# MEDICAL ERRORS: DEFINING THE CONFINES OF SYSTEM WEAKNESSES AND HUMAN ERROR

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## ABSTRACT

Notwithstanding the innovative changes in biotechnology, medical devices and other therapeutics, errors in medicine continue to cause harm to patients. Current definitions of medical error do not reflect the full reality of error causation. Medical error taxonomy is narrowly focused on system weaknesses in health institutions and human error. System weaknesses in licensing and monitoring organizations, health care suppliers, health profession self-regulation and government regulating organizations, conduct by leading health professionals and medical research industry risks, all lead to significant harm that is not recognized in medical error accountability. These players do not fulfill their mandates. Evidence demonstrates negligence, incompetence, unethical conduct and institutional interest and self-interest in the decision-making process. Both the principled approach and institutional ethics (IE) principles are powerful tools to require accountability from stakeholders.

The contemporary understanding of medical errors is deficient and unsustainable. It has not contributed to a decrease in errors. Appropriate definitions of the confines of systems weaknesses and human error are required. This thesis outlines a method to perceive medical errors in a broader way, combining the many agents of error/harm into one system, thereby highlighting accountability and paving the way for reform.

# RÉSUMÉ

Malgré les changements innovateurs dans la biotechnologie, l'équipement médical et d'autres approches thérapeutiques, les erreurs dans la pratique de la médecine continuent à provoquer des problèmes médicaux pour un nombre important de patients. Les définitions actuelles d'erreurs médicales ne reflètent pas la réalité complète de la causalité d'erreurs. La taxinomie d'erreurs médicale est aussi strictement concentrée sur les faiblesses du système dans les institutions de santé et l'erreur humaine. Les faiblesses des systèmes qui autorisent et contrôlent les organisations, les fournisseurs de santé publique, les règlements des professions de la santé, les organismes de règlements gouvernemental des professions de la santé et la conduite des professionnels de la santé, et les risques de l'industrie de recherche médicale, tous causent des problèmes importants qui ne sont pas actuellement explicitement reconnu pour leur responsabilité d'erreurs médicales. Ces joueurs ne réalisent pas leurs autorité actuelle. L'évidence démontre de la négligence, de l'incompétence, d'une conduite non étique, d'un intérêt institutionnel et d'un intérêt personnel dans le processus de prise de décision par ces instances. C'est-à-dire, l'approche du principe que les principes de l'éthique institutionnelle sont des instruments puissants pour contraindre la responsabilité de tous les joueurs. La vision contemporaine des erreurs médicales est déficiente et non durable.

Une telle vision est déficiente et non supportable. Elle n'a pas contribué à la réduction d'erreurs médicales. Une formulation sur les définitions nécessaires des limitations des systèmes liés à l'être humain est nécessaire. La proposition de cette thèse expose une façon de percevoir les erreurs médicales dans le but de rejoindre les nombreux agents d'erreur et de mal dans un système en mettant ainsi l'emphase sur la responsabilité, et ainsi ouvrant la voie à la réforme.

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# CHAPTER I

# INTRODUCTION

Modern medicine has contributed enormously to saving human lives, improving the quality of human life and offering value-added services aimed at improving physical appearance, concealing human aging and the elimination of disease and harmful habits. This success can only be applauded. However, applauding this success does not mitigate the act of aggressively questioning the medical profession in particular, as well as governmental and regulatory agencies and the large medical supply industry, about the unacceptable burden on patients resulting from poor medical practice. It is fundamental that the medical profession investigate, clearly define and eliminate instances of flawed or unethical medical practice that result in medical errors.

The medical profession has not been aggressive enough in its pursuit of exploring the fundamental weaknesses in its organizational structures and individuals that repeatedly generate errors. The profession relies heavily on self-governance and regulation, thereby concealing the weaknesses of a minority of its members who err because of incompetence, negligence, lack of operational process clarity or for other reasons (Kohn, Janet M Corrigan, and Molla S Donaldson, 2000). In addition, the medical profession is finding itself vulnerable to external forces that are making it commit and shoulder additional errors. These external forces are the external regulators and licensers of drugs, medical devices and therapeutics and their suppliers, who are allowing the profession to use unsafe products to the detriment of patients. Only recently, the profession has started to take the issue more seriously, but not in a comprehensive manner (Horton 1998; Horton 2000; Irvine 1999; Irvine 2001; Salter 2007). The contemporary vision of medical errors has many deficiencies that require rethinking to improve accountability and imitate reform. Other industries are much further ahead.

**A brief history of error science**

Since the early 1960s, scientists in different fields have recognized that measurement methodologies and applications cause errors. They also recognized that such errors have classification errors themselves (Berzofsky, Paul Biemer,

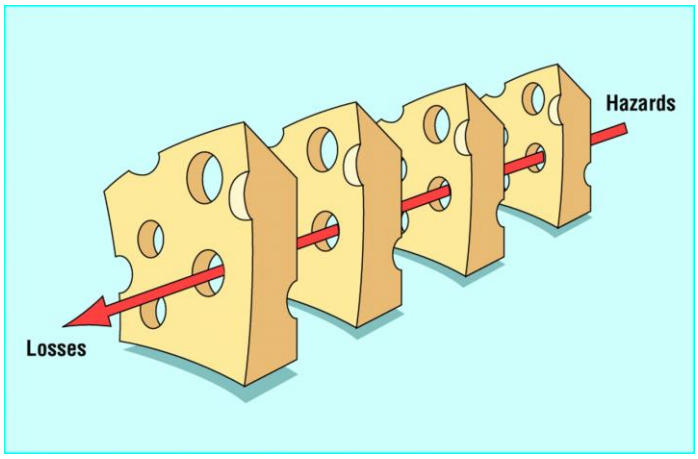
and William Kalsbeek 2008). This scenario repeats itself in all areas. Medical treatment is no exception. Medical treatment in itself can be the cause of medical errors, which in turn can be misclassified. The latter receives little attention from scholars involved in the study of medical errors. In contrast, elaborate statistical models have been created to tackle such problems in other fields. For example, three models were developed to tackle census and interview errors. These include the Census Bureau Model, the Latent Class Model and Finite Mixture Probability Model (Berzofsky, Paul Biemer, and William Kalsbeek 2008). Similarly, data and measurements for geographical information systems have error measurement and error classification. Other detailed error models have also been proposed (Goodchild and Shiren 1992).

Errors in industries based on human-executed operations, such as aviation and nuclear and conventional power plants, cause more serious catastrophes. Unsafe aircraft were the cause of many early aviation accidents. As the aviation industry progressed by improving aircraft design and safety, the cause of accidents became more likely due to pilot error (Murray 1997). However, attributing errors to pilots without investigating the circumstances surrounding the events offers little benefit to error prevention. As a result, it is not surprising that great efforts have been extended to the investigation of aircraft accidents under international standards. No such equivalent international system exists for investigating medical errors.

## Reason and Human Error

Among the many scientists who studied human error, James Reason offered the most significant insight. He and other error scientists approached human error evaluation in two ways; a persons approach and a systems approach. According to them, unsafe acts and violation of processes are caused by individuals. The reason behind errors could be fatigue, recklessness, negligence, inattention or forgetfulness. A common denominator to these errors is aberrant mental processes (Reason 2000). These errors are dealt with by additional education, writing position statements, rewriting processes and “naming and shaming”. The systems approach emphasizes the fallibility of humans and therefore, errors are inevitable

and are generated by weaknesses in the system. The Swiss Cheese Model exemplifies the system approach.




Reason, J. BMJ 2000;320:768-770



Key defenses, barriers and safeguards against errors along the pathway of a process characterize this model. Errors take place because of active or latent failures of the defenses, barriers and safeguards (Reason 2000). Slips, lapses, mistakes and process violations are characteristic of active failures. In the case of medical practice, individuals in direct contact with patients commit these errors. Latent failures are classified as decisions, mistaken or unmistaken, taken by managers, designers, builders and procedure writers. Latent failures include understaffing and faulty equipment and inexperience according to Reason. Latent failures can lie dormant and cause long-lasting deficiencies or create error-provoking conditions in the workplace. Again, in the practice of medicine, these latent failures are common to many organizations that have direct or indirect contact with patients. Currently, unfortunately, little attention is paid to these deficiencies. This cannot be sustainable.

## Current Definitions and Classification of Medical Errors

There is little agreement on a specific definition of a medical error. The Institute of Medicine (IOM) defines medical error in its landmark study, To Err Is Human, as follows:

*"An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning) (Kohn, Janet M Corrigan, and Molla S Donaldson 2000).*

The IOM consolidated this definition from three definitions constructed by Reason in Human Error (Reason 1990). Reason defined three principal types of errors. He stated:

*"Error will be taken as a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome and when these failures cannot be attributed to the intervention of some chance agency". "Slips and lapses are errors which result from some failure in the execution and/or storage stage of an action sequence regardless of whether or not the plan which guided them was adequate to achieve its objectives".* And, *"Mistakes may be defined as deficiencies or failures in the judgmental and/or inferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective of whether or not the actions directed by this decision-schemes run according to plan".*

The above definitions are general and many errors carry characteristics of all three definitions. The IOM's probable intention was to construct a working definition, but it omitted much and tended towards over-simplification. Reason's "Human Error" is, similarly, a landmark culmination of a long interest and work on human error. Reason's Swiss Cheese Model of human error is based on the concept that weaknesses in a system are latent, such as holes in Swiss cheese. Mistakes are averted usually until all weaknesses are aligned and a trajectory for an error is created similar to adjacent holes in Swiss cheese that align themselves in a straight line (Reason 2000). Such a description emphasizes a systems approach at

the institutional level and was not designed for medical error, but has been considered the most valuable of all types of error models (Perneger 2005).

In addition, the above definition narrows the scope of error inclusions by ignoring many ***causal*** categories of medical errors, both systems related and human generated. Lucian Leape defined medical error as: *"an unintended act (either of omission or commission) or one that does not achieve its intended outcome*" (Leape 1994). This definition offers no great improvement over the IOM's definition. The Canadian Patient Safety Institute called medical errors adverse events and defines them as *"harms that resulted from unexpected and unintentional occurrence in health care delivery (Levinson and Gallagher 2007)."* Such a definition also emphasizes problems at health institutions. Dovey and Philips rightly claimed that *"If the beginning of wisdom is knowing what to call things, defining "medical error" is a beginning that has not yet been completed (Dovey and Philips 2004)".*

Despite such an admission, Dovey and colleagues attempted to create a taxonomy of medical errors in family practice (Dovey et al. 2002). Their efforts did not resolve the issues of properly assigning error to a system or human category. For example, they assigned lack of factual knowledge and skills as a system error at the health institution level due to lack of training (Dovey, Meyers, Phillips, Jr., Green, Fryer, Galliher, Kappus, and Grob 2002). Those errors should be more appropriately classified as errors of negligence or incompetence related to regulatory failure, as shall be explained (Chapter III. The learning Curve for New and Established Interventions Concept). Gawande, in his study of errors at three major teaching hospitals, also considered incompetence as a system error at the health institution (Gawande et al. 2003).

Furthermore, in many error-reporting systems, medication adverse events have been classified as errors when not all of them were in fact errors. Some adverse drug events (ADEs) are a possible expected clinical outcome and are not errors. An ADE is the result of an error when it is related to a wrongly administered drug or the wrong dose of a clinically indicated one. Therefore, not all ADEs are

medical errors. The wrong drug prescription or the wrong dose is. Such an action would still count as an error, even if no obvious ADE was recorded. Bates and other authors have defined an ADE as *"an injury resulting from the administration of a drug (Bates, Leape, and Petrycki 1993)".* ADE's, when appropriately categorized, showed evidence of system failure, incompetence, negligence and accidental causations (Benkirane et al. 2009). Furthermore, recent studies have begun to explore some of the concepts of system and human errors more closely. In one surgical errors study, human and not system weakness was found to be the main reason behind medical errors (Fabri and Zayas-Castro 2008).

What complicates the issue further is that the literature ignores the important features of the Swiss Cheese Model, an approach that can be used to highlight and investigate all possible system weaknesses. The reason for this is because Reason defined weaknesses by designers, builders and planners as latent. Currently, Reason's definition applies to health institutions only. However, designers, builders and planners could also be regulators, licensers, suppliers, key opinion leaders (KOLs) and researchers. This further highlights the need a new vision on medical error.

***Current Perspectives on Medical Errors***

## The Burden of Medical Errors

Medical errors may be easily considered the biggest cause of human death and disability among human industries such as aviation, road transport, mining and other industrial activities (DSA 2005). Detailed documentation of errors started decades ago. In the United States in the 1970's, the California Medical Association with the collaboration of the California Hospital Association conducted the first major study on medical errors. The Medical Insurance Feasibility Study was carried out in response to rising medical litigation and rising costs of medical insurance, thereby leading to rising costs in health care (Mills 1978). Public interest was the motive behind the study that helped the medical insurance industry create classifications, nomenclatures and evaluation techniques

for medical adverse events. It was not meant to evaluate the quality of health care, but it did so indirectly. Twenty-thousand eight-hundred and sixty-four (20,864) records of patients admitted in 1974 were evaluated. The identities of patients, treating physicians and hospitals were not recorded. A potentially compensable event (PCE), an adverse event definitely related to medical management, was found in 970 (or 4.65%) of the 20,864 patients. (Mills et al. 1977). Other disabilities were not classified as PCEs if there was no clear evidence of error. A disability scale of seven was created.

**Table 1: The Seven-Grade Severity Scale**

Adopted for the Study and PCE percentile (Mills, 1978)

| Code | Description | PCE Percentile |
|---|---|---|
| **3.0** | Minor temporary disability: not exceeding 30 days and not requiring surgery for its correction or treatment | 35.7 |
| **3.1** | Minor temporary disability: not exceeding 30 days but requiring surgery for its correction or treatment. | 25.7 |
| **3.2** | Major temporary disability: lasting more than 30 days but not longer than two years. | 18.6 |
| **3.3** | Minor permanent partial disability: permanent conditions that are not functionally disabling during everyday living and working. (e.g., loss of spleen, loss of uterus). | 6.5 |
| **3.4** | Major permanent partial disability: substantial damage, but not sufficient to cause complete loss of ability to perform most daily functions. | 2.2 |
| **3.5** | Major permanent total disability: substantial damage, usually sufficient to alter lifestyle into a dependent position. | 1.0 |
| **3.6** | Serious permanent total disability: complete dependency or short-term fatal prognosis. | 0.6 |
| **3.7** | Death | 9.7 |

Table compiled from data published by Mills

Based on the total number of hospital admissions in California in 1974, a statistical extrapolation of these figures yielded 140,000 total PCEs and 13,600 deaths. However, the records reviewed showed that only 0.79% (less than 1%) had an indication of admission of liabilities (Mills 1978).

