Dangerous Bedfellows, Industry and Medicine: Life Savers or Disease Makers

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Abstract for Thesis (in English)

Advertising of products and services has become an accepted and integral part of everyday life, and advancements in mass media technology have made it easy to convey information to a large proportion of the population. However, when addressing health related services and products, the messages contained in today's advertisements have taken on a new purpose and tone. The healthcare industry in North America, especially pharmaceutical companies, and to a lesser extent the diagnostic imaging and the medical device industry, use direct-to-consumer (DTC) advertising to convey a message to a target population. On its face, the promotion of health awareness is an acceptable and worthy practice, but ethical concerns are raised when the health industry plays an instrumental role in creating "illnesses" or "conditions" for which they are providing treatments.

At one time, to protect health consumers, legislation and regulations prohibited directly advertising of prescription healthcare products and services to consumers, since it was thought that physicians were the ones best equipped to deal with this information. However, times have changed, and DTC advertising now is openly allowed in some countries, and in others in some narrowly specific situations.

This thesis examines the ethical and practical issues raised by this development, arguing that the negative consequences of permitting Direct-to-Consumer advertising far exceeds any positive benefits. If governments do not take an active role in preventing the further commercialization of medicine, Canada (and other countries as well) may be destined to become a nation of worried well.

Abstract pour Thèse (en français)

La publicité des produits et des services est devenue partie intégrante et admise dans la routine quotidienne, et les progrès technologiques des médias ont facilité la transmission d'informations à une grande proportion de la population. Pourtant, quand on s'adresse aux services et aux produits liés à la santé, les messages dans les annonces d'aujourd'hui ont pris une finalité et un accent renouvelés. L'industrie de la santé en Amérique du Nord, particulièrement l'industrie pharmaceutique et aussi mais de moindre importance les industries de l'imagerie diagnostique et des appareils médicaux, emploient des annonces Directes-Aux-Consommateurs (DAC) pour transmettre des messages à la population ciblée. A cet égard, la promotion de conscientisation de santé est une pratique approuvée et valorisée, mais on soulève des soucis d'ethique quand l'industrie de la santé joue un rôle instrumental à créer des "maladies" ou des "conditions" pour lesquelles elle fournit des traitements. Cette étude démontrera que les conséquences négatives de l'admission de la publicité Directe-Au-Consommateur dépassent vastement quels qu'ils soient les bénéfices positifs.

À une autre époque et afin de protéger les consommateurs de services de santé, la législation et les réglementations interdisaient la publicité directe des médicaments livrés sous ordonnance, parce qu'on considérait que les médecins étaient les plus aptes à propager cette information. Cependant, les temps ont changé, et les annonces "DAC" sont maintenant ouvertement admises dans quelques pays, et dans d'autres, seulement en situations spécifiques et limitées.

Cette thèse examine les questions éthiques et pratiques soulevées par ce développement, démontrant que les conséquences négatives découlant de la permission de la publicité Directe-Au-Consommateur surpassent tout bénéfice. Si les gouvernements ne s'engagent pas dans un rôle actif pour interdire encore plus lacommercialisation de la médecine, le Canada (et aussi d'autres pays) peut être destiné à produire une population en bonne santé mais malade d'inquiétude.

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Introduction

Today the advertiser's message is difficult to escape. Television viewers endure at least 15 minutes of commercials every hour; magazines offer more advertisements than stories; radio announcements recruit participants for consumer studies; internet surfers are barraged by unwanted pop-up advertising on their computer screens; and newspapers are a source of word-of-mouth and product studies. Moreover, advertisements target more important concerns than household products and services, especially when they are fabricated to influence decision-making about health. A seemingly endless array of advertisements commercializing medicines or pharmaceuticals attract the attention of individuals exposed to these messages. For example, strategically sound advertisements are likely to: influence consumer action for pharmaceutical products, procure sample participants for clinical trials, encourage painful cosmetic procedures, and promote diagnostic tests for potential medical conditions.

Healthcare is a multi-billion dollar business with an intricate network of participants, including front line healthcare providers, researchers, manufacturers, and private business entrepreneurs who establish services such as diagnostic imaging centres outside the healthcare system. As well, many educational institutions have been established to educate these healthcare providers. However, health consumers are the largest number by far of those participating in the business of healthcare.

Most Western industrialized nations spend more on healthcare than on any other single area of expenditure. For example, many nations spend a significant portion of their Gross National Product (GNP) on healthcare. In 2001, Canada spent 9.7% of GNP on

healthcare, whereas the United States' spending was in the double digits at 13.9%.[1] In light of such numbers, it is not difficult to understand that healthcare perceived as a business has a substantial and expanding market. In his book *Worried Sick: Our Troubled Quest for Wellness*, Arthur Barsky observes that "our society devotes enormous human and economic resources to studying the body, staying healthy and treating disease,"[2] although at the same time "every infirmity and every ache seem to merit treatment" so that "we have medicalized a whole range of human miseries and misfortunes."[3] This increasing medicalization of society—particularly in developed nations—has fostered the commercialization of medicine, which has become a multi-billion dollar industry and a public relations sensation. Selling sickness, or at least persuading people to believe they could be sick, is a thriving business.

Certain drugs have been garnering significant media attention of late. One such drug is sildenafil citrate (*Viagra*), an impotence agent. This prescription drug is specifically aimed at North America's growing problem with concerns surrounding male erectile dysfunction. Instead of identifying its product by name (which is prohibited under current Canadian legislation), the most recent Canadian television advertisement for *Viagra* portrays two older men on a golf course. When one man is about to tell the other what he did "last night," a blue tablet appears in front of his mouth, cutting off his spoken reply. This image is followed by a written message across the bottom of the television screen informing the viewer to see their physician. Although neither the drug's name nor the reason for seeking a physician are mentioned, the underlying message is

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[1] Uwe Reinhardt, Peter S. Hussey, and Gerard Anderson. "U.S. Health Care Spending In An International Context: Why Is U.S. Spending So High, and Can We Afford It?" *Health Affairs* 23.1 (2002): 11.
[2] Arthur Barsky. *Worried Sick: Our Troubled Quest for Wellness* (Toronto, Canada: Little, Brown & Company, 1988) 7.
[3] Barsky 9.

clear to the viewer: taking this blue pill will cure male sexual dysfunction. Moreover, since entire sections of news broadcasts and newspapers now are devoted to health and illness issues, promoting the latest tests, drugs, and treatments available on the market, it is very difficult to avoid them.

Although traditionally physicians were the gatekeepers of medical information and the professionals who provided this knowledge to the public, however today, the mass media and the Internet assume this role. In the past, legislation and regulations were an added protection to ensure that medical information was targeted at physicians so they could best disseminate it to their patients. However, this process has changed drastically and now is known as direct-to-consumer (DTC) advertising. DTC advertising permits drug and other medical industries to provide medical information directly to the consumer, thereby, in many instances, effectively bypassing the physician's "gatekeeper" role. Within the past decade, these industries have metamorphosed health advertising into a multi-billion dollar business that directly targets the healthcare consumer.[4]

In itself, DTC advertising may not seem to be significantly different from other advertising forms. However, this assumption is mistaken. The medical industry, namely the pharmaceutical and medical device industries, private diagnostic clinics, and the health care rehabilitation industry are not necessarily in business to "solve" the medical problems of the world. Rather, they are accountable to their shareholders by way of greater profit margins. "According to economic theory, for-profit firms do not engage in promotional activities for the betterment of public health and welfare."[5] This is not to say

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[4] Mollyann Brodie and Larry Levitt. "Drug Advertising: The Right or Wrong Prescription for Our Ailments?" *Nature* 1 (2002): 916.

[5] K. Kaldor. "The Economic Aspect of Advertising." *Review of Economic Studies* 18 (1950): 1-27 as cited in Steven Morgan, Barbara Mintzes and Morris Barer. "The Economics of Direct-to-Consumer Advertising

that industry never partakes in activities that promote health, as corporate sponsorship is necessary for the operation of many disease awareness campaigns and fund raising efforts. But ultimately, industries fiduciary responsibility lies with their shareholders and in order to maximize profits, marketing strategies are aimed at health consumers.[6] Over the years, the commercialization of medicine and the "selling" of sickness have become growing trends. In response to this phenomenon, Lynn Payer, the late medical writer, used the term "disease mongering" to describe what she considered a means of:

> trying to convince essentially well people that they are sick, or slightly sick people that they are very ill ... For people to use a diagnostic product or service, they must be convinced they MAY BE sick. And to market drugs to the widest possible audience, pharmaceutical companies must convince people—or their physicians—that they ARE sick.[7]

Payer also noted another disturbing element of disease mongering in what appears to be the creation or evolution of new diseases, conditions and syndromes for which one must be treated or, according to those making the claims, likely suffer dire consequences. From this perspective, those who claim not to suffer from a new disease or syndrome are only denying the serious nature of their illness.

