
Business ethics, medical ethics and economic medicalization

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Abstract: This paper explores the ethical implications of economic medicalization: where non-medical problems are transformed into medical problems in order to achieve the objective of shareholder wealth maximization. After considering differences between business ethics and medical ethics, economic medicalization arising from corporate marketing strategies is detailed. Both direct-to-consumer and more traditional physician centred marketing methods are considered. In addition, the economic medicalization of medical research practice and publication is examined and future trends are identified.

Keywords: medicalization; direct-to-consumer marketing; muzzle clause; shareholder wealth maximization; SWM; medical ethics.

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1 Introduction

At least since Zola (1972), medicalization has been defined as a process where more and more aspects of everyday life come under medical dominion, influence and supervision. The process of medicalization is part of a larger historical transition involving social values associated with traditional institutions, such as the church, the common law and the family, being replaced by the values of science and the scientific method. Even the practice of medicine has not been immune from this transition, as reflected in the emergence of the evidence-based medicine movement, e.g., Davidoff et al. (1995). The observation that medicine had 'nudged aside' or 'replaced' religion as the dominant moral force in the social control of modern societies is a central theme in medicalization research surveyed in the influential review by Conrad (1992). The lack of cohesion in this research is reflected in the considerable effort that Conrad dedicates to the search for a precise definition of 'medicalization'. Writing over a decade later, a continuing lack of cohesion in the state of medicalization research is reflected by Sismondi (2004): 'for the most part, medicalization is discussed in terms of the politics of professions, with medical

professions gaining importance as they take control over the problems ... The means by which economic interests shape medical knowledge and medical discourse have not been well explored'.

Driven by the remarkable technological and economic evolution of the medical profession in the last two decades, Poitras and Meredith (2008), Conrad (2007, 2005) and Conrad and Leiter (2004) recognise that medicalization is too diverse as a concept to be analysed with a unifying methodology. Building on this insight, the concept of medicalization can be dichotomised into two distinct components: economic medicalization, where the corporate profit motive plays a central role, and social medicalization, where traditional concerns of social control predominate. Following Poitras (1994), the goal of shareholder wealth maximization (SWM) that is essential to economic medicalization involves a sharp ethical divergence with the norms of science and the scientific method associated with medical ethics. Given the frightening global risks associated with the progress of certain elements of modern medical technology, recognition of the distinction may be imperative. In the following, Section 2 discusses the general differences between business ethics and medical ethics. Section 3 details the development of the concept of medicalization, starting with Szasz (1958, 1958a) and Wootton (1959) and continuing to Conrad (2007). Section 4 examines the key aspects of the marketing elements of economic medicalization: direct-to-consumer marketing and the more traditional methods of marketing to physicians. Section 5 demonstrates how the economic medicalization of research and development (R&D) produces ethically questionable outcomes as a consequence of corporate marketing strategies for pharmaceuticals. Finally, the paper concludes with Section 6 which considers the potential dangers associated with currently observable trends in economic medicalization.

2 Business ethics and medical ethics

It is not difficult to find day-to-day examples of the medical profession extending authority over matters not directly concerned with the analysis and treatment of biophysical disorders. Ethical analysis of such developments is complicated because the medical profession includes not only practising doctors and associations of doctors, but also: the pharmaceutical and medical device industry, providing the drugs and medical technologies that are essential components of modern medicine; the academic institutions and journals involved in training doctors and sponsoring essential research activities; the medical insurance industry that processes payments for the bulk of medical services; and the government granting agencies and other sponsors that supply essential funding to the research conducted by the medical profession. In addition, governments also play differing roles as medical insurer and provider of medical services, e.g., in Canada, the monopoly provider of health services is the federal and provincial governments. Significantly, because the source of capital for the corporations producing pharmaceutical and medical devices is the global financial markets, the primary motivation of these important players in the medical profession differs from those of the other players. The implications of this difference are reflected in the legion of studies on the marketing networks of the pharmaceutical companies and the sophisticated efforts involved in selling products. The differing motivations within the medical profession create a range of ethical quandaries.

Due to the diverse and competing ethical norms that impact the medical profession, it is not easy to discern the *de facto* objectives driving particular actions and outcomes. As Poitras and Meredith (2008) observe: 'there is an ethical transparency problem'. The difficulty of discerning the ethical motivations of specific players within the medical profession can even occur for physicians where the ethics of professional fiduciary responsibility would seem to be clear cut, based on ethical standards stretching back to the Oath of Hippocrates which first appeared around the fifth century BC, e.g., AMA (2006, p.ix). The Oath protects the rights of the patient by appealing to the strong character of the physician, no formal sanctions or penalties are contemplated. The Oath was 'Christianised' around the eleventh century AD and remains an essential component of the ideal ethical conduct of physicians up to the present. The evolution of medical practice gradually surpassed the ethical guidance provided by the Oath. Building on contributions from the Scottish physician John Gregory (1724–1773), in 1803, the English physician Thomas Percival (1740–1804) published a 'Code of Medical Ethics' to address the need for more detailed ethical guidance. The Percival code was, more-or-less, adopted by the American Medical Association (AMA) in 1847 (McCullough, 1988). Since that time, a number of major revisions to the code have been made, with four such revisions during the 20th century (1903, 1912, 1947 and 1994).¹

In addition to specifying nine principles of medical ethics, the AMA provides detailed opinions on ethical behaviour for specific situations, e.g., conflicts of interest in biomedical research (AMA, 2006).² Ethical opinions for over 200 situational problems are currently provided. Opinions cover a wide range of subjects, from the controversial to the mundane. In the realm of social policy, controversial issues such as cloning, euthanasia and gene therapy are examined. More mundane opinions cover inter-professional and hospital relationships and patient confidentiality. Though the present code and related opinions have evolved considerably from the early beginnings of the Oath and the Percival code, basic principles still remain: physicians should base clinical practice and research on the best science available; individual self-interest is secondary to the well-being of the patient and medical knowledge is a public trust to be used to the benefit of patients and society. Significantly, 'principles adopted by the AMA are not laws, but standards of conduct which define the essentials of honourable behaviour for the physician' [AMA, (2006), p.xvi].