It took many years until another major detailed study took place. The Harvard Medical Practice Study reviewed 30,195 randomly selected records in 51 hospitals in New York State in 1984. One-thousand one-hundred and three or (1,103; 3.7%) disabling injuries were found to be due to medical management and

not to disease processes. Fifty-eight percent (58%) of those adverse events were due to preventable medical errors. Legal experts categorized 29% of the adverse events as negligent (Brennan et al. 1991; Leape et al. 1991). Drug complications and wound infections accounted for 19% and 14%, respectively. Fifty percent (50%) of the adverse events followed surgical procedures (Leape, Brennan, Laird, Lawthers, Localio, Barnes, Herbert, Newhouse, Weiler, and Hiatt 1991). Deaths accounted for 13.6% and permanent disabilities accounted for 2.6%.

Following the publication of the Harvard study, a similar major study was conducted in Colorado and Utah in 1992 (Gawande et al. 1999). The extensive review covered fifteen-thousand (15,000) non-psychiatric discharges. Sixty-six percent (66%) of adverse events were surgical in nature. The incidence of surgical adverse events was 3%, of which 54% were preventable. The rate of adverse events resulting in death was 5.6%, accounting for 12.2% of all hospital deaths (Gawande, Thomas, Zinner, and Brennan 1999).

In Canada, a major undertaking to record patient adverse events (AEs) was started in 2002. It involved twenty Canadian hospitals in five provinces. The study was co-sponsored by the Canadian Institutes for Health Information (CIHI) and the Canadian Institutes of Health Research (Sibbald 2002). Initial case reviews were conducted by nurses. The AEs discovered are then subjected to further review by trained physicians. The study is on going and the findings of that study are yet to be published. Another Canadian study of 502 patients from an Ottawa Hospital showed 64 patients had AE's (12.7%). The number of preventable AE's was 4.8% and three patients died as a result of medical errors (Forster et al. 2004). Despite its small scale, these figures show that Canadian hospitals are also prone to medical error events at an almost equivalent rate to that of U.S. hospitals. Many other medical event studies have been conducted in Canada (Aaron et al. 2008; Bartlett et al. 2008; Christenson et al. 2004; Forster et al. 2004; Forster, Shojania, and van 2005).

**The Response to the Major Studies on Medical Errors**

Following these findings, many in the medical profession were in a state of shock and skepticism, as shall be detailed. The public was alarmed. How could the medical profession, whose only role is to relieve harm and suffering from disease or trauma, be a major cause of harm, suffering and death? The profession was put under the spotlight and asked to provide explanations and solutions. Not surprisingly, therefore, the profession's disposition was defensive.

The Institute of Medicine (IOM) published its landmark study "*To Err is Human*" in 2000. It is a detailed study, comprehensively summarizing medical error studies and includes many policy recommendations. Many facts, despite their possible underestimation, are shocking. For example, the IOM extrapolation estimated the number of deaths due to medical error in the U.S. to be 98,000 per year during the study (Kohn, Janet M Corrigan, and Molla S Donaldson 2000). This figure is based on the findings of the Harvard Medical Practice Study (Brennan, Leape, Laird, Herbert, Localio, Lawthers, Newhouse, Wealer, and Hiatt 1991). Skeptics doubt the figures. McDonald and others believe that the IOM data are exaggerated and that the Harvard and Colorado and Utah studies were retrospective and observational. According to these critics, the number of deaths, for example, is more likely to be much lower (McDonald, Weiner, and Hui 2000). McDonald's main argument centers on the shortcomings of retrospective studies and the lack of full documentation. Others claim the opposite. Leape believes that the IOM figures are more likely to be an underestimate, since more than half of the surgical procedures took place outside main hospitals. Furthermore, many mistakes are not documented in patient charts (Leape 2000).

In a detailed report, Barbara Starfield estimated that the number of deaths in American hospitals due to unexplained causes ranges from 225,000 to 284,000. The lower figure is based on estimates even lower than those of the IOM and higher estimates yield higher figures (Starfield 2000). Such estimates are only based on hospital admissions and do not take into account deaths occurring outside the hospital as a result of errors occurring in outpatients clinics or

physician surgeries. They also do not include morbidity and disabilities suffered because of errors or adverse events. Starfield categorized deaths as follows:

1. 12,000 deaths/year from unnecessary surgery
2. 7,000 deaths/year from medication errors in hospitals
3. 20,000 deaths/year from other errors in hospitals
4. 80,000 deaths/year from nosocomial infections in hospitals
5. 106,000 deaths/year from non-error adverse effects of medications

Prospective studies support the underestimation. Many prospective studies show higher error rates than the Harvard and Colorado and Utah studies. Classen found higher adverse drug events than the Harvard study (Classen et al. 1991). Bates and others found similarly higher ADE rates (Bates et al. 1995). In a study on medical errors in the intensive care, Donchin found a detrimental error rate of 1.7 per patient per day (Donchin et al. 2003). Such a rate eclipsed the findings of the other two major retrospective studies.

## *The Four-Principles Approach Ethical Analysis of Medical Error Predicaments*

The many dilemmas currently facing the medical profession regarding medical errors requires discussions on their causality and on finding solutions. I will use the four-principles approach throughout this thesis to evaluate the ethical topics raised. According to Beauchamp (Beauchamp 1994; Beauchamp and Childress 2001, 5th ed.), the four principles are:

1. Beneficence (the obligation to provide benefit and balance benefit against risk).
2. Non-malfeasance ( the obligation to avoid the causation of harm).
3. Respect for autonomy (the obligation to respect the decision-making capacities of autonomous persons).
4. Justice (the obligation of fairness in the distribution of benefit and risks).

It is generally understood that these principles are the foundation of ethical analysis and are used in connection with other moral considerations, such as truth

telling, confidentiality, privacy, informed consent and all other moral norms, to inform and interpret specific contexts. There is no scope to detail the argument for and against their merits of the framework of the analysis. Nevertheless, I feel that any conduct under discussion in this thesis that cannot meet such basic moral obligations must be considered seriously lacking in ethical credibility. However, there is a need to use other ethical arguments for some complex issues related to medical errors generated by organizations and institutions throughout this thesis. This is not because the four-principles approach fails to argue for a specific moral conclusion, but because some acts by some organizations are enormously serious.

## Unjustified Profession Protectionism

Health profession protectionism has a long history in medicine. Queensland, Australia is an example worthy of specific mention. Over four decades, complaints made against medical graduates from one Australian university in Queensland went unsatisfactorily answered by the medical board that regulates the health profession in that state. Since the information recently became public knowledge, it was found that the complaints were mainly related to clinical standards of competence. The Health Board's main response was "no further action." As a result, many patients were put at risk because of such unethical conduct by the licensing board (Parker et al. 2010).

The title of the most important publication on medical errors was meant to be a watershed in the history of medical errors. "*To Err is Human*" is, in my opinion, a rather unfortunate title. Such a title implies excuses for the occurrence of medical errors. As a result, one cannot be surprised that a decade after such a landmark publication by the IOM, no major reduction in the level and severity of medical errors has been achieved. The public is becoming more intolerant of the status quo and the insurance industries are refusing to foot the bill for potentially preventable errors (Glick 2009). There are serious deficiencies in accountability, checks and balances and transparency. Such problems drove junior staff to resort to alerting readers through anonymous letters, such as the letter to the British Medical Journal about the failings of a senior surgeon who allegedly caused five deaths as

a result of surgery (Anonymous 1998). Current monitoring standards did not result in any actions on behalf of the deceased by the health authority, despite total agreement among experts that there was something seriously wrong, either mentally or physically, with this particular surgeon.

There were also incidences of falsifying or altering medical records to cover up fatal mistakes committed by various physicians. For example, a trainee showed his senior consultant that he failed to check an electrocardiogram performed on a patient who presented with abdominal pain five days into her admission. The electrocardiogram was read while writing her death summary. The ECG clearly shows that she presented with an acute myocardial infarction. The senior physician erased the true date and the patient was falsely pronounced dead of myocardial infarction on the day of her death (Anonymous 2001). The senior physician's main message to the junior doctor was that they should all learn from the incident. How prevalent is the climate of secrecy, dishonesty and desire to self-protect at the expense of patient's legitimate interests? Does this medical culture propagate from senior to junior physician generation after generation?

As shall also be detailed in Chapter III, the health profession regulating bodies, both governmental and self-regulating, also frequently show disregard to patient safety, justice and respect by knowingly concealing the under-performance of health personnel over many years. Much suffering goes unrecognized and unexposed until it is leaked to the media. The case of the Bristol Royal Infirmary, The Winnipeg Health Science Center, the Health Board of Queensland, Australia and many others will be discussed in painful detail. Physicians' obligations to patient safety and their fiduciary duty towards their patients is significantly compromised.

The concept of fiduciary duty is complex and touches almost all aspects of the physician-patient relationship. It simply demands that physicians, managers, regulators and suppliers aim to act in the best interest of their patients. In practical terms, it means disclosing financial incentives that may compromise patient care, truthfully disclosing errors to patients when they occur, and advising them against

harmful treatment. It also implies fully disclosing the side effects of potential treatments, seeking help from other colleagues when confronted with difficult cases, and respecting patient autonomy and independence in decision-making. Furthermore, it means keeping all treatments private and confidential (Buchanan and Miller 2006; Crone et al. 2006; Faunce and Bolsin 2005; Litman 2007; Sandrick 2006; Slade 2009).

Patient safety is also threatened by the actions of some highly regarded key opinion leaders (KOLs) who, under the influence of financial gain, recommend unsafe practices and falsify research data. KOLs commit actions with flagrant disregard to basic moral values such as truthfulness, integrity, accountability and ethical obligations required by their institution. As one author says, it is akin to "*sacrificing patients for profit*" and disregarding physicians' fiduciary duty (Marsh 1999). Chapter III will address this serious issue in more detail.

## Governmental Regulatory Agencies Failed in their Ethical Obligations to Protect Patients

As shall be demonstrated in detail in Chapter II, the Vioxx story and many similar cases show much disregard to patient safety. For example, Vioxx was approved despite its serious side effects at the time of the initial approval. Patient care requires justice, nonmaleficence, beneficence and respect. The justice principle demands that all vulnerable groups that may be affected by an action be identified and that that action be equitable. It has been known for decades that health differences between countries and within regions of the same country are significant. Similarly, health inequities between different patient groups are also significant. Policies are encouraged to minimize inequity by promoting fairer health care that targets disadvantaged groups and high-risk individuals (Whitehead 1991).

Arthritis patients with chronic conditions are one of the most vulnerable groups; they have a shortened life span and poor quality of life, as well as increased risk of myocardial infarction, stroke and fractures, compared to the general population. To approve Vioxx, despite its risk to them and without full disclosure of these

risks, was against all ethical principles. The FDA did not uphold the principle of nonmaleficence by licensing Vioxx. Nonmaleficence requires that you: 1) identify the groups that could be harmed by a therapeutic action; 2) outline steps to minimize harm; 3) fully communicate the risks to all concerned, truthfully and openly; and 4) have an obligation to avert harm in the event of a disaster (Beauchamp and Childress 2001). The FDA completely failed to uphold the principle of nonmaleficence.

Regulators also did not uphold the respect expected of them by not disclosing all the relevant known side effects. On the contrary, they concealed them and offered a relentless defense for the drug over four years until it was withdrawn. More seriously, regulators failed to fulfill their obligations as required by the statutes regulating their practice, as shall be detailed in Chapter II.

**Litigation Rate does not Reflect Error Burden**

Many authors questioned the motives of "*To Err is Human*." Some considered it an attempt to protect the medical profession from litigation. In fact, there were many references in the IOM report emphasizing that admission of error should not lead to recrimination or legal procedures (Kohn, Janet M Corrigan, and Molla S Donaldson 2000). This is based on the belief that such a policy will aid medical error disclosure. Many health professionals applauded some U.S. states for introducing laws to that effect (Fong 2005).

There is fear and apprehension in the medical profession about litigation. Careers and morale can be destroyed because of it. However unpleasant it is, the litigation rate does not reflect the actual number of errors. Many studies report that the litigation rate constitutes only a fraction of the medical error rate (Sage 2006). In a status report on medical errors in Canada, despite a decreased fear of litigation compared to the U.S., Canadians were not more likely to have been informed of errors committed during their treatment by health professionals (Levinson and Gallagher 2007). Furthermore, many lawyers do not consider litigation that does not qualify for high compensation, and many cost schemes are designed to fit a particular type of litigation (Rubinfeld and Scotchmer 1993). Moreover, the cost

of litigation settlements will be shouldered by future patients or tax payers according to the rising cost of medical care. Surprisingly, in the U.S., the rising cost of care always outstrips the total value of litigation settlements (Roberts and Hoch 2009). Physician's efforts and energies can better be used to prevent medical errors.

Health professionals clearly face an ethical dilemma. Are they treating their patients as a means to financial gain irrespective of poor outcomes? Alternatively, are they treating patients as an end in themselves and from a sense of duty? If the latter, as they always claim, then patients are fully entitled to know what goes right and what goes wrong in their management and treatment without any attempts at qualification. This openness could give health professionals the moral courage to fight and eliminate medical errors. Treating patients with the respect they deserve is an ethical principle that the majority of health professionals cherish. The profession gains no advantage when it forcefully protects a minority who err. It is also not in the best interest of physicians, patients and health services organizations to practice defensive medicine in the hope of protecting themselves from malpractice (Thompson and King 1984). Such behavior is malpractice in itself and a waste of resources in its own right.

**Error Burden and Disclosure**

Although error disclosure is not a topic to be covered in detail in this dissertation, disclosing the truth has an obvious connection to accurate error taxonomy reporting that cannot be understated. There is mounting evidence in the literature supporting the belief that disclosure does not automatically lead to litigation. Fear of litigation should not be an obstacle to full error disclosure. Those who conceal errors may be discovered and lose their patients' sympathy and are more likely to face litigation. Studies support the opinion that disclosure of an error followed by a genuine apology has such an impact on patients that it dissuaded them from resorting to litigation (Bismark 2009; Frenkel and Liebman 2004; Nicole 2007; Baggett 2005; Huff 2005). Telling the truth is a fundamental obligation for all professionals in all cultures, religions and secular societies (Trianosky 1990). It is

expected that health professionals master this art to limit the damage incurred on themselves and their patients (Berlinger and Wu 2005).