The purpose of this dissertation is to explore the growing concerns surrounding the commercialization of disease and examine the role that DTC advertising plays in commercializing illness. The literature review includes studies directly related to the actual and perceived effects that DTC advertising has, or could have, on health professionals, consumers, and others. To provide context, the study begins with a review of the historical evolution of the medical regulation of this phenomenon. Some authors

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of Prescription-Only Drugs: prescribed to improve consumer welfare? *Journal of Health Services & Research Policy* 8.4 (2003) 238.

[6] Morgan et al. 238.

[7] Lynn Payer. *Disease-Mongers: How Doctors, Drug Companies, and Insurers Are Making You Feel Sick* (Toronto, Canada: John Wiley & Sons, Inc, 1992) 5.

argue that DTC advertising directed at health issues is beneficial to all involved, whereas others firmly believe that this kind of advertising—especially when directed to little known and "new" conditions, or to disorders that possibly could be managed better by other means than those being advertised—is causing more harm than good. In concluding, this paper determines whether stricter measurers for DTC advertising need to be established and, more importantly, enforced. In the absence of reform we risk creating a "nation of healthy invalids, crippled not by disease but by the idea of disease."[8] Several "conditions,"—generalized anxiety disorder, social anxiety disorder, menopause, female sexual dysfunction, and cosmetic considerations—are addressed to provide further evidence to support this author's position on DTC advertising and the commercialization of medicine.

[8] Payer 17.

Chapter 1

FROM GATEKEEPER TO INDUSTRY PARTNERS: THE EVOLUTION OF DTC ADVERTISING

In most of the industrialized world, laws or other regulatory instruments govern drug marketing, and Canada and the United States are not exceptions to this norm.[9] However, these instruments are relatively recent innovations when one considers the evolution of healthcare. Historically, physicians have utilized unorthodox methods of treatment that often were seen as "heroic," for example, bloodletting, the application of leeches, and induction of vomiting through various means.[10] The basis for these types of therapeutic approaches dates to the second century, when Galen symbolized their use as a means to restore "harmony among the four essential bodily humors"—air (blood), fire (yellow bile), earth (black bile), and water (phlegm).[11] Regrettably, these approaches persisted for centuries, and those who peddled potions and tonics as alternative means for treating illness often were despised for preying on the vulnerable by taking money for treatments that physicians considered to have no value.

As the nineteenth century progressed, medicine became more reliant on quantitative methods of research, and overall became a more scientifically based practice. Importantly, this era witnessed the advent of antiseptic techniques for treating surgical

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[9] Kari S. Lankinen, et al. "Industry Guidelines, Laws and Regulations Ignored: Quality of Drug Advertising in Medical Journals," *Pharmacoepidemiology and Drug Safety* 13 (2004): 789-795.
[10] Rosa Lynn Pinkus. "From Lydia Pinkham to Bob Dole: What the Changing Face of Direct-to-Consumer Drug Advertising Reveals about the Professionalism of Medicine," *Kennedy Institute of Ethics Journal* 12.2 (2002): 143.
[11] Martin Pernick. *A Calculus of Suffering: Pain, Professionalism and Anesthesia in the Nineteenth-Century America* (New York: Columbia University Press, 1985). As cited in Pinkus 143.

wounds. A result of research conducted by Dr. Joseph Lister,[12] the mortality rate from amputations decreased by 50%. No less significantly in the early part of the century, Dr. Edward Jenner produced the first vaccination against disease (the small pox virus). In addition, the later part of the nineteenth century saw the evolution of electromagnetic radiation known as x-rays.[13] Yet even with all these advances, society still was somewhat leery of the work physicians performed.[14]

Sick and injured individuals often sought alternative means to treat their medical ailments. Many individuals felt "that the medical trade was a recent conspiracy, designed to cheat the laity out of both their health and money," and "healing had been corrupted from paternalism to professionalism."[15] Since medical programs varied in length from a few months to two years, enormous disparities existed between the "formal" medical training and the theories physicians professed.[16] In addition, although *materia medica*[17] was always a part of North American medical school education, it had a limited role in the curricula until the beginning of the twentieth century. Many in the medical

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[12] John Mann. *Murder, Magic and Medicine*, 2nd Ed. (New York: Oxford University Press, 2000) 146.
13 Robert Adler. *Medical Firsts: From Hippocrates to the Human Genome.* (Hoboken, New Jersey: John Wiley & Sons Inc., 2004) 118-124.
[14] The term "physician doctor" carried many meanings. Formally trained physicians were denoted as "regular physicians" and usually were middle class males often trained to utilize heroic measures. The term "surgeon" denoted a lower class of physicians whose work was seen as a skill involving the hands and often taught via apprenticeship. Parallel to the surgeon was the "apothecary"— the physician's underling (the forerunner to the modern day pharmacist)—who dispensed medications. The "lay physicians" were those who had no formal medical training but practiced the art of healing.
[15] Andrew Wear. *Medicine in Society* (Cambridge, U.K.: Cambridge University Press, 1992) 98.
[16] Barbara Ehrenreich and Deirdre English, "Witches Midwives and Nurses: A History of Women Healers," *The Feminist Press*, 1st Ed. (New York: Feminist Press, 1973) 23.
[17] See Douglas Anderson et al. *Mosby's Medical, Nursing, & Allied Health Dictionary*, 5th Ed. (St. Louis, Missouri: Mosby Inc, 2002) 1057. "Materia medica" is defined as "the study of drugs and other substances used in medicine: their origins, preparations, uses and effects."

community—including leading physicians within the well established European medical community—still harboured feelings of doubt and scepticism toward many of the known remedies/drugs of the day in relation to their effectiveness and association to magic and superstition. Moreover, they expressed these views to the established North American medical institutions.[18] For example, in his 1860 lecture before the Harvard Medical School, the prominent physician Dr. Oliver Wendell Holmes's Sr. stated: "If the whole materia medica could be sunk to the bottom of the sea it would be all the better for mankind and all the worse for the fishes" with a few exceptions, such as opium.[19] With these disparities within both the established and non-established sects of the medical community, it is not difficult to understand why society often has held negative views towards physicians.

This mistrust and lack of confidence in the physicians of the era led to the continuing popularity of alternative healers and their wares. They were a more modern day version of quacksalvers,[20] individual entrepreneurs who peddled their tonics and treatments in person and in print. Nonetheless, the physicians of this time held true to their beliefs and refused to use the alternative healers' patented medicine to make a profit from those who were ill.[21]

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[18] John Parascandola. "John J. Abel and the Shaping of a Discipline," *The Development of American Pharmacology* (Baltimore, Maryland: The John Hopkins University Press, 1992) 6-15.
[19] Pinkus 143.
[20] See Evan Morris. "It Looks Like a Duck and Walks Like a Duck, But It Charges $300.00 for an Office Visit," *The Word Detective* (June 11, 1997). As cited in Pinkus 152 as to availibility at <http://www.word-detective.com/bacl-j2.html#quack>. According to Morris, the use of the work "quack" dates back to the sixteenth century, when people "began to use 'quack' to describe the sound made by itinerant patent medicine salesmen made as they hawked their wares. These charlatans, who boasted endlessly about the miraculous properties of the ointments and potions they sold, were known as 'quacksalvers'- they 'quacked' about their 'salves.' The term 'quacksalver' was quickly shortened in common usage, giving us 'quack'."
[21] Pinkus 146.

For example, in 1847, the Philadelphia College of Physicians—the oldest and most prestigious medical organization of the time—condemned the use of ether because it represented an example of "the spirit of commercialism infiltrating into medicine."[22] In the same year, the American Medical Association (AMA) was established. Part of the rationale for the creation of this establishment was to create a professional lobby group for the preservation and advancement of medical knowledge via publications, meetings and licensing. The other motivation concerned the growing resentment that physicians felt towards "their 'unorthodox' colleagues, the homeopathics, eclectes, and midwives." These physicians perceived that the unregulated individuals who possessed and practiced different diagnoses and treatment patterns posed both a personal and financial threat to their livelihood. Membership in the AMA provided a means of protection against competition.[23] Although not as quick to establish a national association, in 1906, Canada's physicians formed the Medical Council of Canada (the precursor to the Canadian Medical Association) both as a means to disseminate knowledge and to protect the interests of their members.[24]

This manner of thinking continued until the turn of the twentieth century when the AMA recognized that there was no way to prevent the use and distribution of patented drugs in the marketplace, especially since many of their own members were prescribing them. At the same time, the North American pharmaceutical industry was continuing to grow as a direct result of their parent German companies' ongoing scientific research, which was developing and testing new chemical substances for their therapeutic

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[22] Pinkus 146.
[23] Jacalyn Duffin. *History of Medicine: A Scandalously Short Introduction* (Toronto, Canada: University of Toronto Press, 1999) 120.
[24] Duffin 122.

benefits.[25] As well, it was becoming evident to drug manufacturers that physicians were gaining a stronger presence in society largely due to new and advanced medical treatments and technologies. Subsequently, both parties acknowledged the benefits of working together rather than challenging the legitimacy of the other group.[26]

The United States Regulatory Approach to DTC Advertising

For the greater part of the twentieth century, physicians in the United States remained the gatekeepers for all forms of medications—both prescription and over-the-counter (OTC)—even though a greater allegiance continued to foster between them and the pharmaceutical industry. Historically, the passage of the 1906 *Pure Food and Drugs Act* not only standardized the drugs outlined in the Pharmacopeia[27] and National Formulary,[28] but also formally sealed the relationship between industry and medicine. This *Act* was an attempt to decrease the exaggerated claims being made for various drugs and to monitor compliance with federal labelling requirements for drug products.[29] In addition, the 1914 *Federal Trade Commission Act (FTC)* was the federal government's attempt to regulate the therapeutic claims of the drug industry—to regulate against false and misleading drug claims.