For physicians and other medical professionals engaged in medical research, there are related ethical standards that also apply. Following Weijer et al. (1997): 'medical research involving human subjects raises complex ethical, legal and social issues. Investigators sometimes find that their obligations with respect to a research project come into conflict with their obligations to individual patients'. In addition to the AMA code and related opinions, ethical standards for medical research have been set out by a variety of government departments, agencies and commissions such as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHS), US Department of Health and Human Services and, in Canada, the Tri-Council of research funding agencies. Medical professionals may also be members of non-governmental organisations that issue statements of ethical standards such as Council for International Organisations of Medical Sciences and the Human Genome Organization. Recognising that there is some variation in the specific ethical statements, the range of standards proposed for medical research can be roughly and briefly summarised as: obtain informed consent, protect the privacy of patient medical information and do no harm.

The long established field of traditional medical ethics is patient centred. While the AMA aims to provide guidance to physicians for dealing with the increasingly complex ethical issues raised by the relentless progress of modern biotechnology, the AMA 'Code of Medical Ethics' is not able to provide sufficient guidance to deal with the multitude of inter-disciplinary ethical problems raised by research into areas such as: cloning, stem cells, genetic modification of foods, euthanasia, DNA data banking, genetic manipulation of human DNA and testing for genetic markers. The issues involved are so varied and significant that the field of bioethics has emerged to address such issues, e.g., Dhanda (2002) and Eaton (2004). Biotechnology has also impacted research areas that have long-standing social and religious significance such as abortion and the determination of death. While medical ethics has considerable interest in such issues, bioethics goes beyond medical ethics to incorporate knowledge from moral philosophy, law, sociology, molecular biology, economics and other subjects. Central to the issues confronting bioethics is the justification for introducing new technologies. In practice, this ethical problem is confounded by the commercial aspects involved in developing these technologies, e.g., Robbins-Roth (2000). The substantial capital investments required for biotechnology advances dictate that bioethics also address the implications of corporate decision-making.

Because some of the largest multinational corporations in the world are directly involved in the market for medical products and services, bioethics needs to incorporate elements of business ethics in order to accurately assess a range of important issues. In business ethics, it is necessary to recognise that corporations pursue strategies consistent with SWM. Following Poitras (1994) and Poitras and Meredith (2008), the goal of SWM depends on the future common stock price and as such, does not have ethical transparency. Some assumption about the efficiency of the stock market in valuing ethical concerns is required. In this vein, the layers of regulatory oversight aimed to restrict unfettered corporate activity come into play. In the key area of medical research, this oversight includes the ethical approval process for medical research in the USA embodied in Title 45, Code of Federal Regulation (CFR), Part 46 that empowers the Institutional Review Board (IRB).³ Similar bodies are empowered in other countries, such as Research Ethics Board (REB) in Canada. Also important in the USA is Title 21, CFR, Part 56 that requires IRBs to oversee clinical trials of drugs involved in new drug applications to the Food and Drug Administration (FDA). Ultimately, it is difficult to expect much more than an 'ethical-is-legal' approach to corporate decisions regarding medical R&D if SWM is the goal. Significantly, higher ethical standards may come at a financial cost that impacts corporate profitability undermining the achievement of SWM.

In setting the legal and regulatory environment for the medical profession, governments are inclined to adhere to utilitarian ethics where decisions are made on the basis of cost-benefit calculations. The precise method of determining costs and benefits can depend on a range of political and social factors, not just a dollar and sense calculation. The history of tragic events such as the more than 100 deaths associated with the 1937 elixir sulfanilamide incident that gave impetus to the Federal Food, Drug and Cosmetic Act (1938) and the infamous 1957–1961 thalidomide tragedy suggests that crisis management is the primary motivation for substantive changes in the legal and regulatory framework. In contrast to the well established code of medical ethics, the legal environment is a myriad of legislation established at different times with potentially competing ethical standards. In turn, relevant legislation will vary from issue to issue. For example, in the area of direct-to-consumer marketing of genetic tests, regulatory

oversight and associated legislation in the USA would include: the Federal Trade Commission, the Centers for Disease Control, the FDA and the state health agencies [Berg and Fryer-Edwards, (2008), p.27]. Similarly, the 'Common Rule' principles that inform the institutional process for ethical approval of medical research as reflected in Title 45, CFR apply to some 17 federal agencies (White, 2007).