Patients desire and expect health professionals to disclose errors to them and they will frequently be less likely to take legal actions (Gallagher et al. 2003; Hobgood et al. 2002; Witman, Park, and Hardin 1996). In the long run, it is unhelpful and ethically difficult to defend the demand by some health professional organizations that the facts disclosed by health professionals on committed medical errors should not be used for litigation purposes. Such a demand linking disclosure to immunity from prosecution is morally difficult to defend. Does it mean that when a physician admits to a family that he caused the death of their mother, or wrongly removed the breast of another woman thinking that it had a cancerous lesion when it did not, that he could be sued because all information was disclosed and could be used against him? What logic can support such a demand? Such a demand will hinder the progress of tackling medical errors head-on.

To some, disclosure means reporting incidents anonymously to an error-reporting centre. However, history shows that the value generated from such an action is limited. It merely functions as a bureaucratic achievement for the records. This will be discussed later, when dealing with the value of data accumulated from error-reporting systems and their effects on error reduction (Chapter III, Anonymous Reporting, Merits and Pitfalls).

### *The Consequences of Failing to Classify and Define Medical Errors*

#### Medical Error Data Is Less Useful

Many countries have established error-reporting centers. Variable error taxonomies lead to reporting variable errors and statistical evaluations. As previously discussed, a system error for one taxonomy is a human error for another (Dovey, Meyers, Phillips, Jr., Green, Fryer, Galliher, Kappus, and Grob 2002). Since there are no generally-accepted taxonomies or validated classification systems of medical errors, many medical error reports are

sometimes based on only one or a few hospitals, and are therefore not representative (Fabri and Zayas-Castro 2008).

Other industries, such as the aviation and nuclear industries, unified their terminologies and error-reporting mechanisms (Wells and Rodregius 2004). The medical industry is lagging behind. In addition, problems are encountered when using the collected data for monitoring the performance of different clinical disciplines, as in the case in the United Kingdom. Many agencies had detailed documentation of clinical outcomes but failed to take action to stop underperforming centers and clinicians (Kennedy 2001). The profession and government departments and agencies did not take the data seriously.

### Government Licensing Agencies of Drugs and Devices and Healthcare Product Suppliers Escape Accountability

The failure to taxonomize medical errors appropriately causes profound injustice to many in the medical profession. Many patients suffer medical errors because of dangerous drugs and medical devices that were licensed by government agencies. The side effects of drugs or problems with devices appear to be overlooked by regulators during the evaluation phase, to the future detriment of many patients. For example, Vioxx, or Rofecoxib, caused an additional 160,000 myocardial infarctions and strokes in the U.S. (Topol 2004). Detailed evidence incriminating the regulators and health care suppliers will be presented in chapter II.

Evidence showed questionable relationships between the FDA and the pharmaceutical industry, resulting in detrimental consequences to patient safety. The industry went to the extent of raising its objection to the inclusion of panel members who were likely to oppose their product (Perler 2004).

Many drugs and devices fall into this category, and ignoring these facts is counterproductive. On many occasions, flawed decisions are only discovered in retrospect. Many health professionals get blamed for errors that are not of their own doing. Failure of procedures can be the result of wrongly licensed devices and not because of negligent operators. In addition, the side effects of wrongly licensed medications can be a stroke or myocardial infarction on an operation

table, thereby placing the blame on the anesthetist or surgeon. The career of many professionals can be ruined by the time they discover the truth. Accurately taxonomizing errors will appropriately shift such liabilities to the regulatory agencies and exonerate many health professionals. This does not mean that identifying regulators and suppliers as sources of medical errors will lessen the risk of accusations of corruption, incompetence and failure in their obligations. The fear of accountability as a culprit in medical error causation might promote practices that are more ethical.

### *The Health Profession Regulating Bodies Escape Accountability*

Health profession regulating bodies carry the major burden of system-related medical errors. The profession has failed to regulate the practice of its members competently. Many professionals are not adequately trained; others are not up-to-date and cannot competently perform their duties. Despite this fact, they continue to be licensed to work and cause harm. The standards set for continuing professional education has serious deficiencies (Burns 2009; Byrne et al. 2007; Eustace 2001; Gunn 1999; Hicks 2005; Kicklighter 1984; Madewell 2004; Roberts 1996). Furthermore, new procedures are performed by unqualified personnel at different centers with high error rates under the slogan of gaining experience or training purposes or "learning curve" justifications. Why is it accepted that the success rates of procedures are significantly different at different centers? Likewise, why is it acceptable that complications or error rates of some procedures are significantly different between centers? Such differences are not routinely declared to patients prior to obtaining their consent. Many other regulatory agencies, such as departments of health and government monitoring agencies, repeatedly fail in their obligations to monitor poorly performing health professionals, as will be detailed in chapter III.

### Some Health Professionals Are a Source of Bias and Prone to Influence by the Medical Industry

There is mounting evidence in the literature to suggest that research and its evaluation and publication by health professionals is influenced by the medical industry. Industry sponsored and even government sponsored research, in all stages of design, questions to be answered, analysis and publication of research results, are prone to bias and potential conflict of interest (Beutels 2004; Smith 2003). Researcher relationships with corporations make it twice as likely that their devices will be promoted for unlicensed indications at medical conferences (Brown et al. 2006). As will be discussed in Chapter III, drugs and devices are sometimes wrongly licensed for use with the blessing of some health professionals presenting themselves as experts, the so-called key opinion leaders. They should shoulder direct blame when it is shown that they unethically manipulated information for the benefit of the medical supply industry.

### Errors Emanating from Research Are Not Recognized by Error Definition and Error Taxonomy

Substantial evidence exists documenting serious medical errors suffered by patients and volunteers from research. This is happening despite monitoring and detailed ethical approval by Institutional Review Boards (IRBs). Progress in research ethics over the last three decades has been remarkable. However, major ethical concerns and risks to patients continue to exist. Fortunately, catastrophes similar to the Tuskegee syphilis study and the New York children's hepatitis study are things of the past (Katz et al. 2008; Katz et al. 2009; Katz et al. 2009; Reverby 2008; White 2008; White 2010). However, many cases of death and morbidity of healthy volunteers continue to shadow the research industry (Edwards, Kirchin, and Huxtable 2004; Fiscus 2001; Gelsinger and Shamoo 2008; Smith and Byers 2002; Stolberg 1999). Many ethical issues continue to challenge research and its safety as well (Klanica 2005; Kong 2005; Liang and Mackey 2010; Puttagunta, Caulfield, and Griener 2002). Medical errors from clinical and scientific research require an urgent intervention by error taxonomy. I believe a

new taxonomy of errors will greatly assist in reducing errors and thereby benefit patients and professionals.

## The Proposed Solution

I believe that any proposed solution should have the ability to provide solutions to the two main areas of medical error science's current deficiencies. The first is to define an appropriate error taxonomy that can assimilate all, or at least most, possible causes of errors. The second is to define what is a medical error, so that such a definition incorporates all relevant sources and types of errors. Furthermore, it should be consistent with the generally accepted concepts of error science and have the ability to be used for the purposes of accountability and reform, and above all, be in the patient's best interest.

### Assign Error Accountability More Appropriately by Defining the Broad Categories of Error Taxonomy

Contemporary medical error literature emphasizes latent operational weaknesses in health services institutions as the main cause of system-related medical errors. Other causes are considered indirect or as other ethical issues such as corruption or conflict of interest. Currently, medical errors are divided into two major categories: 1) system errors at the health institution due to latent operational weaknesses, and 2) human error. The proposed solution emphasizes the separation of the causes of medical errors into more relevant categories that reflect reality. The broad divisions of taxonomy will be categorized as depicted in the two tables below.

| **System Errors** | | | | | |
|---|---|---|---|---|---|
| Due to failures of health agency regulatory licensing and monitoring | Due to unethical conduct of suppliers | Due to unethical conduct of health professionals | Due to failures in professional regulation, either governmental or self | Due to research risks | Due to latent operational weaknesses at the health institution |

Table 2: The new error taxonomy; systems

| Human Error | | | | | | | |
|---|---|---|---|---|---|---|---|
| Negligence | Incompetence | Errors of Judgment | Wrong drug | Wrong drug dose | Communication | Infection transmission | Fatigue |

Table 3: The new error taxonomy; human

The first five system error sources are the result of corruption, incompetence and inadequacies in professional regulation, among other reasons. The error burden from these sources is not reflected in error statistics. The medical errors that result from these sources should be explicitly declared, so that the full truth of error burden is appreciated. A successful taxonomy starts with defining its main categories.

**Defining Medical Errors**

Dovey and Philips rightly claim that defining medical error is still in its infancy and is not yet complete. I feel no hesitation in suggesting a definition based on the facts presented and my understanding of the subject. A working definition of medical error could be stated as: an action or inaction leading to patient morbidity or mortality, caused by system failures in product licensing and monitoring[1], fraudulent behaviors by professionals and organizations[2], failure of health profession regulatory bodies[3], research risks, latent weaknesses in health institution operational processes[4] or human error.

This definition encompasses all potential causes of medical errors. It covers all areas neglected by current definitions and error taxonomies. As in all other industries, a thorough understanding of the mechanisms of error generation is

[1] Therapeutics licensing by agencies, despite clear evidence of harm and against professional advice.
[2] By health professionals for undue financial gain or supplier influence on professionals and agencies
[3] Failure by governmental regulatory bodies and professional self-regulatory bodies; incompetent professionals errors
[4] Classical system latent weaknesses at the institutional level

essential for identifying and eliminating errors. The next two chapters will focus on evidence in support of the proposed new definitions.

# CHAPTER II

# SYSTEM WEAKNESSES IN REGULATORY AGENCIES, HEALTHCARE SUPPLIERS AND LEADING HEALTH PROFESSIONAL MISCONDUCT

System errors in medicine can have multiple sources. The current literature on medical errors primarily identifies system errors generated at health care institutions. These errors are caused by latent system weaknesses (Reason 1990). The literature covers this area in detail. Notwithstanding this, a number of issues remained distorted. First, an emphasis on the unrecognized causes of system error merit specific consideration. Despite their obvious and significant contribution to errors, so far, overall, the literature tabulates these categories under different categories, as shall be described. Three main categories will be covered in this chapter.

***First:*** failures of government health regulatory bodies in their duties of licensing and monitoring are frequent and cause significant morbidity and mortality.

***Second:*** unfounded claims by health care product suppliers and censorship of negative data related to their products is significantly problematic and the root of many medical errors suffered by large cohorts of patients. More seriously, when health regulators and suppliers 'collude' with each other to cover potential risks, the enormity of the burden on patients is profound. Recent history has shown unfortunate tragedies as seen below.

***Third***: failure of some health professionals to uphold the integrity of their profession by falsifying research results and marketeering efforts on behalf of health care suppliers for personal financial incentives have led to high risk medical practices and harm to patients.

The error burden from these system failures are not plainly and explicitly incorporated in the medical errors taxonomy, statistics and reporting. Error accountability should be applied to these sources.

### *The Role of Government Agencies in System Error Initiation and Propagation*

Government health agencies, such as the Food and Drug Administration (FDA) in the USA, the European Medicines Agency, Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom, and Health Canada are responsible for regulating and approving drugs and health care devices. Over the

last half-century, many unfortunate cases of drug approval and licensing of medical devices have led to many fatalities and morbidities. At time of approval, some of those products were presented as revolutionary in medicine, leading to millions of prescriptions and best-selling drugs. As shall be detailed later in this chapter, decisions to approve many of these drugs were made, despite serious side effects known at the time of licensing. Some decisions were approved against advice even from within these organizations. Table 4 (Bunniran et al. 2009) shows a list of drugs withdrawn from the market for safety reasons. A case study will help illustrate the enormity of the crisis.

| Brand name | Manufacturer[+] | Generic name | Year approved | Year withdrawn | Safety concerns |
|---|---|---|---|---|---|
| Oraflex | Eli Lilly | Benoxaprofen | 1982 | 1982 | Jaundice |
| Zomax | McNeil | Zomepirac | 1980 | 1983 | Anaphylaxis |
| Merital | Hoechst-Roussel | Nomifensine | 1984 | 1986 | Hemolytic anemia |
| Suprol | McNeil | Suprofen | 1985 | 1987 | Flank pain syndrome |
| Enkaid | Bristol Myers Squibb | Encainide HCl | 1986 | 1991 | Ventricular arrhythmias |
| Omniflox | Abbott | Temafloxacin HCl | 1992 | 1992 | Kidney failure |
| Manoplax | Boots | Flosequinan | 1992 | 1993 | Increased mortality |
| Seldane | Hoechst Marion Roussel | Terfenadine | 1985 | 1998 | Cardiac arrhythmias |
| Duract | Wyeth-Ayerst | Bromfenac Na | 1997 | 1998 | Liver toxicity |
| Posicor | Roche | Mibefradil dihydrochloride | 1997 | 1998 | Drug interactions |
| Hismanal | Janssen | Astemizole | 1988 | 1999 | Fatal arrhythmias |
| Raxar | Glaxo Wellcome | Grepafloxacin HCl | 1997 | 1999 | Arrhythmias |
| Trovan [*] | Pfizer | Trovafloxacin | 1997 | 1999 | Liver toxicity |
| Lotronex [*] | GlaxoSmithKline | Alosetron | 2000 | 2000 | Constipation |
| Rezulin | Warner Lambert | Troglitazone | 1997 | 2000 | Hepatotoxicity |
| Propulsid | Janssen | Cisapride | 1993 | 2000 | Cardiac arrhythmias |
| Baycol | Bayer | Cerivastatin | 1997 | 2001 | Rhabdomyolysis |
| Raplon | Organon | Rapacuronium | 1999 | 2001 | Fatal bronchospasm |
| Vioxx | Merck | Rofecoxib | 1999 | 2004 | myocardial infarction |
| Bextra | Pfizer | valdecoxib | 2001 | 2005 | Myocardial infarction |

## Table 4: U.S. Safety Based Withdrawals (1980-2005)

[*] Subsequently re-introduced to the market with restricted labelling.

[+] Manufacturer at time of product withdrawal.