It was not until 1938 that Congress finally passed the Wheeler-Lea amendment to address the ambiguity of the *FTC* and food and drug regulations, making "false

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[25] Parascandola 103.
[26] Pinkus 150.
[27] Anderson, et al. 1156. The "Pharmacopeia" is a compendium containing descriptions, recipes, strengths, standards of purity, and dosage forms for selected drugs.
[28] Anderson, et al. 1329. The "National Formulary" is a listing of drugs intended to include a large enough range of medications and sufficient information about them to enable health practitioners to prescribe treatment that is medically appropriate.
[29] Keith B. Leffler. "Persuasion or Information? The Economics of Prescription Drug Advertising." *Journal of Law and Economics* 24.1 (1981): 49.

advertising for the purpose of inducing the sale of an article injurious to health" a violation of the *FTC* regardless of the competitive effects.[30] This amendment also effectively established prescription-only status and provided the Food and Drug Administration (FDA) with regulatory control over pharmaceuticals. Since written material describing many OTC drugs was not readily understandable by the layperson, it was easier to designate a drug as prescription only, and thereby put the onus back on the physician to determine whether the drug would be valuable for the patient. Although this change was meant to provide a safety net for health consumers, much of the information that physicians received about drugs still came from pharmaceutical representatives who were in the business of aggressively promoting their companies' products. Unfortunately, since the Wheeler-Lea amendment still permitted unregulated advertising to physicians who dispensed the drugs, tragedy resulted when almost 100 people died after taking the heavily promoted sulpha drug elixir.[31]

This pattern of monitoring and regulating prescription drug advertising established in the late 1930s continued until tragedy struck again. In 1962, the thalidomide disaster finally forced the FDA to revisit their stance on prescription drug advertising. Even though long before this catastrophe, concerns had been expressed to the US Senate about how pharmaceutical promotions directed to physicians were misleading, uninformative, and led to high drug costs. Together, these culminating concerns inspired amendments to the *Food, Drug and Cosmetic Act* which would now regulate all forms of communication between the medical community and drug industry,

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[30] Leffler 49.

[31] Barbara Mintzes. "An Assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines (DTCA)," *Volume II: Literature Review: Direct-to-Consumer Advertising of Prescription Drugs: What Do We Know Thus Far About Its Effect on Health and Health Care Services?* (Vancouver: UBC Centre for Health Services and Policy Research, 2001) 6.

meaning that drugs only could be promoted for approved uses and that all promotional material including journal advertisements would be scrutinized by the FDA.[32] Although these stricter regulations and harsher penalties were imposed, the pharmaceutical industry continued to thrive and became a staple of the American economy. The prohibition against the pharmaceutical industry advertising to the health consumer remained virtually unchanged until the 1980's.[33]

In the early 1980s, the pharmaceutical industry appealed to the FDA to permit DTC advertising under the auspice that it would be an educational benefit and a means to promote patient autonomy. In 1983 in response to this request, the FDA issued a voluntary moratorium on DTC advertising while it considered making changes to its policy. In 1985, the FDA lifted the moratorium.[34] Providing this greater latitude was the beginning of the end of the FDAs control over DTC advertising in the healthcare industry as a whole. The relaxed FDA regulations stipulated that DTC advertisements must include a brief summary of indications, side effects, and contraindications, and made advertising outside magazines and newsprint difficult. However, it did not stop the growth of the medical market that included specialty services such as private imaging centres.[35] Even though industry initially was slow to take advantage of this potentially lucrative opportunity to expand their position in the market place, in the 1990s DTC advertising flooded the media.

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[32] Leffler 52.
[33] Pinkus 141
[34] Martin S. Lipsky and Christine A. Taylor. "The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising." *Journal of Family Practice* 45.6 (1997): 496.
[35] Robert A. Bell, Richard L. Kravitz, and Michael S. Wilkes. "Direct-to-Consumer Prescription Drug Advertising, 1989-1998," *Journal of Family Practice* 49.4 (1998): 330.

When the FDA proclaimed the *Modernization Act* of 1997—which permitted broadcast advertising of prescription drugs—it lost significant control over DTC advertising. Moreover, even though guidelines were established for broadcast advertising, including the requirement "to reference a print ad, to provide an '800 number' and an Internet site, and to specify the availability of consumer information from one's physician or pharmacist,"[36] important information remained absent. The effects of these guidelines could be seen as inconsequential at best, since the 1997 *Act*

> "loosened the restrictions on the kind of information that pharmaceutical companies could share with physicians regarding 'off label' uses of their drugs, and subsequently, the information that must be included in direct-to-consumer advertisements."[37]

As well, any requirement for the full disclosure of potential harmful effects were noticeably absent. No responsibility was placed on advertisers to disclose their source of funding, or reveal that other available drugs on the market may be just as effective for a fraction of the cost. In 1999, just two years after enactment of the *Modernization Act*, the pharmaceutical industry was the most profitable industry in the U.S., with an 18.6% return on revenue. Perhaps not surprisingly, it has tripled its annual spending on DTC advertising between 1996 to 2000.[38] In 2003, a Harvard Public Health study found that

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[36] Pinkus 153.

[37] Peter Conrad and Valerie Leiter. "Medicalization, Markets and Consumers," *Journal of Health and Social Behavior* 45 (2004): 160. Off-label and unlabeled uses are used synonymously. "Off label uses of FDA approved drugs is one of the easiest routes to the expansion of medical markets. Once a drug has been approved for one use or population, it can be prescribed for broader purposes." Conrad and Leiter 171. An example includes: Olanzapine which is classified as an atypical antipsychotic used in the treatment of psychosis, namely schizophrenia which has the off-label use as an appetite stimulant and is prescribed for individuals with eating disorders, as a major adverse effect of this drug is weight gain. However current literature strongly suggests that Olanzapine is associated with the development of Type II diabetes in individuals taking this drug. See Michael Sernyak et al. "Association of Diabetes Mellitus with Use of Atypical Neuroleptics in the Treatment of Schizophrenia," *American Journal of Psychiatry* 159.4 (2002):561 and Michael E.J. Lean and Frank Pajonk. "Patients on Atypical Antipsychotic Drugs: another high-risk group for type 2 diabetes," *Diabetes Care* 26.5 (2003): 1597.

[38] Conrad and Leiter 161.

"for every $1 spent on direct advertising, drug companies reaped an additional $ 4.20 in sales."[39]

The FDA has realized that they have opened Pandora's box and unwittingly given away any control they once had to regulate DTC advertising. Since the pharmaceutical industry is such a powerful force in the American economy in terms of employment and market presence, trying to enforce new or even existing regulations is an almost insurmountable task. Although some pharmaceutical companies comply with the FDAs request to have their ads screened prior to being aired, corporations regard this request as an infringement on "freedom of trade" and simply ignore it.[40] Moreover, in January 2005, the AMA, the largest medical association in the U.S., rejected a proposal to support the ban on the advertising of prescription drugs aimed at health consumers, although they did agree to further study the topic.[41] Without regulations outlining specifically what information advertisements may or may not contain, the FDA is no longer able to ensure that false and misleading advertisements will not reach consumers, which in turn could have serious consequences on consumers health.

The Canadian Regulatory Approach to DTC Advertising

Currently, the United States and New Zealand are the only industrialized nations that permit direct advertising of prescription drugs to the public. However, both the European Union and Canada are reviewing their existing legislation.[42] In 1949, as a

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[39] Jeanne Lenzer. "American Medical Association Rejects Proposal to Ban Consumer Adverts for Prescription Medicines," *British Medical Journal* 331(2005): 7.
[40] Pinkus 153.
[41] Lenzer 7.
[42] Barbara Mintzes, et al. "How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing? A Survey in Primary Care Environments With and Without Legal DTCA," *Canadian Medical Association Journal* 169.5 (2003): 405.

means of protecting healthcare consumers from injury and deception, the Canadian government through Health Canada under the *Food & Drugs Act* strictly prohibited DTC advertising of prescription drugs. The *Act* further specified that treatments, preventatives, or cures for the diseases listed in Schedule A of the *Act* could not be advertised to consumers.[43] This legislation was designed to effectively prohibit the promotion of the following three types of prescription drug advertisements to the health consumer: *product claim advertisements* which include both the product name and specific therapeutic claims, *reminder advertisements* which provide the name of a product without stating its use, and *help-seeking advertisements* which inform consumers of new but unspecified treatment options for diseases or conditions.[44]

The most significant amendment to this legislation since its inception came in 1978, permitting pharmacies to advertise price comparisons. It stated:

> Where a person advertises to the general public a Schedule F Drug (a prescription drug), the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug. [45]

