptive options available to women in Canada and North America.

Your participation is entirely voluntary. You may refuse to answer any particular question or end the interview at any time. The interview will be digitally recorded. The digital audio file as well as the written transcript will be stored in a password-protected personal computer only accessible by myself and my faculty supervisor. I will transcribe your interview and remove any identifiable information from the transcript. The transcript will be given a study number and the data will not be associated with your name. All interview material will be kept confidential through coding and storing.

The risks inherent in this study are low. It is possible that you may experience some strong feelings in talking about your past or current health problems and healthcare experiences. These feelings and experiences are very important for this study. Anything you say will not be associated with your name in any publications—a pseudonym will be used.

By signing this form, you are consenting to participate in the study.
You can choose to withdraw from this study at any time by contacting me (see Contact Information).

Consent:
I agree to be recorded □ YES □ NO
I agree for the interview material to be used in future related research □ YES □ NO

Participant's Signature: _____
Participant's Name (printed): _____
Date: _____

Researcher's Signature: _____

If you have any questions concerning the ethicality of this project, please contact Lynda McNeil (Research Ethics Officer, McGill University, James Administration Building, 845 Sherbrooke St. West, room 429, Montreal, QC, H3A 2T5, Tel: 514-398-6831, Fax:514-398-4644, Email: lynda.mcneil@mcgill.ca)