**The Vioxx Story as a Prototype Case Study**

Vioxx was approved by the FDA and the European Medicines Agency and subsequently worldwide in 1999 (Kaplan-Machlis and Klostermeyer 1999). That process showed serious and intentional system failures by regulators and the manufacturer, as shall be illustrated. Vioxx was marketed as a safe and well-tolerated medicine from a gastrointestinal point of view as a COX-2 or cyclo-oxygenase-2 inhibitor (Hinz and Brune 2000; Meyer-Kirchrath and Schror 2000; Urban 2000). COX-2 medications were, in theory, a good improvement over conventional non-steroidal anti-inflammatory drugs that were known to cause gastrointestinal upset, ulceration, bleeding and even death. A drug that can control pain and inflammation without gastrointestinal upset was a tremendous asset and a milestone in the history of medicine.

Data from the initial study on which approval was based, included 8076 patients with rheumatoid arthritis. They showed fewer gastrointestinal side effects but seven times the rate of myocardial infarction when on low doses of Vioxx compared to placebo. Despite this, the FDA approved the drug in 1999. The data on cardiovascular safety was not submitted to peer-review until the following year and appeared in print by the end of 2000, 18 months after the drug was on the market (Topol, Karha, and Topol). This was rather unusual and contrary to accepted practices. Incomplete data on cardiovascular mortality and morbidity was submitted to the leading *New England Journal of Medicine* (Couzin 2005). Serious accusations were leveled against Merck, the FDA and the authors of the study. Merck was subsequently discovered to have downplayed the serious side effects profile, mounted a vigorous defense for Vioxx and defended its favorable cardiovascular safety. Another Merck study in 2000, VIGOR, showed five times the rate of myocardial infarction compared to placebo. The FDA made a labeling change, not a warning, to include myocardial infarction risk with high doses of Vioxx only. One of the side effects documented in the initial filings to the FDA by Merck showed that Vioxx raised blood pressure in the study group; the regulators overlooked this finding. High blood pressure is a significant risk factor for cardiovascular and cerebrovascular disease. Post-marketing studies confirmed

increased blood pressure with Vioxx compared to other non-steroidal anti-inflammatory medication (Brinker et al. 2004).

The drug also escaped censorship during the early years of post-marketing surveillance. The regulatory agencies also did not take any action when post-marketing surveys showed clear detrimental cardiovascular morbidities. Ross and colleagues showed that published and unpublished data on 30 randomized controlled trials involving 20,152 patients showed as early as June 2001, an increase of 35% in cardiovascular adverse events or deaths in the Vioxx group compared to placebo, rising to 39% by April 2002 and 43% by September 2004 (Ross et al. 2009). Despite the available evidence, no action was taken to prevent death and morbidity from Vioxx and the drug continued to be prescribed and received vigorous defense from the manufacturer and regulatory authorities, again despite the alerts echoed by independent investigators. In fact, the drug was even studied for prevention and treatment for colonic adenomatous polyps, a pre-cancerous large bowel condition in the APPROVe clinical trial between 2000 and 2001 (Baron et al. 2008). The patient cohort in the APPROVe trial had no known risk factors for myocardial infarction. The trial was discontinued because of the higher risk of myocardial infarction in the Vioxx group compared to placebo, but Vioxx continued to be prescribed for another three years, a fact that is difficult to justify or understand.

The drug was voluntarily withdrawn by the manufacturer Merck and **not by the regulatory agencies**. This action was executed after more than 80 million patients took the drug with annual sales of more than $2.5 billion and an estimated 160,000 cases of heart attacks and strokes in the USA alone (Topol, Karha, and Topol 2004. Applying the U.S. rates on a worldwide basis produced more than **three million** myocardial infarctions and strokes, a staggering number.

### Evidence from within the FDA

The revelations by the experts from within the FDA eliminated any doubt about the validity of the serious accusations leveled against it. Serious concerns about Vioxx safety were raised but were repeatedly ignored. Dr. Graham, a physician

and an epidemiologist at the FDA, in his long testimony at the U.S. congress declared that the FDA knew about the seven-fold increase in myocardial infarctions due to Vioxx compared to placebo in the initial submission by Merck, and that they were also aware of all subsequent study results. As further epidemiological studies appeared to question Vioxx safety, the FDA and Merck continued to mount a vigorous defense for Vioxx. Graham gave an estimate of 88,000 to 139,000 individuals who had a myocardial infarction while on Vioxx. He also estimated that 30% to 40% probably died[5].

One of the more revealing claims in Dr. Graham's testimony to Congress is the fact that when evidence that showed the definite risks from Vioxx was about to be revealed in scientific meetings, he was asked by the director of the FDA Office of Drug Safety to alter the conclusions! Otherwise, he was not to present the material, since the FDA was not contemplating issuing a warning on Vioxx. He also claimed that the Office of New Drugs censored the Office of Drug Safety from revealing any information to the public, without clearing such release from the Office of New Drugs. Senior officials from the Office of Drug Safety and the Office of New Drugs at the FDA insisted that Vioxx was safe up to eight days prior to Merck's decision to withdraw it from the market[6].

**Ethical Analysis of FDA Conduct**

These revelations from within the FDA do not portray an agency concerned with drug safety, but rather an agency doing the bidding of drug manufacturers. Such behavior can be considered corruption. Corruption has many definitions. Corruptness is lack of integrity or honesty (especially susceptibility to bribery) and the use of a position of trust for dishonest gain. Corruption is also defined as moral perversion and impairment of virtue and moral principles[7]. The FDA failed public trust, despite internal and external advice to the contrary.

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[5] http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf; accessed April 2010
[6] http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf; accessed April 2010
[7] http://www.google.ca/search?hl=en&defl=en&q=define:corruption&ei=AoikS-W_NMGAlAfo_ZjHCw&sa=X&oi=glossary_definition&ct=title&ved=0CAYQkAE; accessed April 2010

Patient care demands justice, respect, beneficence and non-malfeasance. As noted previously, justice demands that you identify all vulnerable groups that may be affected by an action and that your action be equitable. Health care differences between countries and within regions of the same country are significant. Policies are encouraged to minimize inequity by promoting fairer health care that targets disadvantaged groups and high risk individuals (Whitehead 1991). In the Vioxx case, the vulnerable groups were the treatment group, but especially high-risk groups. Patients with rheumatoid arthritis (RA) have an increased risk of arthrosclerosis. It is not surprising, therefore, that the initial filing for drug approval on patients with RA showed seven times the rate of myocardial infarction compared to placebo. That rate was the highest recorded among all studies conducted on Vioxx. The FDA actions compromised patient justice and safety.

Justice is also a legal concept. Can the FDA and Merck's conduct qualify as obstruction of justice? The legal definition of obstruction of justice is extensive and has many clarifications and clauses. One statement in the definition is *"the act by which one or more persons attempt to prevent, or do prevent, the execution of lawful process (Nolan 1990)"*. This statement covers all acts at any institution or organization that obstruct a legally required process such as licensing.

The FDA, and for that matter all regulatory agencies, have a duty to uphold the laws governing the obligations in their domain. The prevention of harm and injury from products is especially emphasized. The Food, Drug, and Cosmetic Act (FDCA) created the present FDA in 1938. Despite its frequent amendments, it has two consistent goals or duties. The first is to ensure public safety by ensuring that products be safe, pure and effective. It is the obligation of the agency to seize all unsafe products from the market (USA Food, Drug, and Cosmetic Act 2006; Basile, Tolomeo, and Gluck 2009; Borchers et al. 2007). The FDA failed in this obligation. The FDA's conduct is even worse than that; it was complicit in introducing harmful products onto the market.

The second FDCA Act duty is disclosure of information to the public. This entails truthfulness and completeness in product labeling and other marketing communications. This includes prohibitions and affirmative obligations. The act forbids "*misbranding*" and provides a range of **civil and criminal** enforcement mechanisms against inaccurate product labeling (USA Food, Drug, and Cosmetic Act 2006; Basile, Tolomeo and Gluck 2009; Borchers, Hagie, Keen and Gershwin 2007). The FDA did not honor its obligations in regards to Vioxx. It concealed or at least downplayed the risks posed by Vioxx. It obstructed the true sense of justice. The FDA also knowingly did not uphold the principle of nonmaleficence. Nonmaleficence requires identifying vulnerable groups in a therapeutic action, outlining steps to minimize harm, communicating the risks to all concerned fully, truthfully and openly, and the obligation to avert the harm in the event of a disaster (Beauchamp and Childress 2001). In the case of Vioxx, the FDA failed in all these obligations.

**Merck, Vioxx and the FDA**

Unfortunately, all the above accusations leveled against the FDA are applicable to the manufacturer of Vioxx, Merck. All the information, and maybe more, that was in possession of the FDA was also in Merck's possession. Merck did not lack the resources to identify the risks in the Vioxx trials from the very first study. Merck can be accused of corruption, miscarriage of justice and failure in the biomedical ethical principles pertaining to patient care, beneficence, respect, justice and nonmaleficence. It also failed in its fiduciary duty to patients and the health profession. They concealed risks and disregarded patient's best interests.

Many may raise a legitimate question: why did they do it? Pure incompetence cannot satisfactorily explain the FDA's behavior. The Office of New Drugs at the FDA relentlessly pursued efforts to protect Vioxx. The Senate Finance Committee hearing in November 2004 issued some serious conclusions stating that Merck: *"Knew about the potential for Vioxx cardiovascular (CV) risk quite early in the drug development process. Tried to avoid, disguise, explain away or stifle discussion of CV risk, even designing clinical trials in a way that would minimize*

*that risk. Was enabled by a "too-cozy" relationship with the FDA and delayed warning physicians and patients about the CV risk for nearly 2 years while continuing a multimillion dollar direct-to-consumer marketing campaign for Vioxx"*[8]. Nevertheless, Merck was not apologetic, even after it withdrew Vioxx from the Market. Merck president Raymond Gilmartin told the Senate Finance Committee that: *"Merck believed wholeheartedly in Vioxx. I believed wholeheartedly in Vioxx. In fact, my wife was a user of Vioxx until the day we withdrew it from the marketplace*[9]".

Gilmartin's probable intention was to express honesty and gain sympathy in the Vioxx episode, but lacked the insight expected from a leader of a large company. It also did not truly reflect the facts exposed. The case for considering system errors by regulators and suppliers cannot be made more forceful than that of the Vioxx scenario.

**Withdrawal of Medical Devices for Safety Reasons**

The withdrawal of medical devices for safety reasons provides more alarming numbers compared to the number of drugs withdrawn. The burden on patient safety is profound. The FDA database lists thousands of withdrawn devices[10]. From January 29, 2010 to April 07, 2010 alone, The FDA withdrew more than 500 devices for safety reasons[11]. Many documented cases showed similar disregard for the safety of patients and proper scientific appraisal. For example, a study approved by the FDA on the outcome of a Phase II trial of the AneuRx abdominal graft was submitted by FDA scientists to a leading vascular journal and was accepted after peer review. The FDA changed its mind and asked its scientists to withdraw the article. The FDA stated that Medtronic, the manufacturer, objected to the publication. Medtronic cited proprietary information protected by confidentiality (Cronenwett and Seeger 2004). Medtronic even

[8] http://www.medscape.com/viewarticle/538025; Accessed April 2010
[9] http://www.medscape.com/viewarticle/538025; Accessed April 2010
[10] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/textresults.cfm?q=all&sc=cdd&pn=500; Accessed April 2010
[11] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm; Accessed April 2010

resorted to using lawyers to threaten the journal not to publish data that was not authorized by the company. Researchers were concerned, especially with the response from the FDA, which failed to support the results of its own study (Greenfield 2004). It took four more years before the AneuRx graft was recalled by the FDA in 2008[12].

The FDA demanded from its scientists to withdraw the article and its indifference to patient safety in this case is similar to what Graham revealed in his testimony to the Senate Finance Committee regarding the request of Office of Drug Safety for him not to publish negative results about Vioxx. How contradictory is this conduct from the mission statement of the FDA, which promises *"…high quality, science-based work that results in maximizing consumer protection."* Scientists put the blame on the FDA's political leadership and exonerated its scientists and staff (Perler 2004). Under the influence of the industry, the FDA excludes panel members whom the industry did not regard as supportive of their claims, regardless of the consequences. (See the case of SAPPHIRE carotid stent review panel (Perler 2004).) The consequence on patient safety from one device is significant. When considering the many thousands of devices withdrawn, readers can comprehend the risks faced by patients from the device industry. In January 14, 2009, FDA scientists sent a letter to the President Obama Transition Team describing serious managerial corruption and misconduct within the Center for Devices and Radiological Health at the FDA. They stated that managers corrupted the review process for new devices, thereby placing American people at risk. The letter described intimidation tactics designed to hide scientific debate and proper evaluation processes leading to approval of devices of questionable effectiveness and safety. They cited the approval of mammography computer-aided detection devices against the advice of experts, who on five occasions recommended against licensing. The approval led to many unnecessary breast biopsies and physical, psychological and financial burden on patients[13]. The letter described alarming details of misconduct.

[12] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm; Accessed April 2010
[13] http://www.naturalnews.com/025314.html; accessed April 2010

### *Health Professional Misconduct and Medical Errors*

Throughout history, progress in medical science depended largely on leading, hardworking and able intellectuals. The history of medicine records their illustrious careers and achievements. The authority those leading experts exercised was enormous and often indisputable. However, a significant number of professionals in medical research and clinical practice abuse that trust today. The consequences of their actions on patient safety are profound. Due to limitations of space, only a few examples will be presented to highlight this serious issue.

#### Financial Inducements Affecting Key Opinion Leaders' Recommendations

In almost all fields of medicine, prominent experts recommend off-label use of drugs not licensed for the recommended indications. These recommendations sometimes lead to breakthroughs. But on many occasions, these recommendations are given under undue influence by the health care industry. Despite their deficiencies, these opinions are often highly regarded by many generalists, based on the reputation of these KOLs. The targets of these recommendations vary from children to adults. It is not all scientifically validated advice. As a result, many patients sustain significant morbidity, mortality or even no benefits at all, but always a financial burden to them.