This amendment allowed competition between pharmacies and was designed to benefit consumers through competitive pricing. At the same time, it also remained mandatory for manufacturers to supply full monographs in professional journals for advertising purposes. However, a 1996 policy statement indicated that Health Canada was ready to relax its interpretation of the *Act*[46] by recognizing "the importance to the pharmaceutical industry and the general public of being able to disseminate and access no promotional

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[43] Mintzes "An Assessment of the Health System Impacts..." 15-16.
[44] David M. Garner, Barbara Mintzes, and Aleck Ostry. "Direct-to-Consumer Prescription Drug Advertising in Canada: Permission by Default?" *Canadian Medical Association Journal* 169.5 (2003): 425.
[45] Health Products and Food Branch, Health Canada. Direct-to-consumer advertising of prescription drugs [discussion document]. 1999 April 6. As cited in Garner et al. 425.
[46] Garner et al. 425.

information regarding drugs for human use."[47] As a result, this relaxed policy effectively permitted help-seeking and reminder DTC advertising. For example, reminder ads could contain the name, quantity, and price of medications used during influenza season.[48]

The interpretation, enforcement, and resolution of complaints concerning drug advertising ultimately lies within the purview of Health Canada. Nevertheless, two voluntary organizations—the Pharmaceutical Advertising Advisory Board (PAAB) that oversees prescription drug advertisements for health professionals, and Advertising Standards Canada (ASC) that oversees OTC drug advertising to health consumers—have been enlisted to assist with the review of advertising material for drugs.[49] However, drug manufacturers' submission of advertising material to these two parties is on a voluntary basis.

Moreover, the enforcement of the existing legislation calls into question its effectiveness. In 2000, a television advertisement for the drug *bupropion*, a known anti-depressant with a secondary use as an adjunct for smoking cessation, was marketed under the name *Zyban*. This advertisement was in direct contravention of the law, yet it was permitted to air for months before its removal.[50] More recently, the Canadian market has been flooded with advertisements for the drug *Viagra*. How can an advertisement showing a man jumping in the air to the song "We are the Champions" not be seen as directly promoting a drug?[51] It would be an incredible leap for the manufacturers of

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[47] Dann M. Michols. The distinction between advertising and other activities [policy statement]. Ottawa: Health Canada, Therapeutic Products Programme; 1996. As cited in Garner et al. 425.
[48] Garner et al. 425.
[49] Mintzes 9.
[50] CBC-TV Undercurrents "The battle over a drug ad." [Transcript, Canadian NewsDisk]. 2001 Feb. 4. As cited in Garner et al. 425-426.
[51] Barbara Mintzes. "Direct-to-Consumer Prescription Drug Advertising: Health Canada's Proposals for Legislative Change," Conference Paper presented at the Canadian Health Coalition and Health Action International (HAI-Europe). 2004; January 1-8 at 3.

Viagra to argue that they are promoting an unspecified treatment option for such a condition. What makes this type of advertising even more problematic is that it leaves the viewer with the false and misleading impression that this "unspecified treatment" will cure the problem without any side effects. Even though this kind of advertising directly contravenes the regulations established by Health Canada, authorities have failed to respond at a level which would be expected for such a breach.

In addition, increasing pressure has been directed towards the federal government to replace the federal *Food & Drugs Act* with the new proposed *Canada Health Protection Act*. This proposed change would permit DTC advertising of prescription drugs and eliminate Schedule A of the *Act*—the list of serious diseases for which manufacturers may not advertise treatments, preventatives, or cures to the public.[52] Mounting pressure for these changes has come from many directions, the biggest supporters being the pharmaceutical manufacturers. Yet surprisingly, two of the strongest opponents—the Canadian Medical Association and Canadian Pharmacists Association—are organizations that could potentially benefit through increased revenues.[53] These two organizations have joined forces with the Consumers' Association of Canada and the Canadian Health Coalition to oppose changes that would effectively see industry sponsored DTC advertising become the accepted norm. The aim of these organizations is not to ban DTC advertising or to limit consumer access to health information, but to provide consumers "with independently developed, balanced, comparative information on a full range of medical treatments through publicly funded alternatives."[54]

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[52] Mintzes "Direct-to Consumer Prescription Drug Advertising Health Canada's Proposals..." 1.
[53] Garner et al. 426.
[54] Garner et al. 425-426.

As a response to this growing pressure to make changes to Canada's existing DTC advertising legislation, the Standing Committee on Health was convened to specifically study the issues surrounding prescription drugs, with a focus on clinical trials, post-market surveillance, and direct-to-consumer advertising. In 2004, this committee presented its first report to the Canadian Parliament.[55] The Committee recommended that:

- Health Canada immediately enforce the current prohibition of all industry-sponsored advertisements on prescription drugs to the public;
- Health Canada ensure the provision of independent, unbiased and publicly financed information on prescription drugs to Canadians;
- Health Canada dedicate specific resources to the Health Products and Food Branch Inspectorate for vigorous enforcement of the direct-to-consumer advertising regulations on prescription drugs, including active surveillance of all relevant media, identification of potential infractions, appropriate corrective action, and production of annual public reports;
- Health Canada ensure that all direct-to-consumer advertising complaints about prescription drugs received by Advertising Standards Canada or the Pharmaceutical Advertising Advisory Board are forwarded to Health Canada for investigation and action.

As of 2005, the push for changes to DTC advertising legislation is at an impasse.

DTC Advertising: Who Is The Winner?

In the 1920s, long before DTC advertising of medical treatments, drugs, and tests became a prevalent and pervasive practice, economist Stephen Leacock characterized advertising as "the science of arresting the human intelligence long enough to get money

[55] Bonnie Brown. "Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs." *Report of the Standing Committee on Health.* Ottawa: Communication Canada Publishing, 2004 1-34.

from it."[56] Since DTC advertising is a multi-billion dollar business that saw profits from television ads in the U.S. alone increase sevenfold between 1996 and 2000, it would be a fair assessment to say that Leacock knew what he was talking about.[57] More recently in the 1970s, a physician—Dr. Ingelfinger—suggested that advertising should be recognized for what it really is: "an unabashed attempt to get someone to buy something."[58] This statement certainly could not be challenged in today's health market when pharmaceutical and other health related industries so often post record profits.

The Impact of DTC Advertising

In its second report on the use of essential drugs, the World Health Organization (WHO) established ethical criteria for the management of medicinal drug promotion (for both prescription and over-the-counter drugs) as a way to support and encourage the improvement of healthcare.[59] WHO found that such promotions should be consistent with national health policies and in compliance with national regulations, as well as with voluntary standards where they exist. All promotion-making claims regarding medicinal drugs should contain reliable, accurate, truthful, informative, and balanced information, and should not contain claims that might mislead or promote unverifiable statements. In addition, medicinal drug promotion should never foster omissions which could lead to health risks, and should not be designed to disguise their real economic nature, for

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[56] Sidney Wolfe. "Direct-To-Consumer Advertising-Education or Emotion Promotion?" *The New England Journal of Medicine* 346.7 (2002): 524-525.
[57] Debabrata Mukherjee and Eric J. Topol. "Pharmaceutical Advertising Versus Research Spending: Are Profits More Important Than Patients?" *American Heart Journal* (2003): 563.
[58] F.J. Ingelfinger. "Advertising: Informative But Not Educational." *The New England Journal of Medicine* 286 (1972): 1318-1319. As cited in Mukherjee and Topol 563.
[59] WHO. *The Use of Essential Drugs: Second Report of the WHO Expert Committee on the Use of Essential Drugs*. Geneva: WHO Technical Report Series No. 722 (1985) 43.

example, as educational or scientific activities.[60] The WHO also specifically addressed advertisements and noted that those directed towards health consumers should help them make rational decisions on the use of drugs legally available without a prescription. WHO guidelines further state that the legitimate desire of health consumers to receive health information should be taken into account, and there should not be an undue attempt to take advantage of their concern for their health. As well, the WHO felt that the advertising of prescription drugs, or the promotion of drugs for certain serious conditions that could only be treated by qualified health practitioners, generally should not be permitted.[61] Although the WHO has declared its position on this matter, the reality is that its members do not have an obligation to follow its criteria.

In 2003, several officials from WHO voiced their concerns in *The Lancet* by publishing a statement denouncing Pfizer's advertising and promotion tactics regarding its cholesterol-lowering agent *Lipitor.* These members felt that a print advertisement displaying a corpse in a morgue accompanied by the caption—"A simple test of blood cholesterol could have avoided this"—did not address the commonly accepted factors contributing to high cholesterol such as obesity, poor diet, and a sedentary lifestyle. Instead, this advertisement portrayed a drug as the key to solving the problem of high cholesterol.[62] This statement indicated that Pfizer's advertising campaign was not "accurate, informative, or balanced," but rather misleading and likely to induce "unjustifiable drug use."[63] The WHO has been vocal over the years regarding DTC advertising. However an international organization such as the WHO has no power to

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[60] WHO Resolution. *Ethical Criteria for Medicinal Drug Promotion.* Geneva: Resolution WHA41.17 1988
[61] WHO. "Ethical Criteria ..."
[62] Ray Moynihan and Alan Cassels. *Selling Sickness: How the World's Biggest Pharmaceutical Companies are Turning Us All Into Patients.* Vancouver, Canada: Greystone Books 2005 14-15.
[63] Moynihan and Cassels 15.

sanction, only to condemn, unethical marketing practices. As a result, the ability of this organization to promote universal health standards becomes difficult when they are challenging the business practices of some of the worlds most powerful health industries. To effectively regulate these practices so they favour the legitimate needs of the health consumer, change must be generated from within each individual country.