3 The concept of medicalization

The history of the concept of medicalization can be traced back to the 1950s when Thomas Szasz, Barbara Wootton (1897–1988) and others attacked the advance of psychiatry beyond the treatment of well defined mental disorders into areas of dysfunctional behaviour related to crime and delinquency (Wootton, 1959; Szasz, 1958, 1958a, 1961). These contributions build on Parsons (1951) where the identification of medicine as an institution of social control was initially proposed. Following Szasz and Wootton (1959), 'science' was replacing traditional areas of social morality as the means of distinguishing the 'undeniably mad' from those 'who are simply unable to manage their lives' [Davis, (2006), p.51]. Yet, the distinction between 'mentally incompetent' and 'sinful' needs to be determined by social values. Allowing 'medical science' to encroach on this decision shifts attention to the individual rather than the environment as the source of the problem. As Wootton (1959) observes: 'always, it is easier to put up a clinic than to pull down a slum'. While insightful, the early contributions by Szasz and Wootton (1959) only examined the narrow confines of psychiatry where the social implications of medicalization are readily discernible. During the 1970s, the extension of these initial notions to a wider field of applications was proposed by Freidson (1970) and Zola (1972) where the connection between medicalization and social control was established.

Development of the connection between social control and medicalization is consistent with traditional sociology where social control is a central concept. As noted previously, the observation that medicine had 'nudged aside' or 'replaced' religion as the dominant moral force in the social control of modern societies was a central theme in medicalization research surveyed in the influential review by Conrad (1992). The lack of cohesion in this research is reflected in the considerable effort that Conrad (1992) dedicates to the search for a precise definition of 'medicalization'.⁴ Driven by the remarkable evolution of the medical profession in the last two decades, it is becoming gradually apparent that the medicalization concept is too diverse to be analysed with a unifying methodology (Conrad and Leiter, 2004; Poitras and Meredith, 2008). In particular, considerable ethical transparency is gained if medicalization is dichotomised into two categories: *social medicalization*, dealing with the type of social control issues that originate with Szasz and Wootton (1959), and *economic medicalization*, dealing with the markets for medical technology and professional services driven by the corporate profit motive.

Defining medicalization as a process where more and more aspects of everyday life come under medical dominion, influence and supervision involves 'the turning of non-medical problems into medical ones' [Sismondi, (2004), p.153]. This process can occur for various reasons. Drawing a distinction between economic and social medicalization focuses attention on the ethical motives of the medical professionals involved in the process. Social medicalization is concerned with encroachment of the

medical profession into areas traditionally controlled by other professions, such as the legal profession for deviant behaviour or the ecclesiastic profession for reproductive decisions. This often leads to a sociological examination of issues surrounding the competition of the professions for social control. While the profit motive may play some role, the complexity of issues surrounding the ethics of the market place is not a central concern. In contrast, economic medicalization encompasses cases where the profit motive plays a substantive role in the transformation of non-medical problems into medical ones. Healy (2004) identifies economic medicalization with the 'marketing of disease'.

Numerous instances of economic medicalization have been identified. For example, Conrad and Leiter (2004) examine the direct-to-consumer marketing campaigns by pharmaceutical companies and the development of private medical markets. Conrad (2007) finds evidence of economic medicalization in numerous cases such as: male disorders associated with aging including andropause, baldness and erectile dysfunction; behavioural disorders such as ADHD in adults and hyperactivity in children; and certain applications of biomedical enhancement drugs such as steroids and human growth hormone. Avorn (2006) details the deceptions that pharmaceutical companies have used to hide the evidence of adverse drug effects. Jones and Hagtvelt (2008) consider the tragic implications of treatments for malaria. Instead of seeking the cost-effective solution of eradication by treatment of the local populations, available treatments are targeted at the more profitable Western visitors and ex-patriots sojourning in those regions. In contrast, social medicalization includes studies where the profit motive plays a lesser role, such as studies of spouse battering or gender deviance. The classification of some areas of medicalization research depend on the methodological approach taken, such as studies of childbirth, infertility and abortion, where the profit motive may or may not be of central concern.

Since the public policy disasters created by drugs such as elixir sulfanilamide and thalidomide, it has been recognised that medical R&D is an area where the conflict of interest between private sector firms and those of government needs to be managed through regulatory oversight. Though the specific regulations involved vary depending on the particular type of medical product or device, the *raison d'être* of the IRB is to ensure that ethical norms of the general population are not put at risk by the private sector firms conducting the bulk of medical R&D that are motivated by the ethical standards of the marketplace. The profit motive provides strong incentives: to recoup R&D expenditures as soon as possible; to recoup acquisition costs related to the takeover of other firms that have developed potentially marketable technologies for drugs or devices; to exploit first mover advantages where the danger of a 'race to market' with potentially competing innovative drugs or devices may be apparent; to develop alternative (off-label) applications and delivery mechanisms for existing drugs; and to extend drug or device patent protection by reformulations combining these drugs with other existing medications. Faced with a limited time to patent expiration, there is great economic pressure on pharmaceutical companies to move drugs to market as quickly as possible. Rewards are more closely tied to the number of prescriptions written for a drug than to the incremental medical value of the treatment.

Once the regulatory infrastructure for conducting research through clinical trials is juxtaposed against the corporate requirement of profitability through successful marketing of pharmaceuticals or devices, the stage is set for serious ethical conflict to emerge between the players. This conflict is central to the analysis of economic medicalization where the ethical norms of 'science' are confronted with the ethics of the

market place. In science, accuracy of measurement and validity through replication are fundamental elements. In contrast, the objective of profitability is supported by research, biased or unbiased, that recommends prescription of the treatment on offer. Examples of such bias are accumulating. For example, Heres et al. (2006) examines 33 company sponsored studies of second generation anti-psychotic drugs and finds that in 'head to head' studies involving competing products, the reported total outcome was in favour of the sponsor's drug 90% of the time (Heres et al., 2006; Bhandari et al., 2004). Such an 'empirical' result is outside the bounds of scientific credibility.