Psychiatrists caught the attention of politicians and independent investigators after more and more children were diagnosed with varying psychiatric conditions, including bipolar disorder. Many investigators (Harris and Benedict, 2008) and politicians became interested in the relationship between KOLs and the drug and device companies. Senator Charles Grassley, member of the Finance Committee of the U.S. Senate followed the trail of some psychiatrists. He discovered that Professor Joseph Biederman, the leading psycho-pharmacologist at Harvard Massachusetts General Hospital who recommended treating children as young as two years of age with powerful psychiatric drugs for bipolar disorders, received $1.6 million from drug companies. The drugs he was recommending were not licensed for children less than ten years of age. His recommendations were based on his own loosely designed and inconclusive studies (Biederman et al. 2005;

Biederman et al. 2007; Biederman et al. 2007; Frazier et al. 2001; Joshi et al. 2010). Senator Grassley also found that Dr. Alan F. Schatzberg, Chair of Stanford's Psychiatry Department, controlled more than $6 million worth of stock in a company that was investigating mifepristone, a drug for psychotic depression (Belanoff et al. 2001; Belanoff et al. 2002; Belanoff et al. 2002; Flores et al. 2006; Schatzberg 2003). At the same time, Dr. Schatzberg was the principal investigator in a study of the same drug that received a grant from the National Institute of Mental Health. Senator Grassley also discovered that Dr. Charles B. Nemeroff, Chair of Emory University's Department of Psychiatry, failed to declare, as required by University regulations, $500,000 he received from GlaxoSmithKline for promoting their drugs in talks and speeches. In 2004, Nemeroff made a commitment to the University to declare all the money he received. He declared $9,999, just one dollar less than the amount needed to be declared to the National Institute of Health. In that same year, Nemeroff received over $171,000 from GlaxoSmithKline. If these leading researcher's practices and recommendations were scientifically based, why did they hide their connections to the pharmaceutical industry, especially when they were legally required to fully do so? The table below shows a list of some senior professionals' receipts and declarations[14]; readers are encouraged to read further from the senate website via the link http://grassley.senate.gov/about/upload/07072009.pdf

[14] http://grassley.senate.gov/about/upload/07072009.pdf; accessed April 2010

| Researcher | Industry Income Disclosed | Total Received | Status |
|---|---|---|---|
| Melissa DelBello, University of Cincinnati | About $100,000 over 2 years | More than $238,000 from AstraZeneca | UC has increased monitoring of DelBello's industry activities |
| Joseph Biederman, Harvard/Mass General Hospital | About $200,000 over 7 years | About $1.6 million | MGH and Harvard are still reviewing, but Biederman agreed to suspend his industry related activities in December 2008. Harvard is reviewing its conflicts policy. |
| Thomas Spencer, Harvard/Mass General Hospital | About $200,000 over 7 years | About $1 million | MGH and Harvard are reviewing. |
| Timothy Wilens, Harvard/Mass General Hospital | About $200,000 over 7 years | About $1.6 million | MGH and Harvard are reviewing. |
| Alan Schatzberg, Stanford | More than $100,000 | $6 million in stock | Stanford says it knew the stock's value. Stanford's medical school soon plans to publicly disclose faculty members' industry ties but not dollar amounts. |
| Charles Nemeroff, Emory | $1.2 million Over 7 years | More than $2.4 $1 million | NIH suspended a $9 Million grant to Emory. The HHS Inspector General is investigating the case. Last December, Nemeroff stepped down from research and as department chair. |
| Zachary Stowe, Emory | Not available | $253,700 over 2 years from GSK for about 95 lectures | Emory told Stowe to eliminate his conflicts in April. The school recently banned promotional speaking. |
| Karen Wagner, University of Texas, Austin | About $100,000 over 7 years | more than $236,000 | UT is reviewing. |
| Augustus John Rush, University of Texas, Southwestern | About $600,000 over 7 years | more than $600,000 | Rush left UT for Singapore last August and is no longer being investigated, according to Grassley's staff. |

Table 5: Industry Income Disclosure by Expert

**Medical Errors from Exaggerating Benefits and Downplaying and Concealing Risks; Falsifying Research Data by Industry and Experts**

The pharmaceutical industry also exerts tremendous influence on the health profession in many other ways. They generously pay for advertising in medical journals that cover free journal circulation (Smith 2003). They sponsor health professionals to attend international medical conferences, as well as conferences and symposia organized by themselves for their product promotion. While the benefits from these medical meetings for continuing medical education cannot be ignored, many meetings are heavily biased, with many KOLs doing promotional work for the pharmaceutical industry (Agrawal 2002; Henry et al. 2005; Komesaroff and Kerridge 2002; Ortonne et al. 2000). The pharmaceutical companies design study protocols and write and analyze the results, and present them in a fashion that shows the positive sides of drugs but conceals adverse events, the so-called ghost writers or corporate co-authors (Fugh-Berman 2005; Healy 2002). There are no systems of accountability that are consistently applied, especially when the authors are prominent in their fields (Davidoff et al. 2001; Holmer 2002; Landow 2002; Relman 2002).

This style of *"doing business"* has not significantly changed over the years. Many abstracts and presentations are heavily promotional and favor the sponsors' drugs (Bero, Galbraith, and Rennie 1992; Cho and Bero 1996). Some independent authors even claim to have been harassed when presenting negative studies (Healy 2002). By using their financial muscles and inducements, the pharmaceutical industry effectively controls most of the output of their sponsored research (Berger 2008). Such interdependence leads many prescribers to favor a particular drug, irrespective of merits or side effects. However, the majority of physicians are caught unaware and don't know that industry did not fully disclose their study results. When pressed, the health care suppliers cite confidentiality and commercial interests. Not surprisingly, disasters ensue.

**Selective Serotonin Reuptake Modulators**

Selective Serotonin Reuptake Inhibitors (SSRIs) exemplify the exaggeration of the positives and the hiding of negatives. When these new treatments were introduced for depression, their prescriptions markedly increased, paralleling their proclaimed superiority over conventional antidepressants. It transpired that pre-marketing studies on healthy volunteers showed that some of their side effects included agitation and apprehension and increased risk of suicide. These side effects were not published. Post-marketing by independent experts showed an increased suicidal risk and deliberate self-harm (Healy 2002; Donovan et al. 2000). A suicidal risk as low as 5% can result in 50,000 deaths per one million treated patients. Given the number of patients treated for depression, the consequences on patient safety are profound. In addition, there was no evidence that they lowered the psychiatric disease burden to society (Moncrieff 2001).

As early as 1994, clinicians were alerting colleagues to be wary of the exaggerated benefits of SSRIs compared to traditional antidepressants such as tricyclics. A meta-analysis of studies comparing SSRIs with tricyclic antidepressants showed no differences between the two drugs groups (Owens 1994). Studies also showed that publication bias in favor of SSRIs' positive results were significant. In one such study, authors found that among 74 FDA registered studies on antidepressants, 31% were not published. Of the positive studies, 31 were published, and only one study was not published. On the other hand, of the negative studies, only three were published and 22 were not published. To add a further twist, eleven negative studies were published after manipulation to convey positive outcomes (Turner et al. 2008).

Whose hands were manipulating the information available to prescribers and their patients? The manipulation of scientific evidence continued in other forms. These were related to even more serious issues concerning the true value of the positive results. A meta-analysis of studies comparing SSRIs to placebo showed statistically insignificant benefits of SSRIs compared to placebo (Kirsch 2009).

Both regulatory agencies and drug companies refused to voluntarily disclose this information to prescribing physicians and patients.

Following many cases of suicides of patients on SSRIs and legal challenges, the FDA and the pharmaceutical industry were forced to release their data on SSRIs, including risk of suicide, based on the Freedom of Information Act. That data vindicated those who were raising the alarm. It created further doubts about some KOLs and the conduct of regulatory agencies and pharmaceutical companies. After analyzing the data submitted to the FDA on antidepressants submitted for approval between 1987 and 1999, Kirsch and colleagues confirmed the findings of many independent investigators; that SSRIs were not statistically significantly better than placebo (Kirsch et al. 2002). The FDA, the pharmaceutical industry and KOLs could not challenge these conclusions but rather downplayed them. The FDA was forced to include a black box warning for both young adults and children on all SSRIs in the drug leaflets (U.S. Food and Drug Administration 2004; U.S. Food and Drug Administration 2009; Kondro 2004; Kutscher 2005; Lenzer 2004; Licinio and Wong 2005; Newman 2004; Richmond and Rosen 2005). That led to a dramatically lower rate of SSRI prescriptions and, curiously, other antidepressants. Was that a reflection of mistrust towards psychiatric health services? On the other hand, was it a reflection of the awareness of patients of the true value of the benefits of antidepressants? The use of placebo in drug trials has many complicated ethical issues. But active therapy that is not significantly superior to placebo should be clearly and forcefully declared (Shapiro, Fergusson, and Glass 2010).

**Fraud in Research**

The law defines fraud as *"the knowing breach of the standard of good faith and fair dealing as understood in the community, involving deception or breach of trust, for money."* This definition assigns the following qualities for fraud to be prosecutable (Sheehan 2007): 1) knowledge of the conduct and bad intention; 2) the expected standard of conduct within the research community is not upheld; 3)

the expected standard in the community at large is not upheld; 4) falsifying data or steeling other researchers' data; and 5) for financial or reputational gain.

Fraudulent research and data manipulation is not restricted to industry sponsored research, but also significantly affects government sponsored research. As a tenured professor who is an internationally recognized expert in ageing, menopause and metabolism at the University of Vermont, Eric Poehlman committed 54 counts of scientific misconduct over the years, which he subsequently admitted to the courts. He gained fame from publishing falsified data (Dahlberg and Mahler 2006). On separate occasions, Poehlman also falsified National Institute of Health grant applications and research data (Kintisch 2005). What is curiously surprising is that most of Poehlman articles indexed in PubMed, except the articles of his retractions, had multiple authors in addition to himself (Ades et al. 2002; Ades et al. 2005; Brochu et al. 2002; Conus et al. 2004; Karelis et al. 2004; Kimm et al. 2002; Mentuccia et al. 2002; Poehlman et al. 2002; Rawson et al. 2002; Sites et al. 2002; St-Jeor et al. 2004; St-Pierre et al. 2004; Tchernof et al. 2002; Toth et al. 2002).

The above references were not comprehensive but used as examples. Each author of these articles could be accused of falsification. This is so, unless he also falsified the names of his co-authors. This is precisely what another fraudulent researcher did. John Darsee and some of his colleagues falsified data and even invented collaborators on cardiovascular research initially at Emory University. Darsee was discovered when he moved to Harvard University. He managed to publish in the *New England Journal of Medicine* and secured a job at Harvard University because of his previous work (Culliton 1983; Culliton 1983; Culliton 1983; Culliton 1983). Unfortunately, fraud in medical research is widespread (Sheehan 2007). The following list shows some high-profile fraudsters (Sheehan 2007).

1. Sigmund Freud fabricated cases studies.
2. Isaac Newton altered records of lunar and solar sightings to fit his theories.

3. Louis Pasteur made false statements about the first public trial of his anthrax vaccine.

4. Gregor Mendel's plant breeding results were too good to be true.

5. Professor Elizabeth Goodwin of the University of Wisconsin resigned in 2006 for making false statements in genetic research.

6. Dr. Gary Kammer of Wake Forest University resigned in 2005 for fabricating two families in a National Institutes of Health (NIH) grant application.

7. Professor Ali Sultan, a malaria expert at Harvard University, resigned in 2004 after falsifying a grant application.

What complicates matters in medical research is that data reliability techniques are not routinely used, thereby leading to manipulation of the original data, and at times changes that catch the original authors of-guard. Editors and reviewers reserve the right to edit articles submitted for publication. This accepted practice generally leads to better presentation of data without changes in actual figures and numbers. Baerlocher et al. estimated that as high as 21% of data submitted for publication to leading medical journals gets incorrectly altered, with 4.1% of the changes fraudulent (Baerlocher et al. 2010). Many practicing clinicians and researchers do not have the ability or the time to scrutinize the small print and may use the falsified data in making health care recommendation to patients. Is this pure carelessness or intentional modification of more than a quarter of the submitted data? This question needs further scrutiny from research analysts and academics.

**Conflict of Interest and Medical Practice**

Much of the conduct by leading professional is tainted by conflict of interest (COI). COI has many definitions. COI is: 1) *"a term used to describe the situation in which a public official or fiduciary who, contrary to the obligation and absolute duty to act for the benefit of the public or a designated individual,*

*exploits the relationship for personal benefit, typically pecuniary*[15]*".* Or COI is: 2) *"a situation in which someone in a position of trust, such as a lawyer, insurance adjuster, a politician, executive or director of a corporation or a medical research scientist or physician, has competing professional or personal interests"*[16]. Clinicians and researchers are expected to act for the benefit of patients and scientific integrity. They are also expected to declare any form of COI and all financial gain they receive from pharmaceutical and medical device companies. The pharmaceutical and device companies spend $57 billion a year on marketing. The majority of this expenditure is directed to physicians (Kirkland 2010). It is not surprising; therefore, that many opportunities for COI exist. The table below describes some of the potential COI for authors submitting to leading medical journals (Blum et al. 2009).

[15] http://legal-dictionary.thefreedictionary.com/conflict+of+interest. The Free Dictionary. Accessed July 6, 2010

[16] http://www.google.ca/search?hl=en&defl=en&q=define:conflict+of+interest&sa=X&ei=BlUzTPfYB4KClAfRk5G-Cw&ved=0CBkQkAE. Accessed July 6, 2010

**Table 2.** Definitions and Examples of Potential COI for Authors as Stated in Journal Instructions for Authors and Manuscript Submission Forms

| COI Definition | No. (%) | | |
|---|---|---|---|
| | Overall (n = 197)[a] | Instructions for Authors (n = 197) | Manuscript Submission Forms (n = 197) |
| Financial relationships | | | |
| Equities interest/stock ownership | 175 (89) | 103 (52) | 114 (58) |
| Consultancies | 165 (84) | 99 (50) | 109 (55) |
| Royalty income under patent license or copyright | 139 (71) | 78 (40) | 89 (45) |
| Employment (officer, director, or other fiduciary role) | 133 (68) | 80 (41) | 86 (44) |
| Honoraria | 114 (58) | 58 (29) | 80 (41) |
| Paid expert testimony | 83 (42) | 44 (22) | 56 (28) |
| Ownership, partnership, or principal of an enterprise | 42 (21) | 21 (11) | 27 (14) |
| Programmatic support | | | |
| Research grants | 108 (55) | 62 (31) | 71 (36) |
| Funding of salary or position | 34 (17) | 16 (8) | 20 (10) |
| Travel grants | 23 (12) | 18 (9) | 7 (4) |
| Fellowship support | 2 (1) | 1 (1) | 1 (1) |
| Nonfinancial relationships | | | |
| Personal | 82 (42) | 65 (33) | 35 (18) |
| With organizations | 51 (26) | 31 (16) | 24 (12) |

Abbreviation: COI, conflict of interest.
[a]Journals that defined COI, of 256 journals studied.