If Canadian policymakers should decide to change the government's current position on DTC advertising and follow US in terms of permitting unbalanced and potentially misleading information regarding drugs, the ethical criteria established by the WHO would certainly be challenged. One would think that prior knowledge of the U.S. experience with loosening the ban on DTC advertising would motivate Canadian policymakers not to introduce sweeping changes to permit it. Rather, Canada should be more stringent in its policy for DTC advertising and address on breaches in a timely and appropriate manner as recommended by the Standing Committee on Health.

If DTC advertising is so beneficial, why is there such intense lobbying to ban its practice in New Zealand—the only other industrialized country aside from the U.S. that openly permits DTC advertising? With the introduction of the *Medicines Act* in 1981, New Zealand openly permitted DTC advertising of both prescription and non-prescription medications, since no legislative provisions in the *Act* prohibited its practice.[64] Not until 1998 was the first review of this policy carried out when the Minister of Health called for an inquiry, an action motivated by the mounting concerns about the rapid growth of this advertising activity.[65] As a result, the government

[64] Les Toop et al. "Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?" Report to the Minister of Health supporting the case for a ban on DTCA. New Zealand Departments of General Practice, 2003.
[65] Toop 1.

instituted a "watch-and-see approach" to observe the effects of industry self-regulation before deciding on the next course of action. Subsequently, in 2000, the Minister of Health initiated a second review "to solicit feedback on the appropriateness of DTCA of prescription medicines in New Zealand and to form the basis for advice to the Minister of Health on any changes that may be required to the current DTCA regime."[66] This second review found that a majority of the submissions supported a ban, or at least a swift and significant tightening of regulations, on DTC advertising. One of the largest and most vocal supporters of the ban was a lobby group led by professors of general medical practice from all four of New Zealand's schools of medicine. This group demonstrated their position on DTC advertising in a detailed report—"Direct to Consumer Advertising of Prescription Drugs in New Zealand: FOR HEALTH OR FOR PROFIT?"—submitted to the Minister of Health in 2003.[67] Thus far, even with overwhelming support from the prescribers of prescription medicines and two formal governmental reviews calling for reform, no change has yet materialized. Perhaps Canada could learn from the U.S. and New Zealand experiences—their continuing struggles to reform current legislation and policy on DTC advertising—and soberly consider whether the pharmaceutical industry and their media partners should control the information health consumers receive.

[66] Toop 1.
[67] Toop 1.

Chapter 2

ETHICAL CONSIDERATIONS

It cannot be denied that modern medicine has, and will continue to have, much to offer individuals suffering from legitimate medical conditions. Nevertheless, a more cautious approach is warranted when considering the impact of medicine setting its sights on the "well." Under no circumstances does this approval mean stopping or curbing illness prevention and health education; rather it means understanding the difference between convincing people that they are ill, versus educating them on how to stay healthy and prevent illness, or at least lessen illnesses' effects.

The crucial questions one must ask when examining the ethical implications of DTC advertising: Does it promote health consumers' well being? Does it assist physicians in fulfilling their professional obligations? Does it benefit the healthcare system to the advantage of Canadian society as a whole? Through the application of a principled/consequentialist ethical framework, these questions will be explored in terms of actual and potential, and negative and positive consequences. When examining the negative consequences of DTC advertising, a key area that has had, and continues to receive, significant attention is the compromising of health consumer safety. This is often attributed to misleading, biased and inaccurate research, usually resulting from conflicts of interest in the medical industry. The economic implications also will be addressed especially in relation to the increasing pharmaceutical costs, their direct impact on health consumers, organizations and governmental agencies. Finally, the affect DTC advertising has had, or may have, on the physician/patient relationship is examined.

In terms of the actual and potential positive consequences of DTC advertising, the role of the health consumer is vital. Empowerment through education and self-awareness places the ownership of one's health squarely within the individual's grasp. As well, autonomy is encouraged and fostering truth-telling, as well as strengthening a "partnership" between the physician and patient.

Nevertheless, while examining the ethical implications that DTC advertising has, or may have on, Canadian society, the relationship between the medical industry and the media establishment (and this relationship's potential affects) cannot be forgotten. It is not inconceivable that this relationship may contribute to convincing people that they are sick as "medicalization narrows the definition of health and widens the definition of sickness."[68] Howes and Salkovskis believe that the "culture of journalism has an interest in making a disease sound as serious and as widespread as possible. It simply makes a better story, one that will make the front page and the journalist's career."[69] As national spending on prescription drugs have more than tripled in the US in the past 10 years[70], Howes' and Salkovskis' speculation of the role journalism would play in disease "awareness" appears to have come to pass.

A well known phenomenon reported by clinical instructors is that medical students often begin to develop fears about, and symptoms of, the diseases they are studying.[71] Many terms have been used to describe this state, which best can be described as a mild form of health anxiety or transient hypochodriasis.[72] Some of the

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[68] Conrad and Leiter 171.
[69] Payer 59.
[70] Andrew Robinson et al. "Direct-to-Consumer Pharmaceutical Advertising: Physician and Public Opinion and Potential Effects on the Physician-Patient Relationship." *Archives of Internal Medicine* 164(2004): 427.
[71] Oliver Howes and Paul Salkovskis. "Health Anxiety in Medical Students." *The Lancet* 351 (1998): 1332.
[72] Howes and Salkovskis 1332.

most common descriptions are: medical student's disease, medical studentitis, hypochondriasis of medical students, and nosophobia. Generally, the duration of the condition is relatively short lived but often repeated as new diseases and their symptoms are learned.[73] Two studies completed in the 1960's—important contributions to the limited research into this significant phenomenon—suggested that over 70% of medical students experienced some degree of this state.[74] Although it may be questionable that these numbers accurately represent the facts, this phenomenon is something that many medical students experience during their training. If medical students are so susceptible to the power of suggestion, how would the general population fare, especially when the persuasive power of the mass media becomes involved?

As with any argument, competing claims need to be carefully assessed. Those who advocate the benefits of DTC advertising, such as the Pharmaceutical Research and Manufacturers Association (PhRMA)[75], who have become a vocal proponent of this belief, often focus on the argument that consumers will become empowered, as they will be more capable of identifying their "condition," with the result that treatment compliance will be reinforced.[76] Also, advocates suggest that consumers will become aware that alternative medications, treatments, and diagnosis options are available, as well as foster "dialogue between patients and physicians, which can lead to the

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[73] Oliver Howes. "Hypochondriasis: An Overview With Reference to Medical Students". 19 August, 2005. <www.studentsbmj.com/back_issues/1199/education/410.html>.
[74] R. Hunter et al. "Nosophobia and Hypochondriasis in Medical Students." *Journal of Nervous & Mental Disorders* 130 (1964): 147-152 and S. Woods et al. "Medical Students' Disease: Hypochondriasis in Medical Education." *Journal of Medical Education* 41.8 (1966): 780-790. As cited in Howes.
[75] The industry and trade group representing most of the brand name U.S. pharmaceutical manufactures.
[76] Francis B. Palumbo and C. Daniel Mullins. "The Development of Direct-to-Consumer Prescription Drug Advertising Regulation: Analyzing the Law, Regulations, and Policies Affecting FDA-Regulated Products." *Food and Drug Law Journal* 57.3 (2002) 436.

education"[77] and self-determination and autonomy for patients.[78] However, from a different perspective, these arguments can be seen as weak and potentially dangerous. Knowledge is a powerful tool, but if misused and/or misunderstood (especially in relation to medical issues), serious or even fatal consequences may be the result. On the other side, those who seek to ban—or at least strictly regulate—DTC advertising see this form of persuasion as potentially having a negative effect on the doctor/patient relationship by increasing healthcare costs, preying on the vulnerable, and minimizing health consumer concerns.

Negative Consequences

Compromising Health Consumers' Safety

Many recent studies suggest that medical research may be fraught with misleading, inaccurate, and biased results, especially when the research is sponsored by industry.[79] Traditionally, the reputation of leading and well established peer-reviewed journals—e.g., the *New England Journal of Medicine* (NEJM), *The Journal of the American Medical Association* (JAMA), *Lancet*, and *The Canadian Medical Association Journal* (CMAJ)—has been built on the prerequisite that the efficacy and safety of published studies rest on the premise that clinical trial data have been gathered and presented in an objective and dispassionate manner, free of conflict of interest.[80]

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[77] Palumbo and Mullins 436.
[78] Edward Guadagnoli and Patricia Ward. "Patient Participation in Decision-Making." *Social Science of Medicine* 47.3 (1998) 329.
[79] Mohit Bhadari et al. "Association Between Industry Pro-Industry Findings in Medical and Surgical Randomized Trials." *Canadian Medical Association Journal* 170.4 (2004): 477-480. Also see Laurence Hirsch. "Randomized Clinical Trials: What Gets Published and When?" *Canadian Medical Association* 170.4 (2004): 481-483; Ian Chalmers. "In the dark" *New Scientist* 181.2437 (2004): 19.
[80] Frank Davidoff et al. "Sponsorship, Authorship and Accountability." *Journal of the American Medical Association* 165.6 (2001): 786-788.