4 Direct-to-consumer and direct-to-physician marketing

A significant instance of economic medicalization appears in the direct-to-consumer television marketing campaigns by the pharmaceutical companies designed to put in place a public perception of illness and health consistent with the portfolio of prescription drug products on offer. Where bodies were once understood as normatively healthy and only sometimes ill, effective marketing has individuals seeing their bodies as inherently ill and only able to be brought towards health with the effective medical treatment. The history of Viagra and the erectile dysfunction drugs attests to the ability of the direct-to-consumer marketing by pharmaceutical companies to transform a non-medical problem into a medical one. The treatment of risk factors for illness and not just the associated illness has also allowed pharmaceutical companies to dramatically increase the sales of prescription drugs. Other instances of the types of drugs that have exhibited substantial direct-to-consumer promotional spending are anti-psychotic agents, proton pump inhibitors, COX-2 inhibitors and HMG-CoA reductase inhibitors [Donohue et al., (2007), p.677]. Given the difficulty of determining whether a good outcome has resulted from the perceived 'risk' being successfully treated, this is a potentially much more profitable area for pharmaceutical company marketing campaigns to pursue than the development of drugs that treat actual diseases.

Economic medicalization involves a complicated web of interaction between physicians, responsible for prescribing drugs and delivering medical care and the pharmaceutical and medical device companies that supply the products that are essential to the practice of modern medicine. Rules on direct-to-consumer marketing vary across jurisdictions and medical products. For example, regulatory oversight of the direct-to-consumer marketing of genetic testing kits in the USA would involve the Federal Trade Commission, the Centers for Disease Control, the FDA and the state health agencies [Berg and Fryer-Edwards, (2008), p.27]. In the realm of direct-to-consumer marketing, only the USA and New Zealand currently leave this marketing method largely unrestricted. Other countries, such as Canada, allow such marketing with relatively lenient restrictions and may reduce restrictions further in the future (Cassels, 2006). In the USA, direct-to-consumer marketing was permitted through a regulatory decision of the FDA in 1998. Pines (1999) provides a historical overview of direct-to-consumer advertising up to the administrative change in FDA rules.

Understanding the marketing methods that companies use to influence treatment selection assists in identifying sources of ethical conflict in the medical R&D process (Angell, 2004; Caplovitz, 2006). Following Donohue et al. (2007, p.676), spending on advertising and promotion to medical professionals and consumers in 2005 was: \$4.2 billion for direct-to-consumer advertising, \$18.4 billion for free samples mostly given to

physicians, \$6.8 billion for detailing and \$429 million for journal advertising. One key marketing strategy revolves around influencing the opinion leaders.⁵ Applying this strategy to the case of medical drugs and devices, opinion leaders can be identified with groups such as specialists, research faculty, heavy prescribers in a drug/device category and product champions. Considerable effort is given in finding opinion leaders willing to speak favourably about a company's product. In many cases, opinion leaders derive financial gain from interacting with medical product marketers at a number of levels. Marketers try to influence opinion leaders because these groups, in turn, affect the purchasing habits of other buyers who respect the opinion leaders' knowledge base and authority in a particular area. The lack of ethical transparency in the motivations of opinion leaders in this process raises a number of ethical issues.

The points of interaction between opinion leaders and companies are numerous. Opinion leaders are retained: to provide presentations regarding research results at various venues; to deliver lectures at conferences financed in whole or in part by the corporations that retain the opinion leader; to act as paid consultants to those corporations; and to offer symposia for continuing medical education in their fields of expertise. These interactions, which are arguably the business of the participants, cause ethical concern when it is difficult to determine the degree of independence that the opinion leaders are able to exercise given the financial and personal relationships that have developed between themselves and the corporations with whom they interact. Concerns arise that these 'relationship marketing' strategies may positively influence physician perceptions of the corporation and the products on offer, e.g., in qualitative evaluations of drug efficacy (Gross et al., 2003). The extent of this marketing strategy is somewhat staggering. Excluding free drug samples, Campbell (2007) estimates that 78% of US physicians have been financially involved with industry: 35% received reimbursements, 18% were paid for consultancy, 16% had funded speaking engagements, 9% served on advisory boards and 3% were involved in clinical trials recruitment.

While it is tempting to conclude that opinion leaders are of sufficient ethical stature, the actual and substantive knowledge of the subject will dictate an unbiased reading of the evidence. However, it is not always clear whether published research by a given opinion leader is free from the influence of economic medicalization. In particular, 'ghost-writing' is a marketing/research strategy where a drug company will carry out research and then forward the manuscript to an author in attempt to secure their endorsement (Lynch, 2004). Obviously, only those research results favourable to the product are forwarded to the prospective author. By attaching a respected author's name to the research results, the company hopes to achieve more rapid acceptance of the drug or device in the marketplace than if the product was only advertised (Healy, 2004). This strategy is particularly attractive to academic research faculty where publications in prestigious journals have considerable value to career progress. In turn, ghost-written and other positive published research permit the sales representatives of drug or medical device company to bring these trial results to the prescribing physician in an effort to influence prescription pattern choices.