The financial relationships of KOLs with pharmaceutical companies discussed throughout this chapter justify describing their relationship as actions with COI accusations. Health professionals and regulators are expected to be conscious of the risks of COI. Fortunately, many institutions and leading journals are making great progress in demanding from clinicians, researchers, writers and epidemiologists to make full declarations of COI. However, many problems still exist. The process of declaration of COI is hindered by a lack of uniform policy. Journals and institutions describe their own lists of COI circumstances. Furthermore, the declarations by authors are insufficient (Blum, Freeman, Dart, and Cooper 2009).

## Conclusion

Deeply entrenched irregularities and unethical practices in government agencies and medical suppliers continue to be a significant, largely undisclosed, cause of medical errors and patient morbidity and mortality. When combined with the influence that the health industry has on KOLs, who are few in number but immense in reach, the burden escalates significantly. Fraud in all types of sponsored research is significant, leading to clinical practices that are detrimental to patients. The main aim of this chapter is to show that medical errors are generated by the weaknesses of regulatory agencies, medical product suppliers and some experts helping the industry market potentially unsafe products. This recognition of error causation is justifiable and could be a pathway to solutions. Leaving it to the moral credentials of individuals to promote ethical conduct does not seem to work in the small minority who are tarnishing the sincere image of the vast majority of health care professionals and organizations.

In addition, many health professionals have paid for errors that are not of their own making. Many do not realize the fact that they are not to blame for morbidity and mortalities incurred by their patients. The blame goes to a drug or a device that was inappropriately licensed or inappropriately promoted under undue influence by health care suppliers, and frequently against sincere professional advice. Health care suppliers are expected to provide the full evidence available to them on their products to the public and health professionals. It is hoped that the burden of error emphasis will serve as another warning to such agencies/organizations and professionals by directly making them vulnerable to investigation as a source of these errors. Such an approach will also show the true burden of medical errors in terms of its magnitude and its perpetrators.

# CHAPTER III

# SYSTEM WEAKNESSES IN HEALTH PROFESSION REGULATION

Failures in health profession regulations are the fourth of the unrecognized system weaknesses that lead to medical errors. Over a century, the health profession exercised an unparallel authority in self-regulation that shielded it from much outside pressure and criticism. In addition to self-regulating and licensing its members, this authority was sometimes used to protect the profession's members from criticism related to deficiencies, unethical treatment or research and overall accountability. The conscience within the health profession itself and the contributions of scholars over many areas led to the development of current biomedical ethics at the interface of medicine, law, philosophy and religion.

However, as medical services expanded to include an ever-increasing number of therapeutic interventions, sophisticated devices and novel drugs, it became abundantly clear that health profession regulations must keep pace with that rapid advancement.

***Who Is Regulating the Health Profession?***

The health profession is composed of many disciplines including physicians, nurses, academics, technicians, allied health disciplines, pharmacists and managers amongst others. A complex network of organizations and institutions regulate the different health profession disciplines. These include: the legislatures through statutes; national health departments through implementation of statutes, guidelines and policies; national health institutions such as the CDC and the NIH through policies and guidelines, independently or under the supervision of health departments; government regulatory agencies on drugs and devices; government licensing agencies of health personnel; self-regulation by professional health boards, academies and royal colleges by exams and licensing; self-regulation by academic and non-academic health institutions by training and internal licensing of health personnel; and indirect contributions to regulation by multi-disciplinary discussions on topics such as bioethics through debates suggesting policies, principles and critical appraisal.

Such a comprehensive regulatory network should lead to an impeccable outcome. However, this complexity creates weaknesses that get repeatedly exploited,

thereby inflicting serious medical harm on patients. An illustration using case studies will highlight some of these fundamental concerns. As a result, the greatest emphasis will focus on the regulatory bodies associated with the cases presented. The concerns raised are universal and do not afflict just a few jurisdictions. The failure to do so thus far is leading to rising rate of litigation. In the U.S., for example, studies show that in the 1960s, one in seven physicians were sued during their career for malpractice. More recently, one in seven physicians were sued every year (Kereiakes and Willerson 2004). These figures reflect the rising burden of medical errors. In general, the causes of medical errors are often similar across jurisdictions. Therefore, using specific cases with the most documented evidence is essential and justifiable in these circumstances.

***Bristol Royal Infirmary, U.K.***

For a period spanning more than a decade between 1984 and1995, many infants and children undergoing cardiac surgery were dying at the hands of pediatric cardiac surgeons at the Bristol Royal Infirmary (Dobson 1999). The majority of the professionals, such as cardiologists, anesthetists, perfusionists, nurses, pathologists, trainees and administrators, were aware of these findings. The regulatory institutions, as well as government departments that had direct or indirect connections with the provision of the services to those infants and children, also became aware of these instances of substandard treatment. The regulating and monitoring professional organizations did not take any action. Surgeons continued to practice, protected by the management of the institution and its leading clinicians. Many families suffered through the process with inadequate explanations over the years. When some professionals quietly and internally raised serious concerns, those concerns were dismissed. Only the involvement of the public media and its detailed description of catastrophes led to action. Pediatric surgical services were then stopped and surgeons were suspended pending inquiry (Dyer 1999; Dyer 2001). The General Medical Council (GMC) of the U.K. conducted an inquiry. Following the findings of the GMC, the government was forced to announce the establishment of a public inquiry in 1998.

**Results of the GMC Inquiry**

The GMC Professional Conduct Committee (PCC) conducted the longest and most important inquiry in its history on the Bristol Royal Infirmary pediatric cardiac services. Among the many professionals involved, only three, Drs. James Wisheart and Janardan Dhasmana, both surgeons, and John Roylance, the Chief Executive of the Hospital were investigated by the PCC. After a long closed-door investigation, the GMC charged the three doctors with professional misconduct and struck them from the medical register (Fox 2001). The GMC did not advise further action. The decision of the GMC came under some criticism from doctors who accused it of surrendering to political pressure (Dunn 1998). A public inquiry seemed a fairer way to investigate the situation.

**Findings of the Bristol Royal Infirmary Public Inquiry**

The Secretary of Health established the Bristol Royal Infirmary Inquiry in 1998. After lengthy interviews with many clinicians, parents, administrators and experts, it released its final report on July 18, 2001. The main report was 500 pages and the full report was more than 12,000 pages (Kennedy 2001). The report explored the outcomes of selective surgical procedures only, where more than 30 to 35 children died in Bristol between 1991 and 1995, much more than the national average. I will quote and refer to significant parts of the statements in that report. I consider the report authentic and valuable, and based on detailed evidence and arguments that rarely can be found in a single document that details the pitfalls in health profession regulations. The ethical analysis of these findings will follow.

The report spoke of individuals who lacked insight, had flawed behavior, failed to communicate and failed to work as a team. The report described a "club culture", where there was an imbalance of power "with too much control in the hands of a few individuals". The report also emphasized that when concerns were raised, it took years to take them seriously. One third of children undergoing heart surgery received *"less than adequate care".* The report also declared that "*there was no requirement on hospital consultants at that time (nor is there now) to keep their*

*skills and knowledge up to date. Surgeons were able to introduce new techniques without any formal system of notification".* The report also clearly documented the absence of adequate monitoring of physician performance and appraisal, stating that *"consultants enjoyed (and still enjoy) what is virtually a job for life. Their relationship with the trust that employs them makes it difficult to bring about change."*

The report also stressed the discrepancy between the perceived and actual standard of care, and that families were made to believe in the former and were totally unaware of the latter. *"Parents taking their children to be treated in Bristol assumed that the level of care provided would be good. Their children were cared for in a `supra regional centre' designated as such by the Department of Health. They trusted the system. Few had any idea that there were no agreed standards of care for pediatric cardiac surgery (PCS) or for any other specialty".* The report also declared that families were kept in the dark regarding the clinical performance of PCS from as early as the late 1980's.

Data existed about high mortality rates and substandard services but were concealed from families. There was no openness. There was also no monitoring. *"The clinicians in Bristol had no one to satisfy but themselves that the service which they provided was of appropriate quality. There was no systematic* mechanism *for monitoring the clinical performance of healthcare professionals or of hospitals." "The Chairman and the Trust Board were either part of the `club' or treated as outsiders",* the report claimed. The cardiac surgery postoperative intensive care was *"highly disorganized with conflicting decisions". "It was never really clear who was in charge"*, according to the report.

The report also declared that the bodies who were supposed to do the monitoring of the quality of care did not do it. *"The Supra Regional Services Advisory Group (SRSAG) thought that the health authorities or the Royal College of Surgeons was doing it; the Royal College of Surgeons thought the SRSAG or the Trust was doing it, and so it went on. No one was doing it. We cannot say that the external system for assuring and monitoring the quality of care was inadequate. There*

*was, in truth, no such system.*" This is further complicated by the fact that *"The clinicians involved in providing the PCS service collected, recorded and analyzed data on procedures and deaths, set up and maintained computerized information systems, produced and circulated figures and reports, made annual returns to the national UK Cardiac Surgical Register (UKCSR) and received back aggregated data about national performance. They also held regular meetings to discuss the results of audit, and reviewed individual cases and series of cases."* Sir Terence English and Dr. Alan Bailey established the UKCSR in 1977. *"It is based on voluntary and anonymous reporting of activity and hospital mortality for all cardiac surgical procedures performed in National Health Service Hospitals*[17]*."* The report declared, *"The system for delivering PCS services in Bristol was frankly not up to the task."*

These statements implicated all health services regulatory and monitoring bodies in the U.K. The list included: the Department of Health and its associated monitoring agencies; the Royal Colleges of Surgeons, who were monitoring and licensing surgeons; the health boards; the institution's management; the General Medical Council, who certify the licensing of clinicians and keep a register; and other professional organizations such as the Royal Colleges of Radiologists, Physicians and Nursing, among many others. The report repeatedly emphasized that lack of funding was not an explanation for inferior results in Bristol compared to the national average. Bristol was not more under-funded compared to the national average. The report also exposed the clear disparity between the claim and reality in the U.K. NHS. Politicians, managers, regulators and clinicians consistently overrated the performance of the NHS.

On the issue of lack of response to poor performance, the report stressed that concerns were first raised as early as 1986-1987. From 1988, concerns were raised within Bristol Royal Infirmary itself. In 1990, Dr. Bolsin, the anesthetist, wrote to Dr. Roylance, the chief executive, formally echoing warning signs but no actions were taken. He followed this by collecting data and showed them to many

[17] http://www.scts.org/doc/890. UKCSR website accessed, July 2010.

colleagues. By 1992, SRSAG at the Department of Health had evidence of poor performance. Clinicians themselves knew as early as 1990 that their mortality rate was twice the national average, but admitted nothing and did not seek assistance. The Department of Health knew of the poor results by 1994, but also did nothing. Surgery was discontinued after the news leaked to the public media and a new cardiac surgeon was recruited.

To complicate matters, the Department of Health had full national data on mortality rates across all the NHS from 1990, but it was not used to monitor health institution performance and the data was considered of no value at the time. The report went on to name key personnel, both within the health institution and in different regulatory and monitoring bodies, who shouldered most of the blame. The report went on to issue 200 recommendations. These recommendations were organized into different relevant major categories and divided into subcategories. The major categories were: 1) respect and honesty; 2) a health service that is well managed; 3) competent health professionals; 4) the safety of care; 5) care of an appropriate standard; 6) public involvement through empowerment; 7) the care of children; and 8) health services of children with congenital heart disease (Kennedy 2001).

***The Winnipeg, Manitoba, Canada Inquest***

The BRI case was not a unique incident in demonstrating the gross failures of medical regulations that lead to catastrophic outcomes in patient morbidity and mortality. An inquest in Winnipeg, Manitoba, Canada, in the mid 1990's looked into the death of 12 infants from cardiac surgery within 10 months in 1994. In 1994, pediatric cardiac services were reopening after being closed for a number of years. It was the longest and most complex inquest in Canada. Many parties, physicians, nurses, the Health Sciences Centre (HSC), the dead infants' families and the government sought representation at the inquest. The inquest was carried out after an external review declared that the mortality rate was unacceptably high (Sibbald 1998). The inquest's main finding was that parents were not told at the time of consent that the surgeons operating on their children were relatively

inexperienced. It talked of changes required in the culture of health services, a similar problem to what the BRI inquiry called a "*club culture*."

Nurses' concerns were dismissed and treated as irrelevant. The catastrophe took place in an atmosphere where human errors in communications and execution were also abundant, thereby complicating the situation (Sinclair 1998). The report called on existing agencies to look into disciplinary actions against specific individuals. The report showed that management did not appreciate the loss of experienced staff in 1992-1993. The report also stressed that the process that followed to replace lost medical staff was flawed and led to the hiring of inexperienced staff that significantly underperformed compared to national standards. The Winnipeg Health Sciences Center recruited a surgeon, Dr. Odim, on word of mouth references, without looking into his surgical skills and without seeking references from his trainer surgeon, Dr. Mayer, whom he was working for in Boston, USA. Dr. Mayer declared that Dr. Odim was not yet ready for the task he was recruited for. There were also issues related to the financial compensation offered to pediatric cardiac surgery staff. It was inferior to the national average and inferior to those working in adult cardiac surgery. This led to experienced staff leaving for better pay elsewhere (Sinclair 1998).

### *Ethical Analysis*

#### The "Learning Curve" for a New and Established Intervention Concept

The learning curve concept is frequently used and abused to legitimize the under-performance of some health professionals. It is considered a necessity for training and for a time after certification, when professionals are not required to be as fully competent in procedures they perform as those professionals who have much more experience. It is also considered vital when introducing new techniques to a service. In the case of the Winnipeg HSC cardiac surgery failures, the concerns of the nurses and anesthetist were dismissed under the learning curve excuse (Sinclair 1998). When consent was obtained from parents, the learning curve argument was not discussed**.** In Winnipeg, poor performance was allowed to go

on for only 10 months, unlike in Bristol, U.K., where it continued for more than 10 years.

The learning curve ethos for new and established techniques as a cause of undisclosed burden of medical error is common in all fields of medicine (Becerra Garcia et al. 2009; Horton 1998; Jacob and Raakow 2010; Kravetz et al. 2009; Raman, Scott and Cadeddu 2009; Solomon et al. 2010). If it is necessary for propagating the practice of medicine from senior to junior generation, as some may argue, (Sibbald 1998; Sibbald 2001), why is it not explicitly declared to patients prior to their consent?