However, recently, industry and joint-industry sponsored published studies have become a growing tread. For example, Clifford, Barrowmen, and Moher found that 66% of 100 clinical drug trials published between 1999-2000 in 5 peer-reviewed journals—*JAMA, Lancet, NEJM, Annals of Internal Medicine* (AIM) and *British Medical Journal* (BJM)—involved industry funding.[81] They also noted a significant growth in articles that do not declare funding, but in are industry sponsored. This worrying trend may not only be supporting published research that is unduly biased in favour of the sponsored drug, but also, perhaps even more disturbing, suppressing unfavourable information. Moreover, the suppression of unfavourable studies vis-à-vis non-publication is becoming commonplace.[82]

The changing economic market of the late 1980s and early 1990s has led to a dramatic decrease in federal funding of universities, and has forced these universities and their researches to seek economic support from industry. As their funding scheme changed, it became difficult for university academics—traditionally, the independent clinical investigators—to take a leading role in the design, recruitment, and data interpretation of clinical trials.[83] The universities' greater dependence on industry coupled with lax enforcement of sanctions on those who by-pass DTC advertising

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[81] Tammy Clifford , Nicole J. Barrowman , and David Moher . "Funding Source, Trial Outcome and Reporting Quality: Are They Related? Results of a Pilot Study." BMC Health Services Research 2 (2002): 18; Guy Amsden. "Industry sponsorship in research and publishing: who is really to blame for perceived bias?" *The Annals of Pharmacotherapy* 38 (2004): 714-716; Lee Friedman and Elihu Richter. "Relationship between conflicts of interest and research results." *Journal of General and Internal Medicine* 19 (2004): 51-56; Susan Buchkowsky and Peter Jewesson. "Industry sponsorship and authorship of clinical trials over 20 years." *The Annals of Pharmacotherapy* 38 (2004): 579-585.

[82] Robert I. Bell, Hershey H. Friedman and Linda Weiser Friedman. "Conflict of Interest: The Common Thread Underlying Ethical Lapses." *Electronic Journal of Business Ethics and Organizational Studies* 10.1 (2005) 6.

[83] Davidoff et al. 786. Also see Patricia Baird. "Getting it right: industry sponsorship and medical research." *Canadian Medical Association Journal* 168.10 (2003):1267-1269 and Joe J. Collier and Ike Iheanacho. "The pharmaceutical industry as an informant." *The Lancet.* 360 (2002): 1405-1409.

legislation may leave health professionals and consumers vulnerable to an industry driven market.

The capitalizing out-of-pocket pre-approval costs of bringing a new drug to the market approval stage, is estimated by industry to be between $600[84] to $802 million U.S.[85] and has been shown to be spiralling upward at an unprecedented rate, creating intense pressure on the pharmaceutical industry.[86] Specifically, the pharmaceutical industry is under tremendous pressure to bring "winners" to market to recoup research and development expenditure and generate substantial profits while the drug has patent protection. Moreover, industry-funded trials are the predominant means of testing new drugs. In essence, it would appear that pharmaceutical companies are sponsoring their own clinical trials. This process has significant ethical dimensions, especially in relation to the concept of conflict of interest. The critical issue raised is: how do pharmaceutical companies find and market their "winners"?

The majority of clinical trials published in the medical literature are sponsored fully or jointly by the pharmaceutical companies that have a vested interest in the intellectual property rights to the drug's patent.[87] In response to this growing phenomenon, unprecedented research is being directed towards the problems associated with the current data results from these clinical trials that are commonly published in medical journals. A common theme emerging from this research in the *NEJM*, *JAMA*,

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[84] Annonymous. "Look, No strings: Publishing Industry-Funded Research." *Canadian Medical Association Journal* 165.6 (2001): 733.
[85] Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski. "The price of innovation: new estimates of drug development costs." *Journal of Health Economics* 22 (2003):151.
[86] DiMasi, Hansen and Grabowski 151.
[87] Clifford et al. 18.

and *CMAJ* is that "industry-funded trials are more likely to be associated with statistically significant pro-industry findings, in medical trials."[88]

As part of their practice, physicians, rely on studies published in leading and peer-reviewed journals. As well, in their prescribing practices, commercial information from the pharmaceutical industry itself also often plays a role in the decision making processes. If these professionals are unable to discern among suspect studies, there is reason to wonder how the ordinary lay person be expected to critically assess this information. Moreover, the same industry that publishes in leading medical journals and popular consumer magazines is often the biggest proponent of DTC advertising.[89] This is a marketing promotion that utilizes clever strategies aimed at the consumer's most vulnerable mental and emotional needs. As a result, when it comes to questions of diagnosis and treatment, neither physicians nor consumers may have the most accurate information available to make an informed decision. Importantly, the *British Medical Journal* cited a U.S. Congressional inquiry report which noted that between 1997-2002 eighty-eight letters were sent to various drug companies alleging advertising violations, the most prevalent complaints being that the drug companies overstated the effectiveness of a drug, or minimized risks involved.[90] Concerns also have been raised that some advertisements make false or misleading claims, or omit adverse effects and other

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[88] Mohit Bhandari et al. "Association Between Industry Funding and Statistically Significant Pro-Industry Findings in Medical and Surgical Randomized Trials." *Canadian Medical Association Journal* 170.4 (2004): 477.

[89] Aparna Deshpande, Ajit Menon and Matthew Perri III. "Direct-to-Consumer Advertising and its Utility in Health Care Decision Making: A Consumer Perspective." *Journal of Health Communication* 9 (2004): 500 and Steven Wolshin et al. 1141.

[90] Richard Smith. "Medical Journals and Pharmaceutical Companies: Uneasy Bedfellows." *British Medical Journal* 326 (2003) 1203.

important information appropriate for prescribing purposes.[91] The issue then becomes who can be relied upon and trusted to provide accurate, reliable and information?

A common misperception exists that only "safe" or "extremely effective" prescription drugs are advertised to the general public.[92] The assumption holds true for medical treatments and diagnostic procedures. In the U.S., DTC advertising spending is highly concentrated, as approximately 40% of annual expenditure is focused on only 10 products. Moreover, since these 10 products are likely to be new or for a new indication, advertising spending is used to stimulate sales in the marketplace, and often little is known about their adverse side effects or longer-term risks.[93] Similarly, the 1992 *Prescription Drug User Fee Act* gave the *FDA* the power to more quickly approve drugs. This *Act* resulted in several drugs making it to market that should never have been available to consumers.[94] A 1998 survey conducted on the *FDA*s Medical Officers (physicians responsible for coordinating reviews of new drugs) found "27 new drugs within the last three years that should not have been approved, but were approved nevertheless."[95] The U.S. General Accounting Office, which reviews risks of newly approved drugs, "found that 52% had serious risks that only emerged post-approval, most often in the first few years."[96]

In Canada, the Patented Medicine Prices Review Board (PMPRB) places newly patented medicines into one of three categories as a means to determine if the

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[91] Pillar Villanueva et al. "Accuracy of Pharmaceutical Advertisements in Medical Journals." *The Lancet* 361 (2003): 27.
[92] Robert Bell, Richard Kravitz, and Michael Wilkes. "Direct-to-Consumer Prescription Drug Advertising and the Public." *Journal of General Internal Medicine* 14.11 (1999): 656.
[93] Mintzes "An Assessment of the Health System Impacts..." vii.
[94] Mintzes "An Assessment of the Health System Impacts..." 10.
[95] Mintzes "An Assessment of the Health System Impacts..." 10.
[96] R.W. Rhein. "Law Enforcement and the Internet Superhighwaymen." *Scrip Magazine* (December, 1996): 18. As cited in Mintzes "An Assessment of the Health System Impacts..." vii.

introductory price is excessive. Between 1996-2000, 416 newly patented drug products, most of which were prescription only and designated for human use, were introduced to the Canadian market. Of these drugs, "only 25, or just over 6%, were either, 'breakthrough' medications or substantial improvements over existing therapies, and the rest were line extensions (40%) or products that provided moderate, little, or no therapeutic benefit."[97] Similarly, in 2001, *Prescrire International*—an independent French drug bulletin—reported that in a 1981-2000 study of 2200 new preparations or new indications for existing drugs, only 74 were ranked as major or important therapeutic claims, and greater than 1400 were redundant because they had no advantage over existing preparations. Moreover, a most troublesome finding from the same study was that 58 preparations were "worse than existing treatments, that is, less effective and/or riskier."[98] In light of this mounting evidence, it could be argued that a striking number of prescription drugs entering the market place have no, or limited, benefit, and that DTC advertising often provides misinformation.