While the enlistment of opinion leaders plays a fundamental role in corporate marketing strategies, it has traditionally been the prescribing physician that drug companies need to influence the most. Though this approach has changed somewhat with the rise of direct-to-consumer marketing, the bulk of advertising and promotion spending is still targeted directly at physicians. A key element in this strategy is the 'detail man'. It is estimated that there is approximately one pharmaceutical company sales representative

for every ten doctors in most developed countries. The history of the modern detail man can be traced back to the 1940–1960 era when the prescription drug industry was in a period of enormous expansion (Greene, 2004). To address the dramatic changes in the medical profession brought on by the advent of a host of new and important prescription drugs, detail men during the period were transformed ‘from specialised salesmen into quasi-professionals’. The pharmaceutical companies recognised the value to drug sales if detail men could be seen as assistants to doctors, conveying useful information about important drug developments rather than being mere salesman for products. Greene (2004) argues that this change of image ‘required a careful negotiation around doctors’ spaces, both figuratively and literally’.

The lack of ethical transparency in the activities of detail men is apparent (Poitras and Meredith, 2008). Though detail men cannot be seen as telling doctors what to prescribe, their role is ultimately to influence prescription behaviours. To do this, detail men want to be seen by physicians as allied professionals, consciously modelled as having the same ethical objectives as doctors. For example, Greene (2004) reports that manuals for detail men reproduce parts of the AMA’s code of ethics. To be effective, detail men need to have the ability to interact with doctors and require training to develop this ability. Detailing has to at least appear to educate, rather than merely to sell. In this process, the research pipeline of positive results is an invaluable tool for the detail men. Marketing to doctors often takes the form of getting doctors up to speed on the latest research. The range of techniques that can accomplish this goal includes not only marketing by pharmaceutical representatives, but also advertisements in professional journals, funding continuing medical education conferences and so on.

Given that drug detailing and sampling are based on the marketing tactics used to generate demand for any product, not just pharmaceuticals and medical devices, the suspicion of economic medicalization is difficult to displace. Drug and medical device sales representatives bring research literature and clinical trial results to the doctors in efforts to influence prescription pattern choices, while at the same time, company funded research ensures that unsuccessful clinical trials are not published so physicians are exposed mainly to studies supportive of the drug or medical device (Turner et al., 2008). Influential opinion leaders tend to be involved in the clinical trials that are positively predisposed toward the sponsoring company’s drug or medical device (Anderson et al., 2006). This can have a positive effect on the perception of their peers toward the product (Steinman et al., 2006). Sales representatives attempt to influence physicians through ‘relationship marketing’ where personal interaction with physicians is used to influence decisions. One example of such relationship marketing occurs where company representatives pay ‘preceptor fees’ (in some cases, up to \$1,000 per day) to accompany surgeons in operating rooms and clinics. While the stated objective is to learn how physicians actually used the drug or medical device, serious concerns for medical ethics are raised regarding the protection of patient confidentiality and the potential for private funds flowing to doctors influencing physician choices of medical products.

A key element in marketing to physicians is the provision of free samples in order to impact on prescriptions patterns. Chew et al. (2000) conclude that the availability of drug samples led their primary physician respondents to prescribe drugs different from their preferred choice, especially if it avoided costs to the patient. Campbell (2007) in a national US survey reported that 78% of 1,255 physician respondents had received free samples. Pharmaceutical companies do not undertake that level of free sample distribution unless it has a track record of producing results. Marketing research has long

established that providing free samples is one of the strongest cues in terms of producing product trial and adoption. Medical products representatives donate substantial quantities of free samples to hospitals and clinics, presumably with the objective of slowly infiltrating the facility and subtly influencing staff usage patterns of drugs, devices and medical supplies. With the goal of promoting product efficacy, drug representatives aim to interact directly with hospital staff instead of, say, working through hospital pharmacologists who possess far greater knowledge of drug efficacy and safety and are much better equipped to evaluate drug alternatives.

5 Economic medicalization of research studies⁶

The medical research literature abounds with examples of bias in empirical studies of pharmaceutical effectiveness such as: studies with fundamental design flaws where no control groups or placebo arms are involved and studies where poor comparators are used, e.g., the sponsored drug is compared to a placebo (no treatment) instead of the most effective comparator drug available (Bero and Rennie, 1996). Additional bias can be introduced by the method of comparison used. For example, economic cost comparisons are sometimes avoided when the effectiveness of new experimental drugs is being assessed. Due to large accumulated R&D expenses, such long patent-life drugs can be substantially more expensive than comparable predecessor drugs. Effectiveness measurement could emphasise, say, patient mortality instead of the increase in mortality compared to cheaper generic drugs that have comparable effectiveness. Sample bias can also be compromised through the impact of study entry criteria, such as excluding pregnant women or restricting ethnic minorities into the sample population.

Economic medicalization of research studies is a process where the traditional values associated with the scientific method are replaced by research ethics that reflect the values of the market place. While traditional scientific values demand the researcher to be as objective as possible in order to reduce the possibility of bias in the interpretation of the observed data, the ethics of the marketplace are more concerned with abnormal gains (losses) associated with 'positive' (negative) research results. In statistical terms, economic medicalization occurs when there is a decided bias towards unjust acceptance and against unjust rejection. One documented instance where this occurs is 'publication bias': a tendency to publish only favourable clinical trial results of an experimental drug. Corporate sponsors have little interest in providing negative information regarding a product in which they may have already invested millions of dollars. Even journal editors may show a predilection for publishing successful, as opposed to failed, clinical trial results (Schafer, 2004). Consequently, the medical community observes the positive research study results for the drug that accumulate in the published literature rather than the failed trials of the drug which languish in the 'file drawer'.