The inquest in Manitoba suggested that the presence of inexperienced staff should be disclosed at time of consent. Some argued that in Canada, such a proposition would be difficult to implement because of a ruling by the Supreme Court of Canada in *Hopp v. Lepp* (Sibbald 2001). However, in that case, the supreme court of Canada dealt with a slightly different issue. *"In setting aside the judgment of the Alberta Court of Appeal, ruled that prior consent by a patient to proposed surgery or therapy does not protect a physician from liability for negligence unless the patient has been provided sufficient information about attendant risks to make an informed choice whether or not to submit to the surgery or treatment. The physician need not describe every detail of the procedure unless asked specific questions, but should, without being asked, reveal the nature of the proposed operation or treatment, its gravity, and any special or unusual risks involved (1980, 112:67-83).* The main issue in *Hopp v. Lepp* was the extent of the details demanded by patients during the consent process, under all circumstances, for them to agree to undergo surgical procedures or not. In the case of inexperienced surgeons, the issue was declaring upfront their inexperience, and by virtue, the surgeon's higher mortality rate and rate of complications compared to the national average. A closer look at the *Hopp v. Lepp* ruling implicates the surgeons to a greater extent. However, there remains the practicality of legislating recommendations as suggested by Judge Sinclair (Editorial 2001; Borton 1999; Davies 2000; Hinam 1999; Sibbald 2001).

The defense used the learning curve concept of the Bristol Royal Infirmary Pediatric cardiac surgery argument. One simply cannot comprehend the need for more than 10 years for improvements in performance that ultimately did not materialize. The competency of those surgeons was not adequate from the outset and could not have improved without proper training. They could not train themselves on the job using unfortunate children. It was essentially a long duration experiment.

The Winnipeg inquest also highlighted a fundamental concern regarding the gulf between *"the impressive paper certifications"* by academic boards and medical organizations and the real expertise of the certified health personnel. Dr. Odim had impressive paper credentials that made him eligible for any cardiac surgical job. However, in reality, he was not qualified for the job. Who is to blame for this serious and significant failure? The certifying and regulating organizations have a lot to answer for. None of Dr. Odim's credentials were forgeries. The issue gets more complicated when health personnel cross borders to seek employment elsewhere outside their country of certification. They can claim to be authorities in their fields.

The Bristol Royal Infirmary Inquiry also noticed the existence of a gap between paper credentials and real credentials. In the case of the U.K., almost all certifying and regulating academic organizations failed in their regulation and certification mandates (Editorial 1992; Brahams 2000; Grenneberg 1984; James 2000; Kennedy 2001). This is because once trainees are certified as consultants, they are fully autonomous and under no obligation to report to other colleagues or authority on the quality of their work or to obtain approval. If they do not seek help on their own, their errors might not be discovered, except maybe by a surprise external audit. An internal audit is usually not sufficient, as in the case of Bristol and many other institutions.

It was rarely stressed in the U.K. and Europe, for example, that political interference in the late eighties and early nineties forced the medical profession to shorten the specialist training period by almost a third. The European Union

wanted to unify training and the U.K. had to change the duration of their training programs (Raftery 1996; Rhodes and Biester 2007). Up until then, training was apprentice based with ***no*** time limit. Certification was sought from the regulating and certifying authorities when the trainers were fully satisfied. Many trainees did not make it and had to settle for lower grade supervised jobs. Training now is more impressive in terms of its paper documentation. Again, this highlights the gap between paper and real credentials. Specialists are now certified three and four years earlier than previously (Cibula and Kesic 2009; Jaffer et al. 2009; Julian and Rogers, Jr. 2006; Waurick et al. 2007).

The duration is further compromised by new regulations restricting the number of hours trainees can perform per week. The number of procedures performed by trainees dropped by more than 70% over a decade (Elbadrawy, Majoko and Gasson 2008). No detailed studies have been conducted to highlight the effects of this change on the quality of performance of specialists trained under these new programs.

Despite the high profile cases that dragged the reputation of the medical profession so low, there still remains a huge gap between politicians and the health profession. Politicians want to exercise managerial control over practicing physicians and deprive them of significant power of self-governance. The medical profession, on the other hand, wants to keep its historic autonomy by proposing revalidation to maintain the quality of medical performance (Heffron, Simspon and Kochar 2007; Madewell 2004; Marasco, Ibrahim and Oakley 2005; Newble, Paget and McLaren 1999; Rhodes and Biester 2007; Rosier 2006; Salter 2007; Youngson et al. 2010)

**Anonymous Reporting Merits and Pitfalls**

Anonymous reporting was championed and introduced by concerned and conscientious personnel in many jurisdictions as an alternative to full disclosure reporting. This compromise was made to overcome profound resistance in the health profession to full disclosure of therapeutic outcomes and errors. Throughout the decades, authorities in the medical profession praised its success

and value (Kohn, Janet M Corrigan and Molla S Donaldson 2000). Apart from knowing anonymously the overall quality of the services, when the statistics are regularly evaluated, they have no value in defining who is adequate, who is poor and who is worse. For example, if five centers report the mortality of a procedure X as 2%, 2.1%, 2.4%, 2.3%,and 6%, then the data will yield an average national mortality rate for the procedure at 2.96%. Such a mortality figure does not raise any concerns and will not initiate any formal inquiry, especially if the centers reporting do not know the mortality rates of each center. Each center has access to the average and its own figures only. Bristol was reporting its true results to the UKCSR anonymously and receiving the compiled results over more than ten years, but did nothing to correct its performance. They knew how poor their figures were compared to the national average. Their results raised the overall U.K. mortality rate from pediatric cardiac procedures. As in the example, the numbers showed that centre number six was three times worse than the best center, but only twice as bad as the national average. Excluding centre six from the statistics, the national average dropped to 2.2%.

Many argue that public reporting of figures of physician performance makes them reluctant to treat high-risk cases so that they can keep their mortality and complication rates low. In one study, 79% of cardiologists in New York claimed that public reporting influenced their therapeutic decisions. Eighty-four percent agreed that they would refuse to operate on high-risk patients (Narins et al. 2005). This is certainly a serious setback. A legitimate worry about such a stand is the potential of its use to manipulate legislation and reclaim lost authority and autonomy. This is because, it is known particularly by physicians, and generally by the public, that high-risk patients have higher mortality and complication rates than low-risk patients. This fact is accepted and not disputed. A declaration of that risk at the time of consent should be mandatory for the protection of all. In addition, it is unethical to deny high-risk patients life-saving therapeutic interventions merely to safeguard a better public reputation. Furthermore, the real motive for public reporting should be to identify professionals who are

inexperienced or incompetent, so that they can get better training or have their activities suspended. Competent professionals need not fear public accountability.

Nonmaleficence, doing no harm, cannot be truly compatible with concealment of poor performance. Nonmaleficence is generally associated with errors of commissions such as surgical errors, inappropriate drugs doses and hospital acquired infections (Sharpe 2003). Errors arising from the actions of incompetent surgeons are possibly the worst possible errors of commission, since they could be deemed intentional. Surgeons know when their skills are inadequate for the task they are willing to perform. On the other hand, the principle of beneficence carries moral obligations against errors of omission (Sharpe 2003). Incompetent surgeons frequently err by omission by not taking or delaying to take appropriate actions, and are therefore judged to be in violation of the principle of beneficence as well.

### The Regulation of Health Professions, Conflicts of Interest and Conflicts of Responsibility

Conflict of responsibility is generally associated and defined in contexts related to conflict of interest. It is based on the conflict between competing aims or obligations. Conflict of interest was discussed earlier in detail when dealing with errors from corruption in research or clinical activities triggered by undue desire for financial gain.

Conflict of responsibility is a term I will use for the failure of regulations of the health profession by having more than one organization **apparently** responsible for monitoring the performance of the profession, but none of them actually doing it. As listed at the beginning of this chapter, eight types of organizations have a direct or indirect responsibility for regulating the medical profession. In the U.K., for example, the Department of Health, the Royal Colleges, the General Medical Council, U.K., voluntary registers and the management of institutions, among others, are all responsible for monitoring performance. The Bristol Royal Infirmary Inquiry comprehensively demonstrated that for more than ten years, all organizations failed in this crucial task. Organizations merely respond to crisis incidents.

Other inquiries into poor performance have also demonstrated clear failure of regulations, as in the case of gynecologist Rodney Ledward. Managers and colleagues knew him for ten years before he was struck from the medical register because of his *"high complication rates and cavalier manner"* (Dudley 2005). *"A culture of not telling tales was a big part of the problem",* the chair of the enquiry concluded. Conspiracy of silence and a culture of censorship were used to describe the medical profession's state of denial (Connolly 2005; Cowling and Hedley 2005; Harley et al. 2005; Hart and Hazelgrove 2001). Such a case demonstrated issues of conflict of interest. Why do colleagues and medical administrators not act on information they clearly possess that a specific colleague's performance is suboptimal and he/she is a danger to patients? Are they behaving in such a way to protect the reputation of the medical profession? A negative reputation of their profession is not in their best interest. This is despite their fiduciary obligations to all patients who seek medical treatment at their institution. In addition, it is often not in their best interest because they could be a target of scrutiny by colleagues who consider them disloyal to their profession. The anesthetist, Stephen Bolsin, who raised the alarm about the serious problems within the Bristol Royal Infirmary pediatric cardiac surgery, was effectively driven out of the U.K. and had to seek employment elsewhere (1998). No one questioned his abilities, but his **loyalty** was. Therefore, financial gain may not be the sole reason for conflict of interest.

**The Medical Profession on the Defensive**

The backlash from the public media in the U.K. was fierce, with prominent editors describing the GMC as "*drunken*" and called for it to be disbanded, much to the displeasure of some leaders in the health profession (Horton 2000). Smith, the *BMJ* editor, described the situation as follows: *"Doctors in Britain have been insufficiently regulated for too long. It has been too easy for doctors to sink into poor and dangerous performance without anybody doing anything*"(Smith 1998). At the same time, Smith decried overregulation as a result of public outcry. *"Now—in response to a storm of publicity about bad doctors—we may be in*

*danger of overregulation. The dangers of overregulation may be less obvious than those of underregulation, but in the long run they may be just as damaging"*. (Smith 1998). Smith was trying to satisfy the demands of the public and the medical profession. It is not in the best interest of the profession to resist the applications of rules the profession itself constructed for self-regulation and rules agreed to by the employer and the government in the case of a national health service. However, Smith missed the point that current regulation and monitoring obligations were simply not being regularly implemented. This fact is repeatedly demonstrated. The need for new "waterproof" rules might not have been as overriding as following current rules. No current rules condone the employment of health professionals to perform tasks that they cannot or no longer can perform.

However, there are some vague rules in the regulation process. One such rule is the secretive nature of the GMC investigations of professional misconduct. This undermines the GMC and strengthens the call for its demise. For example, the GMC Professional Conduct Committee (PCC) inappropriately acquitted a general practitioner in a professional misconduct case related to the death of a five-year-old boy under his care. The GMC wanted to review its decision and the general practitioner objected. The case was taken to the high court, which ruled that GMC's secretive investigations were flawed and against the Human Rights Act. The judge warned the GMC that its investigations must be transparent and seen to be fair, especially when doctors are still in practice (Brahams 2000). The GMC, the Government and the health profession struggled for many years to agree to guidelines on clinical governance (Irvine 1999; Irvine 2001).

Risks were exacerbated by a temporary work force covering shortages and holidays for regular staff. One such case was that of a German plastic surgeon acting as a general practitioner. He killed his first two patients on his first night of duty by overdosing one with diamorphine and by missing a heart attack in the second (Dreaper 2010). The coroner described the doctor as "*incompetent*" and was of "*an unacceptable standard*" (Triggle 2010). He also called for a shakeup of the off-hour care system to ensure patient safety. This example illustrates the poor quality of regulatory monitoring. Who licensed him to be a general

practitioner? This again shows an incident of a category of medical error due to system failure in regulation. Such a category is not akin to negligence. Negligent professionals could be competent but behave negligently on occasion. Incompetent surgeons cause medical errors, irrespective of their conscientious and caring intentions. They are simply not up to the task. Those who gave them that task and those who regulate them and monitor their performance are accountable.

The above proceedings show overwhelming evidence that current medical regulations are either lacking or not implemented effectively. This situation has resulted in a category of medical errors that are the result of hiring practices that encourage incompetent professionals and professionals who have lost their competency over the years. This error category is unique, significant and is easily distinguished from classical human error based on negligence or operational weaknesses. The regulatory authorities, both governmental and professional, are collectively to blame for this system failure and should be accountable. Despite overwhelming evidence, a power struggle continues between the health profession and their regulatory organizations and governments, each blaming the other for the continuous disaster. As a result of that struggle, each side is proposing contradictory proposals to solve the problem as they see it (Bogle 1998; Salter 2007). It is ironic that all sides ignore the fact that none of them is appropriately exercising its current mandate of the obligation to monitor the performance of their professionals. New mandates are not needed as much as the application of the current mandates. Writing lengthy proposals for new regulations is likely to be for the shelf only. A change in mind-set is a fundamental prerequisite to an effective resolution.

# CHAPTER IV

# INSTITUTIONAL ETHICS; AN ALTERNATIVE TO THE FOUR-PRINCIPLES APPROACH OF SYSTEMS ERROR ACCOUNTABILITY

Many might express the opinion that since licensers, medical suppliers, self-regulators and government regulators do not have direct patient contact obligations similar to that of health professionals, that they should not be judged by the four principles that govern doctor-patient relationships. Therefore, they cannot be accused of failing their ethical obligation on issues pertaining to justice, respect, beneficence and nonmaleficence towards patients. It is the physicians' and other health professionals' sole responsibility to decide on patient welfare and best interests.

Assuming that there is merit in such an argument, is there any other ethical approach that can be used to hold regulators, licensors, suppliers, profession regulators, researchers and KOLs accountable? The answer is affirmative. The term institutional or organizational ethics is a concept that almost all governments and private organizations aspire to reinforce in their working culture. Many organizations introduced it as a necessity to fight a proliferating unethical culture due to many external and internal influences. The term institutional ethics (IE) is used to give different emphasis depending on the ethical issues of concern. All these emphases have merits that serve a specific ethical issue of concern to a specific institution or organization. All intend to enforce an ethical culture within their institutions. One definition of IE by the Oregon Health and Science University (OHSU), and incorporated into their Institutional Ethics Committee Charter, demonstrates clarity in exploring the ethical dilemmas facing all health care agencies and services. OHSU defined IE as: "*Institutional ethics" refers to an organization's articulation, application, and evaluation of values and moral principles related to its practices, procedures, and policies. In a health care institution, such as OHSU, the term broadly encompasses the ethical principles that apply to the clinical, research, educational, financial, managerial, and contractual components of operation.*[18]"

[18] http://www.ohsu.edu/xd/education/continuing-education/center-for-ethics/ethics-programs/institutional-ethics.cfm. Oregon Health and Science University website accessed June 2010.