The recent recall (in September 2004) of the anti-inflammatory drug *Vioxx* (rofecoxib) produced by the pharmaceutical giant Merck and Co. demonstrates the growing problem with not only aggressive DTC advertising but also the publication bias in leading medical journals. In 2000, even though the *New England Journal of Medicine* (NEJM) published a study indicating that *Vioxx* appeared to increase the risk of heart disease, Merck continued to focus solely on marketing *Vioxx* as the drug that caused fewer gastrointestinal problems than its forerunner, the much cheaper drug *Naproxen*. Merck alleged that *Naproxen* may provide protective properties against developing or

[97] Joel Lexchin and Barbara Mintzes. "Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No." *Journal of Public Policy & Marketing* 21.2 (2002): 194.
[98] Lexchin and Mintzes 194.

lessening the effects of heart disease, thereby effectively denying that there could be a problem with their product.[99] Merck continued with its aggressive advertising strategy, focusing on how *Vioxx* decreased gastrointestinal problems, and on how using *Vioxx* allowed people afflicted with arthritis to participate in a variety of physical activities once treatment had started. Ominously, in 2001, a second study completed by the *Journal of the American Medical Association* (JAMA) again demonstrated that a linkage existed between *Vioxx* and heart attacks. Although Health Canada and the U.S. FDA issued new warning labels about this drug at the time, both Merck and North American regulators did not take action to resolve this problem, and the advertising continued.

At the time when *Vioxx* was removed from the market, Merck was conducting clinical trials on its secondary off-label effectiveness on precancerous colon polyps. It found that patients who had been on the drug for greater than 18 months had a near double risk of heart attack and stroke.[100] Why did it take nearly four years after the first questions were raised about *Vioxx*'s adverse effects for the product to be taken off the market? For four years, this drug was heavily marketed to both unsuspecting physicians and consumers, and according to the recent studies that led to *Vioxx*'s recall, thousands of consumers were put at serious risk for heart attack and stroke. There can be no argument that DTC advertising played a key role in *Vioxx*'s success.[101] Prior to its recall, *Vioxx* was the 10th most dispensed drug in Canada and the second most popular anti-

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[99] Claire Bombardier et al. "The VIGOR Study Group. Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis." *The New England Journal of Medicine* 343 (2000): 1520-1528.

[100] Eric Topel as cited in Sharon Kirkey "Vioxx-maker Valued Sales Over Safety: Journal." in Vioxx-Maker Valued Sales Over Safety: Journal. Montreal Gazette (October 7, 2004): A12.

[101] Meredith B. Rosenthal et al. "Promotion of Prescription Drugs to Consumers." *The New England Journal of Medicine* 346.7 (2002): 502-504 and Matthew F. Hollon. "Direct-to-Consumer Advertising: A Haphazard Approach to Health Promotion." *Journal of the American Medical Association* 293.16 (2005): 2030-2032.

inflammatory drug on the market: "The problem of secrecy in science is particularly troubling when it involves conflicts of interest between a company's marketing objectives and the public's right to know."[102]

Strategies that involve conflict of interest are only a subset of numerous other means and methods that the medical industry may utilize to ensure their product make it to the health consumer market. For example, it has been estimated that between "89 to 98% of comparative drug treatment studies funded by the pharmaceutical company yield results that are favourable to their company's products."[103] In his study on design and reporting modifications in industry sponsored comparative studies, Safer uncovered numerous modifications which were then grouped into 13 categories. Some of the categories that were addressed included: masking unfavourable side effects, repeatedly publishing the same or similar findings for impact, selectively high-lighting findings favourable to the sponsor, and withholding unfavourable results.[104] Safer believed that these types of studies sponsored by major pharmaceutical companies were often very expensive, likely misleading, and wasteful comparisons, when similarly effective drugs already exist. Nevertheless, the results of such studies appear to influence the prescribing practices of some physicians as Vioxx, for example, became a top seller when cheaper and safer drugs already existed.

DTC advertising not only focuses on drugs, but also on screening and diagnostic procedures, such as, computed tomography (CT) scans and magnetic resonance imaging

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[102] Sheldon Rampton and John Stauber. "Research Funding, Conflicts of Interest, and the "Meta-methodology" of Public Relations." *Public Health Reports* 117 (July-August 2002): 335.
[103] Daniel Safer. "Design and reporting modifications in industry-sponsored comparative psychopharmacology trials." *The Journal of Nervous and Mental Disease* 190.9 (2002): 583; Benjamin Djulbegovic et al. "The uncertainty principle and industry-sponsored research. *The Lancet* 356.9230 (2000): 635-638.
[104] Safer 883.

(MRI). In North America, full-body scanning services have become thriving businesses. Some private scanning clinics offer discounts when the consumer has more than one test. Others utilize certain causes to promote business: for example, March is colon cancer awareness month in the U.S., and some private scanning clinics offer reduced rates on colon cancer screening.[105] In the U.S., screening and diagnostic imaging procedures, unlike prescription drugs, can be purchased without a physician's referral.[106] However in Canada, the unwritten recommendation put forth by Health Canada is that no diagnostic imaging procedure can take place without prior clinical evaluation and a written referral by a health professional. As well, many private clinics in Canada will not accept referrals for full body scans for screening purposes unless the person is over age 40.[107] Nevertheless, there is no stopping Canadians from purchasing screening and diagnostic imaging services in the U.S., if they are unable to obtain them in Canada.

DTC imaging advertisements are fraught with many of the same problems as advertising done by the drug industry, since they also omit serious risks and mislead consumers about the benefits of the procedures. One study on DTC and imaging found that in terms of the positive valence, the content of the advertisements included messages of happiness and the benefits of the scan, whereas the negative valence often included fear invoking messages such as "30 minutes can save a life—my own" and "I had a time bomb in my body..."[108] Moreover, potentially harmful effects of these procedures were minimized or ignored. For example, virtually no advertisements referred to secondary

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[105] See Be Well Body Scans, LLC. 17 March, 2005. <http://www.bewellbodyscan.com/ >.
[106] Judy Illes et al. "Advertising, Patient Decision Making, and Self-referral for Computed Tomographic and Magnetic Resonance Imaging." *Archives of Internal Medicin* 164 (2004): 2416.
[107] Jim Donnelly. "Yuppie Scans" Unethical Marketing Ploy." *Canadian Medical Association Journal* 168.9 (2003): 1167.
[108] Illes 2418.

sources of information; rates of false-positive results were not addressed; and most troubling, no mention was made of "the potential risk of irradiation associated with CT scans."[109] Recently, the *Medical Journal of Australia* published an article which found that whole-body screening leads to an estimated radiation exposure of somewhere between 1 and 24 mSv per CT scan, with a 10 mSv radiation exposure being associated with an increased risk of fatal cancer in about 1 in 2000. As well, compared with "10 other types of x-ray, CT scans are responsible for the largest number of radiation induced cancers per year in nine cancer sites examined."[110] Health Canada also warns that "whole body CT screening exposes you to radiation levels that are 500 to 1000 times as high as those of a routine chest x-ray."[111] Considering these statistics, it is difficult to comprehend why this information is not made readily available to consumers. Based on DTC advertising, consumers often seek these specialized screening services as a means to potentially diagnose a condition, not to potentially produce a condition they would not have had to worry about in the first place, if they had not had the procedure.

The marketing of body scans for screening purposes can be seen as a purely entrepreneurial enterprise, since consumers must purchase these procedures with their own private funds. However, depending on the consumer's circumstances, false-positive results and their subsequent consequences such as further unnecessary diagnostic tests—which also may lead to potential psychosocial issues—often will need to be dealt with at public expense. In other words, scarce medical resources will be diverted from those

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[109] Illes 2418.
[110] Cleola Anderiesz et al. "Whole-Body Computed Tomography Screening: Looking for Trouble?" *Medical Journal of Australia* 181.6 (2004): 295-296.
[111] Health Canada. *Whole Body Screening Using MRI or CT Technology.* 2003. 20 March, 2005. <http://www.hc-sc.gc.ca/english/iyh/medical/mri.html>.

who are genuinely ill and in need of medical attention to someone who may not be suffering from anything at all.

Nevertheless, it can be argued that screening centres are providing services that the public sector is unable or unwilling to offer in a timely fashion. It is a well-accepted phenomenon in the Canadian healthcare system that even though a CT or MRI scan has been ordered for diagnostic or screening purposes, it may take a year for the test to be conducted. For many patients this is an unacceptable time frame, especially when uncertainty, or perhaps a suspicion, exists as to the probable cause of the problem for which the test was ordered in the first place. Having to wait for a confirmation of a diagnosis can cause significant psychological, emotional, financial, and physical set-backs. Therefore, if anyone can afford to have the test conducted sooner, why should they wait? Proponents of private screening use this rationale to justify their necessity, to offer services in a timely manner when the public system cannot. In an age of health conscious consumers, people believe that they are entitled to the best care available, which includes access to MRIs and CT scans. No one can deny that some people have improved their quality of life and, in some instances, saved their own lives by obtaining a diagnostic or screening procedure through the private sector. However, they also may have increased their risk for future harm by undergoing an unnecessary test.