Another instance of economic medicalization is 'muzzle clauses' in the contracts of investigators involved in clinical trials. These clauses are intended to prevent researchers from releasing any information about the clinical trial without the sponsor's permission. This can be problematic if the physician discovers significant safety concerns related to the trial. If the researcher releases the negative information, the terms of the muzzle clause are breached and a variety of undesirable outcomes can result. Examples of possible outcomes include: threats of civil lawsuits; the sponsoring company withdraws financial support for the researcher and possibly, also reduce or eliminates philanthropic

contributions to the host institution and the sponsoring company engages outside experts to refute the researcher's findings. However, if the researcher sits on the information, the doctor-patient accord to act in the best interests of the research subjects recruited for the drug trial is breached. Many facets of muzzle clauses emerged in the the Nancy Olivieri versus Apotex case that received international coverage in medical and ethics journals and is used as a classic example of the failure to deal effectively with the problems posed by restricting negative results from drug trials (Schafer, 2004; Somerville, 2002; Thompson et al., 2001).

The controversy involving Apotex Inc., Dr. Nancy Olivieri and the Hospital for Sick Children in Toronto (the hospital) originated in clinical studies of the drug L1 (deferiprone) that generated disputes between Apotex and Dr. Olivieri, between Dr. Olivieri and other investigators and between Dr. Olivieri and the Hospital. L1 was first synthesised in 1987 and a research study by Dr. Olivieri and Dr. Gideon Koren of L1 patients at the hospital began in 1989, funded by the federal government's Medical Research Council of Canada (MRC). When this funding ended in 1992, an alternative source of funding was received from Apotex. While the company was initially reluctant to get involved with the development of L1 because of its impaired patent status and because it produced serious side effects in some patients, Apotex ultimately obtained a licence to develop L1 from the patent holder and a drug trial conducted by Olivieri and Koren was sponsored which involved patients with thalassemia major, a disorder that impacts hemoglobin production. Participants in the study were randomly assigned to receive either L1 or deferoxamine, the established treatment for iron toxicity. The randomised trial was constructed to compare the effects of the two drugs on body iron levels. The contract between the researchers and Apotex governing the drug trial contained a muzzle clause.

The details of the subsequent L1 drug trial are well-known, e.g., Thompson et al. (2001). There was tension between Dr. Olivieri and the officials of Apotex almost from the beginning, at least partly due to differences in expectations between the investigators who viewed the trials as continuing research work done under the MRC grant and Apotex whose expectations were consistent with the usual procedures for the initiation and conduct of industry funded drug studies. While in April 1995, the investigators published a paper indicating a 'favourable effect of deferiprone on iron balance', by the autumn of 1995, some negative data were emerging from the compassionate use trial. This data was seen by Dr. Olivieri as a 'loss of response' or 'loss of efficacy' in some patients receiving L1. Apotex objected to this characterisation, interpreting the findings as being due to variability in response that is seen with most drugs. In March 1996, Dr. Olivieri reported her findings of loss of response to the REB for the hospital and was instructed to modify the patient information and consent forms and to advise physicians treating patients with L1 at other centres of the findings.

In early May 1996, Apotex indicated to the REB that investigators in other centres involved in the drug trial did not agree with Dr. Olivieri's interpretation and that Apotex had convened an expert panel of international stature to review the data. On May 24, 1996, Apotex wrote to Olivieri and Koren informing them that Apotex was not renewing the trials contract which had expired some weeks earlier. In this communication, Apotex reminded the researchers of the contract's confidentiality provision that:

"All information whether written or not, obtained or generated by the investigators during the term of the LA-O1 [randomised trial] Agreement and for a period of one year thereafter, shall be and remain secret and confidential

and shall not be disclosed in any manner to any third party except with the prior written consent of Apotex. Please be aware that Apotex will take all possible steps to ensure that these obligations of confidentiality are met and will vigorously pursue all legal remedies in the event that there is any breach of these obligations.”

On the same date, Dr. Olivieri was informed that an additional consulting contract with Apotex would not be renewed and the same warning was issued to her about breaches of its confidentiality provisions.

Needless to say, Olivieri was not deterred by the muzzle clause. In July 1996, the expert panel appointed by Apotex produced a report that supported the Apotex interpretation of the variability in response to L1. Dr. Olivieri produced a commentary rebutting these findings and reaffirming the negative conclusions about the efficacy of L1. Starting in early December 1996, Dr. Olivieri began to disseminate the negative L1 results at a variety of professional conferences including the American Society of Hematology. In the time leading up to these presentations, Apotex indicated repeatedly that the company did not concur in the findings that L1 caused liver fibrosis in some patients and would not consent to the submission of the abstracts for publication. Dr. Olivieri was again notified that she would be breaching the contract if she proceeded to do so. Apotex also questioned the data supporting the conclusion and arranged to have an independent analysis done by a leading expert on liver pathology. This expert came to a different conclusion than Dr. Olivieri, finding that L1 did not exacerbate liver fibrosis. Much of the subsequent notoriety and public attention the case received was due to the desire of Olivieri to publicise the events.