The explicit mention of all operational processes as potential milieus of unethical behavior reinforces the general belief that ethical conduct is expected by all personnel and not only by some. The charter further clarifies IE by acknowledging two important characteristics of an ethical culture within an institution: 1) *"It is a culture where the missions and vision of the institution are consistent with its operations and management and these are integrated with ethical goal", and 2) "It demands and facilitates ethical behaviors of those who are associated with the institution*[19]*"*

***Unethical Conduct within Institutions***

The substantial evidence presented in the preceding chapters point to a common underlying basis for the system failures that are the focus of this thesis. The first is that the health regulatory agencies, suppliers, some health professionals and their regulatory bodies knowingly display substandard conduct. The second is that they are incompetent. This substandard conduct might include deliberate concealment of critical information (or lack of transparency), obstruction of justice, complicity, conflict of interest, conflict of responsibility, unjustified protection of colleagues and unjustified professional protection, and scientific fraud. All such unethical conduct disregards patient safety, is incompatible with patient advocacy and therefore, may lead to medical errors and harm.

Sources of incompetence are sometimes government and health professional regulators and incompetent health personnel. Such incompetence leads to personnel that continue their clinical duties when they are not up to the task of carrying out such duties. As a result, patients endure medical errors and harm. The outcomes of this substandard conduct and incompetence on patients is the same. Both situations result in patients being exposed to medical errors. There is also no reasonable ground to exempt the perpetrators of their obligations.

Many organizations and professions have painstakingly created professional codes of ethics to promote the integrity of their organizations and professions. The

[19] http://www.ohsu.edu/xd/education/continuing-education/center-for-ethics/ethics-programs/institutional-ethics.cfm. Oregon Health and Science University website accessed June 8 2010.

medical profession is at the forefront of them all. The medical codes of ethics were born with medicine thousands of years ago. The Hippocratic Oath is the most recognized in this tradition. As the profession expanded its services, its ethics codes expanded to safeguard patient welfare. The majority of health profession and health organization personnel conduct themselves ethically and with dedication. Only a minority commit and continue to commit unethical acts that lead to great damage inflicted on a large number of patients.

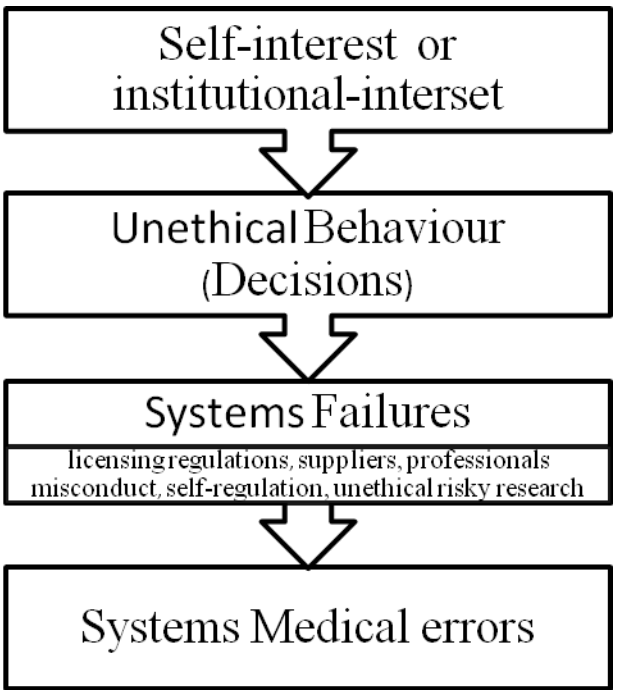
On what moral grounds did an organization such as the Medical Board of Queensland, Australia, base its indecision on complaints for over four decades against incompetent doctors who were allowed to continue to work (Parker, Zhang, Wilkinson, and Peterson 2010)? Likewise, how do the Bristol Royal Infirmary, the Winnipeg Health Science Center and many others justify their actions? How do authors and publishers publish research findings that are mostly false, when their statistical evaluations are analyzed in detail, as claimed by Loannidis and others (Goodman and Greenland 2007; Ioannidis 2005; Ioannidis 2007)? Such behaviors are not consistent with any ethical code.

### *Self-Interest, Institutional Interest and IE*

The detailed exploration of the cases representing unethical conduct by institutions or personnel points to a common underlying reason. Self-interest or institutional interest is the trigger that sets a chain of events that result in decisions that are harmful to patients. Self-interest or institutional interest are powerful motivations that make and continue to make organizations and personnel behave unethically. They affect all organizations, including those in public office representing the people (Kau 1979). They affect large and small organizations. For example, studies on middle management found that middle managers could derail, delay or even sabotage a company's plans and development when their self-interests are at risk (Guth 1986).

It is in the institution's interest for regulators to conceal weaknesses in their profession or the profession they are regulating as an agency of government. Exposing weaknesses and poor services reflects badly on them as well as on the

profession. Some decisions made by self-interested motivated regulators are forever irreversible. This is unlike so many other industries, where damage is material-based, and although losses are painful, they may be recoverable in the end. Self-interest that leads to incompetent health personnel who continue to practice might cause irreversible damage that may not be exposed until it is in excess or after many years of patient suffering. A diagram may help elucidate the sequential relationship between self-interest, unethical behavior, system failures and medical errors.




**Self-interest and institutional interest and medical errors**

Self-interest that infringes on people's rights and privileges is unethical and in contradiction to the fiduciary duty that sound-minded persons are expected to uphold while dealing with others representing themselves or their institutions. Fiduciary duty is not merely for physicians to act in the best interest of their patients while leaving out others. Currently, it is argued that fiduciary duty obligations cover almost all organizations and human interactions (Litman 2007;

Sandrick 2006). Fiduciary duty means abiding by the laws and regulations that govern the operational processes of any organization. No operational process at any organization allows the concealment of harm, the commercialization of unsafe products, accepting the behavior of negligent or incompetent personnel and condoning scientific fraud. But the reality showed strong evidence of misconduct of different forms in many organizations. The inclusion of medical errors from these sources in medial error taxonomy and error burden is justifiable and vital. It is imperative that conduct for the sake of undue self-interest and organizational interest be exposed, isolated and eliminated.

Therefore, both I.E. concepts and the four-principles approach that directly govern doctor-patient relationships have compatible objectives. Both serve the best interest of patients, while keeping the highest possible moral standards to protect the reputation of the institutions and their personnel. Failing institutions have no way out of their obligations and accountability. The sooner they realize this, the sooner will we achieve significant medical error reduction. This will leave no associated party disadvantaged. Disregarding self-interest could create a momentum in the quest to fight medical errors and improve accountability and reform.

# CHAPTER V

# THE PROPOSED SOLUTION AND CONCLUSIONS

The sources of medical errors are multiple and are generated by both the highest decisions makers and the person with the least responsibility for dealing with patients in hospitals or health centers. All must be accountable. Currently, there is no agreed definition of medical error. The most popular definition is that of the IOM: *"An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning) (Kohn, Janet M Corrigan, and Molla S Donaldson 2000).* This definition does not represent an accurate description of medical errors in terms of their true burden, causality and accountability. It conceals a great deal of injustice towards patients and health personnel in general. In addition, it offers respite and protection to significant numbers of high-level organizations and senior personnel. This list includes government regulatory and licensing agencies, health care suppliers, health profession self-regulation bodies, key opinion leaders and research. In addition, it offers protection to the medical profession's relentless attempts at its desire to fully self-regulate and its quest at concealing harm and weaknesses within its personnel and processes. On many occasions, loyalty to the profession overrides the profession's fiduciary duty towards patients with detrimental effects. This vision contributes to inconsistent and inadequate error reporting. It also highlights many unresolved practical issues arising from the lack of clarity of appropriately labeling errors, thereby leading to difficulties in creating error-reporting system models (Holden and Karsh 2007).

None of these weaknesses is compatible with acceptable patient advocacy and patient risk and safety monitoring. Many have echoed the need for change, but with little emphasis on error definitions and taxonomy (Bogner 2009; Burda 2009; Carlisle 2009). Furthermore, the current approach does not stress the reporting of medical errors that affect many patients as a result of device failures, performance of medical procedures, wrongly licensed drugs or wrong interpretations of advanced technological investigations (Chafe, Levinson and Sullivan 2009). Most of the above errors are the result of system failures that currently are not explicitly recognized.

Medical error taxonomy also does not fare better than medical error definition. It is generally categorized as human error and errors resulting from latent system weaknesses at the health institution. Medical errors from other system weaknesses outside the health institution discussed in chapters II and III are not generally the focus of attention when such systems are being evaluated. As clearly stated before, the highly regarded Swiss Cheese Model of system errors considers the faults of designers, builders and managers as latent weaknesses that trigger errors. This understanding should also apply to all health care related organizations, institutions and personnel.

Industrial processes in this era of sophisticated technological application are the results of many partners collaborating to achieve successful product creations. All partners' contributions are essential for successful outcome. Equally, any partner failure affects the outcome. The failing partner is accountable. Medical treatment, likewise, depends on many partners including suppliers, regulators, leading researchers and academics, managers and health professional. Every partner in the treatment process is responsible for the failure it generates. Regardless of the previous objectives, the attention given to traditional causes of errors should also be directed to other system failures as described in this thesis.

### *The Proposed Medical Error Definition and Error Taxonomy and its Merits*

#### The New Medical Error Definition and its Merits

My proposed medical error definition is: an action or inaction leading to patient morbidity or mortality caused by anyone or more of the following: system failures in product licensing and monitoring, fraudulent behavior by professionals and organizations, health profession regulatory failures, undeclared research risks, health institution operational system weaknesses or human error. It has many advantages over the current definitions. First, it is more inclusive. All possible causes of medical errors are included, making error recording and evaluation of error data much more rewarding and useful. Second, it brings many issues of negligence and corruption into focus instead of having a fraction of these issues dealt with by the legal system. The health profession should hold the pivotal

position in the quest of tackling negligence and corruption. Although many other parties, including governments, the insurance industry, the public and patient pressure groups, have a vested interest in monitoring corruption and negligence, the health profession's role is the most crucial. The health profession has the greatest to lose with continuing adversity.

Third, it clears the ambiguity that prevails in the current medical error's accepted wisdom of associating medical errors with health professionals and their institutions. Licensing bodies, regulators, suppliers and KOL errors are more serious because they are replicated millions of times. Incorrect licensing of a drug or a device legitimizes its clinical practice despite its dangers. Remember the case of Vioxx, where tens of thousands of physicians happily prescribed it to millions of patients. Fourth, it includes and highlights medical errors suffered by patients in the course of medical research. Goodyear, Eckwenwiler and Ells emphasized that the *Declaration of Helsinki,* in spite of its regular revisions, does not protect patients and research volunteers from risks (Goodyear, Eckenwiler, and Ells 2008). To resurrect research from an all-time low in public confidence, they stressed that *"a robust approach to ethical research requires a rethinking of the concepts of autonomy, justice, vulnerability and benefit"*. Their proposal will be strengthened by adding research risks to medical error definition. Fifth, this definition operates in synergy with medical error taxonomy. Such a definition will bring us many steps forward from the reality declared by Dovey and Philips who rightly claimed that *"If the beginning of wisdom is knowing what to call things, defining "medical error" is a beginning that has not yet been completed"* (Dovey and Philips 2004). We will no longer be at the beginning point.

**The New Medical Error Taxonomy and its Merits**

Error taxonomy and error reporting are both known to have their own error potentials that require continuous review and evaluation and, when necessary, models should be formulated to account for such errors (Berzofsky, Paul Biemer, and William Kalsbeek 2008). Medical error classification significantly lags behind other industries that have formulated error-correction models to error

reporting. In the case of the health profession, we are still not in agreement on error models for reporting errors, let alone deciding on how to formulate correction models for medical error reporting. The proposed broad taxonomy is a step forward in this direction (See Tables 2 and 3).

First, it defines all possible broad medical error categories. It introduces five new categories that were not previously explicitly mentioned. These are: 1) licensing errors; 2) suppliers' unfounded claims or concealment of risks; 3) medical profession regulatory failures, either government or self; 4) corruption by KOLs who have the power to recommend potentially unsafe practices for the sake of financial gain; and 5) harms that emanate from research risks. Such explicit declarations are ethically and psychologically vital.

Second, it presents the situation more realistically and fairly. Third, it carries an element of deterrence in the battle against medical errors by legitimately including those parties who are essentially the managers, designers, builders and intellectual leaders. Fourth, the new taxonomy recognizes all previously agreed error causations at the institutional level as well as individual human errors, while at the same time excluding those errors that do not fit in the previous categorization by moving them into the new error categories. Simply put, no parties responsible for error initiation or causation should escape accountability and, equally, no parties should shoulder errors that are not of their own making. Justice must be served for the sake of patients and for the sake of all other stakeholders.

Current medical practice carries many avoidable risks to patients when serious attempts are made a priority of tackling the serious deficiencies of the above-listed agencies and institutions. Attention to the true value and spirit of agreed ethical principles of beneficence, nonmaleficence and justice, while serving and deciding on the merits of decision making at all levels, will reward those concerned with the welfare of patients with greater success than we are witnessing now. Ethical obligations are not solely tailor-made for physician-patient relationships. Ethical duties oblige all personnel within organizations connected to health services provision. Fighting the seemingly insatiable material desire of the

selfish and careless human nature of a minority of individuals as proposed in this thesis will reward the majority of the health professionals and all patients with long awaited objective in patient care and safety.

Institutional Ethics (IE) can be a robust mechanism, when practiced effectively, to safeguard patients' best interests from any misconduct perpetrated by regulators, licensers, suppliers, self-regulators, KOLs and researchers. IE demands truthfulness, accountability, disclosure of conflict of interest, justice and fiduciary duty obligations. IE requires personnel to be foremost guided by the best interests of patients at all levels. An ethical culture should shape all operational processes and all personnel within any institution especially those that have potential causal links to patients' harm.

For these reasons, it is in the best interest of all parties that a formulation on a proper definition of the confines of systems weaknesses and human related medical errors be reached. The proposal in this thesis has outlined a way to perceive medical errors in a broad way, joining the many agents of error/harm into one system, thereby highlighting accountability and reform.

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