Muzzle clauses are a relatively obvious implication of economic medicalization. Other implications are less obvious. Consider the issue of drug trial sample design. While concerns of public safety argue for a time series analysis of experimental medical products, economic pressures to bring a drug to market as soon as possible result in cross-sectional static (as opposed to dynamic) analyses. This fosters large Phase 3 trials where sample sizes are substantial, but the elapsed time may be insufficient for dynamic or cumulative effects of the experimental product to emerge. Phase 4 or post-marketing approval trials can be longer term and much more effective at detecting time series based cumulative effects. Yet, there is no requirement that Phase 4 post-marketing or tracking studies be conducted or reported. The tragic consequences of OcyContin, Neurontin, Paxil, Accutane (Caplovitz, 2006), Baycol, Aprotinin and Vioxx (Avorn, 2006) speak clearly to the dangers of long-term cumulative effects that have emerged only after extended periods of time in the market place.

Because present regulations do not require drug and device firms to carry out and publicly vet Phase 4 research programs, the law and the ethical issues surrounding Phase 4 clinical research trials are ill defined. A company that is concerned about the longer term side effects of a drug might carry out a longitudinal tracking study as a means of exhibiting due diligence. If negative results are found, the company would arguably have an ethical responsibility to make those side effects known and if serious enough, voluntarily pull the drug from the market. However, there is evidence that in some serious cases, voluntary withdrawal did not happen, a consequence of the desire to avoid the multi-million dollar investment losses for the pharmaceutical company stockholders that can occur when such negative news is released to the capital market (Caplovitz, 2006; Avorn, 2006). In economic terms, a decision not to withdraw a drug (e.g., Vioxx) has to be weighed off against the danger of civil litigation associated with the damage

done by the drug side effects. This ethical-is-legal conundrum may also lead to effective Phase 4 trials not being carried out since if no negative side effects are found, then there is no obligation to report them publicly (Avorn, 2006).

6 Future trends in economic medicalization

Recent evidence suggests that a form of economic medicalization is impacting in Phase 4 studies. In 2000, Phase 4 studies accounted for 3.1% of all clinical trials worldwide that were registered with the US National Institutes of Health. In 2008, Phase 4 trials accounted for 16.7% of all registered trials, though it is difficult to tell whether this increase was due to the increased registration of Phase 4 trials or to an actual increase in the number of such studies. In this vein, evidence points to the increasing use of primary physicians to conduct Phase 4 trials where remuneration is paid for participation. At this point, it is unclear whether these studies constitute 'real research' with properly structured Phase 4 research protocols that would meet IRB standards or are just disguised 'drug seeding' marketing strategies. Deshpande and El-chabini (2005) certainly point to the latter hypothesis, providing advice to pharmaceutical companies on how Phase 4 studies can be used to attract physician participation in order to generate new drug sales. This approach appears to be supported by Andersen et al. (2006) where it is reported that when general practitioners were paid US\$800 per patient to recruit subjects for an asthma study, there was an increase in the long-term use of the trial sponsor's drug.

One disturbing aspect of economic medicalization is the transformation of the process for doing clinical trials into exercises that are motivated more as marketing vehicles than needed R&D. One immediate advantage of such a marketing strategy is that physicians can legitimately receive fees for the recruitment and tracking of subjects admitted into the clinical trials. In some instances, these fees are not inconsequential. For example, Sismondi (2004, p.149) describes a US research study by Biovail that paid a fee of \$1,000 for doctors, plus \$150 for office management expenses, for patient data when at least 11 of their patients renewed a prescription to Cardizem, a drug intended for long-term use. In this case, paying doctors to get patients started on a course of treatment could lead to substantial profits from these prescriptions. Doctors who signed up for the trial, but did not keep 11 patients on the drug received US\$250 for participation. According to ethicists who commented on the case, a US\$1,000 payment to doctors was unusually high for a post-marketing research trial.

Another ethically disturbing aspect of the evolution of economic medicalization concerns off-label prescription drug usage. The prescription drug approval process is based on research and clinical trials where specific drugs and medical devices are approved by review boards for specific applications. However, once approved, companies have economic incentives to promote the use of the drug for other medical conditions without further research reviews by the government. Delays in seeking approval for alternative uses are consistent with obtaining a maximum revenue stream for a given product, if only because alternative uses can be a basis for a further round of patent protection. For example, Pfizer admitted guilt in the case of gabapentin (Neurontin), a drug originally intended for the treatment of epilepsy. The company subsequently used opinion leaders to market the drug to physicians for a range of other indications. Steinman et al. (2006) estimate the company spent US\$40 million in

advertising and promotion with 50-66% of that budget going to professional education between 1996 and 1998. Significantly, increased market penetration was achieved by selling gabapentin off-label. In general, Radley et al. (2006) estimate that 21% of all drug use in the USA among office based physicians was for off-label indications and that 73% of off-label uses lacked strong scientific evidence.

Discernible trends in the pattern of economic medicalization indicate a number of flash points that threaten to undermine the validity of the present medical R&D clinical trial approval process. Regarding Phase 4 or post-approval research studies, there is currently no requirement that results of such studies need to be released or even that such trials be conducted according to IRB approved protocols. In situations where negative or ineffective results are found, companies will be reluctant to release such results and without IRB oversight, will not be required to do so. Two particularly egregious cases where this has occurred is Bayer admitting to a 'mistake' in suppressing a study that showed dangerous side effects associated with the drug Baycol and Merck's suppression of studies that showed Vioxx doubled the risk of myocardial infarction and stroke (Avorn, 2006). These studies only came to light because the adverse negative reaction spread over a large population was sufficiently detectable by other means. At present, exact information on the number of unregistered Phase 4 trials is not available, nor is the amount of remuneration flowing to physicians who enrol patients in these 'trials'.

Unfortunately, aiming to increase the reach and depth of ethical oversight in order to prevent questionable research practices may, in the end be self-defeating. Faced with rising costs associated with obtaining clinical trial approval in developing countries, pharmaceutical companies are moving certain types of medical R&D offshore to third world jurisdictions where the ethical requirements of the drug approval process are substantially less due to lower costs, lax regulations and uneducated research subjects that make for more freedom in research design and lower all-in costs of doing experimental trials (O'Neill, 2008). Arguably questionable randomisation procedures have been observed in some research protocols used in third world countries. The classic case involved the randomisation of African subjects to a placebo arm of an HIV drug study where an existing 'gold standard' treatment was available for comparison. Consequently, certain HIV pregnant women received no treatment at all under the placebo arm of the study when a life-saving drug could have been administered without adversely affecting the trial results. Cost effectiveness in medical R&D seems an appropriate iteration on the economic medicalization theme.

A final point of ethical concern can be found in the now rapidly emerging development of private research databases. Such databases are being created when clinical trials request subjects give blood and tissue samples for 'future research'. Modern technology permits these samples to be analysed to the molecular and genetic level and this information entered into the database. Such requests for blood and tissue samples are now commonplace in the consent forms and clinical trial protocols submitted to IRBs. The databases are conducive to in-house analysis by pharmaceutical companies. At present, even though the data were obtained from an approved clinical trial, there is no process to ensure that negative findings associated with experimental drugs obtained through the exploitation of the database which will be subjected to public scrutiny by the IRB (Avorn, 2006). It is fascinating that, as with other areas of marketing research, large databases appear to have become the currency of R&D in the new millennium. With the rapid development of such large scale databases in the last decade, Phase 4 studies can also be conducted in house using multivariate observational analysis, more-or-less

ensuring the privacy of the Phase 4 statistical results and avoiding problems of public scrutiny.

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Notes

- 1 As stated in the revised 2001 version, the nine principles of the AMA code are [AMA, (2006), p.xv]:
 - a a physician shall be dedicated to provide competent medical care, with compassion and respect for human dignity and rights
 - b a physician shall uphold the standards of professionalism, be honest in all professional interactions and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities
 - c a physician shall respect the law and also recognise a responsibility to seek changes in those requirements which are contrary to the best interests of the patient
 - d a physician shall respect the rights of patients, colleagues and other health professionals and shall safeguard patient confidences and privacy within the constraints of the law
 - e a physician shall continue to study, apply and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues and the public, obtain consultation and use the talents of other health professionals when indicated
 - f a physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate and the environment in which to provide medical care
 - g a physician shall recognise a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health
 - h a physician shall, while caring for a patient, regard responsibility to the patient as paramount
 - i a physician shall support access to medical care for all people.
- 2 Similar ethical codes and procedures have been established by the medical associations in other countries, e.g., the code of ethics of the Canadian Medical Association is similar to that of the AMA.

- 3 In the USA, the 'IRB' is also referred to with similar names such as the 'Independent Ethics Committee' or 'Ethical Review Board'. The purpose of the IRB is to approve, monitor and review biomedical and behavioural research involving humans. The primary motivation of IRB activities is to protect the rights and welfare of the human subjects involved in the trial. The legal authority for the IRB can be found in the legislation empowering the FDA and Department of Health and Human Services (HHS). It is the HHS regulations that specifically empower IRB's to approve, require modifications in (to secure approval) or disapprove R&D clinical trials. IRB's are governed by the Research Act of 1974, Title 45, CFR, Part 46. This legislation defines IRBs and requires that IRBs approve all research that receives funding, directly or indirectly, from HHS. Oversight of IRBs resides with the Office for Human Research Protections (OHRP) within HHS. For present purposes, Title 21, CFR, Part 56 is also important as this requires IRBs to oversee clinical trials of drugs involved in new drug applications to the FDA. In Canada, the regulatory authority for ethical issues under the Food and Drug Act resides with the 'Review Ethics Board' (REB) which is a similar counterpart to the US IRB. The REBs represent the major health catchment regions across the country. Under the Act, REB approval is required to carry out clinical trials involving humans. The corporations seeking approval from an IRB, REB or other such entity in other jurisdictions, are in most cases, multinationals that are involved in acquiring government approval to market patent protected drugs across a number of legal jurisdictions.
- 4 Writing over a decade later, this lack of cohesion in the state of medicalization research is reflected by Sismondi: 'for the most part, medicalization is discussed in terms of the politics of professions, with medical professions gaining importance as they take control over the problems and sometimes the lives and movements, of a typically disempowered group. Somewhat less frequently, medicalization is discussed in terms of the economics of healthcare industries, including associations of doctors, insurance companies and drug companies; a few cases include analyses of depression, hyperactivity, osteoporosis and sexology. The means by which economic interests shape medical knowledge and medical discourse have not been well explored'.
- 5 The following discussion relies on Poitras and Meredith (2008).
- 6 This section is derived from Meredith and Poitras (2008, Sec. 3).