One of the most disturbing studies relating to health consumer safety was conducted by the San Francisco Health Department in 2001. The department surveyed 1000 men who attended the city's sexual health clinic and released the results of the first 262 men who were interviewed. The survey found that homosexual men who reported regularly seeing advertisements for antiretroviral treatment for HIV/AIDS were more

likely to engage in unprotected sex than men who seldom saw or noticed the advertisements. As well, 62% of the men surveyed felt that seeing the advertisements for HIV/AIDS drug treatment affected their decision to have unprotected sex.[112] The advertisements portrayed "physically healthy" appearing men with hiking gear on the top of a mountaintop. Jeffrey Klausner, an epidemiologist with the San Francisco health department, noted that "these medicines don't enable anyone with HIV to climb mountains, the side effects make it impossible."[113] This DTC advertisement is a dangerous illustration of how this kind of advertising can promote misleading and unrealistic treatment outcomes for a disease that is not fully understood and has no cure. By portraying men allegedly infected with this disease as living "normal" lives vis-à-vis antiretroviral treatment, it is openly deceptive and preys upon vulnerable individuals. Individuals regularly exposed to this kind of misleading advertising may unwittingly partake in risky behaviours (unprotected sex), since they believe an "effective" treatment is available.

The Influence of DTC Advertising on the Physician /Patient Relationship

Historically, the physician/patient relationship was patriarchal: the patient dutifully followed the physician's orders without question. However, this relationship has changed. Health consumers are more knowledgeable about health in general. However, this increased knowledge and desire to be fully informed regarding health issues has created greater demands on and criticisms of physicians. The Internet (as a

[112] Mintzes "An Assessment of the Health System Impacts..." 49.
[113] Gavin Yamey. "You Can Always Pop a Pill." *Western Journal of Medicine* 174 (2001): 382. Mintzes "An Assessment of the Health System Impacts..." 49.

health resource), various forms of mass media DTC advertising of drugs, products, and services, and segments of news broadcasts and popular magazines dedicated to "health issues" have all contributed to this change in the physician/patient relationship. There is no question that taking an interest in one's health and demonstrating autonomy is a positive step forward. Individuals should take ownership and responsibility for their personal health, but problems can arise when the knowledge they possess, and the views they hold, are based on potentially false and misleading information that may not adequately address the risks versus benefits of a health care decision. Possessing inadequate information and making requests for drugs and/or treatments that may not be in their best interest could negatively affect patients' relationships with their physician, and worse, their lives.

In 2003, Mintzes et al. conducted a study examining the effects of DTC advertising on physicians' prescribing practices, and on their relationships with patients.[114] The study compared two cities—Sacramento, California and Vancouver, British Columbia—which have different legislation governing DTC advertising. The study found that patients in Sacramento were more than twice as likely to request an advertised prescription drug (7.2%) than Vancouver patients (3.3%). Although Canadian legislation prohibits DTC advertising aside from reminder and help-seeking purposes, it would be implausible to suggest that Canadians are immune to this kind of advertising. Many Canadians receive U.S. cable networks, magazines, and have access to the Internet, all of which are likely sources of information for Canadian patients in this study. Importantly, these numbers suggest that greater exposure to DTC advertising led to more requests for prescription drugs, which were fulfilled by physicians in most instances—

[114] Mintzes et al. "How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing..." 404-412.

78% in Sacramento and 72% in Vancouver. On the surface, this situation does not appear to be problematic, but issues arise when physicians feel pressured to simply prescribe what their patients request, especially when they are ambivalent because they do not believe the patient needs the drug, similar and often cheaper drugs are available, or the long term risk/benefit data is not accessible.

Evidence exists that indicates physicians are under increasing pressure to prescribe advertised drugs even though they felt these medications were not appropriate. For example, a survey conducted by the Minnesota Medical Association found that physicians felt their consultation time was increasing because of DTC advertising, since now they had to take more time to dispel the myths and misinformation received from this advertising, a situation which also resulted in their patient's decreasing satisfaction with their services.[115] Overall, physicians now are spending more time with their patients educating them on why various advertised treatments are not appropriate, especially when changes in lifestyle would be more helpful, better or more effective and often cheaper treatments are available, or a patient does not even have the condition for which they are requesting treatment. A New Zealand study found that 61% of general practitioners felt DTC advertising created "disharmony" within the physician/patient relationship.[116] New Zealand, like Canada, operates on a fee-for-service funding model, which requires physicians to rely on patient loyalty for their income. Moreover, if the physician/patient relationship becomes damaged, patients may engage in physician shopping until they get what they want, or in a worse case scenario, distrust the medical

[115] Minnesota Medical Association. *Pharmaceutical issues survey for Minnesota physicians. Survey Results*. 2000.5 < http://www.mmaonline.net/Protected/pharmresults.htm>. Toop et al. 20.
[116] Toop et al. 20.

professional to the point that they no longer seek out medical attention. This outcome could be fatal in situations where they truly need medical care.

Ultimately, the increasing pressure many physicians are feeling in regard to fulfilling their patients' requests for advertised prescriptions or referrals for diagnostic and screening tests may be putting both in danger. If physicians do not provide their patients with what they seek, they may lose their patient base or the rapport they once had with them. As well, if the physician yields under increasing demands from his or her patients, they may end up prescribing more than a treatment and rather become an instrument of greater harm, especially if no indication exists that the treatment a patient is requesting is appropriate for them. Almost 80% of physicians believe that DTC advertising encourages patients to seek treatments they do not need,[117] and less than 10 % consider DTC advertising a positive health trend.[118] The American Medical Association (AMA), which has opposed many aspects of DTC advertising for a number of years, published a position paper in 1998 outlining several of their concerns, including how this form of advertising may be impacting the doctor-patient relationship.[119] The AMA calls upon "vigilance on the part of physicians to prevent false expectations by patients" and advocates for advertisements to utilize the language, "Your physician may recommend other appropriate treatments."[120] The impact of DTC advertising geared towards patients could likely result in physicians finding it much more difficult to engage patients in discussions of relevant and important health issues.

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[117] Joel Weissman et al. "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising". *Health Affairs* (Jan-June 2004): 219-234.
[118] Andrew Robinson et al. 431.
[119] See American Medical Association, House of Delegate (October 22, 2002). As cited in Palumbo and Mullins as to availability at <http://www.ama-assn.org/meetings/public/annual98/comm-e/res506.htm>.
[120] Palumbo and Mullins 439.

Economic Pitfalls

In part, DTC advertising is responsible for the rapidly increasing costs of prescription drugs, especially those specifically targeted for mass marketing. For example, pharmaceutical companies spent approximately 1.8 billion U.S. on DTC advertising in 1999, a 40% increase over 1998. This spending in 1999 was almost exclusively concentrated on 50 drugs.[121] The National Institute of Health Care Management (NIHCM), a non-profit foundation governed by the U.S. managed care and health insurance industries published a report in 1999 which found that "the use of new, costlier drugs where identified as the primary factor driving the increase in average drug cost per prescription."[122]

Also, DTC advertising plays a significant role in the ever-expanding realm of private cosmetic services, and diagnostic and screening procedures. Moreover, this type of advertising can be seen as creating an inequity and disparity among various health consumers, for example, between those with extended or private health plans and deposable incomes, and those with limited or no private health plans and limited financial resources. This process places pressure on the allocation of limited and finite health resources. In addition, DTC advertising significantly increases the demand for a small array of more expensive treatments which do not necessarily offer advantages over other therapies, for example, as noted earlier with the situation with *Vioxx* and a number of new medicines judged as "breakthroughs" by the PMPRB. Studies indicate that pharmaceutical expenditures account for an increasing proportion of health care expenditures in most countries, and that drug costs are growing at the rate of 15-20% per

[121] Steven D. Findlay. "Direct-to-Consumer Promotion of Prescription Drugs: Economic Implications for Patients, Payer and Providers." *Pharmacoeconomics* 19.2 (2001): 109.
[122] Mintzes "An Assessment of the Health System Impacts..." 78.

year, faster than any other health expenditure.[123] In 1999, DTC advertised drugs were found to be the fasting selling drugs in the U.S., leading to a 19% increase in pharmaceutical spending.[124] It would be difficult to argue, in the light of such statistics, that a direct correlation between DTC advertising and the increasing costs of health related products do not exist. In 2000, Marcia Angell, the former editor-in-chief of the *New England Journal of Medicine*, wrote:

> The pharmaceutical industry is extraordinarily privileged. An industry so important to the public health and so heavily subsidized and protected by the government has social responsibilities that should not be overshadowed by its drive for profits.[125]

The close ties between the pharmaceutical industry and governmental bodies in relation to prescription medications and other health product costs makes it all the more difficult to implement change and impose regulations that may better protect health consumers from these spiralling expenditures.

Drug "formularies" are lists of reimbursable drugs established by a health service or insurers. Often, they are made up of different tiers that indicate whether the drugs are fully or partially covered, and whether they require approved authorization before reimbursement can occur. Formularies provide two functions. First, they may contribute to more rational therapy because ineffective and unnecessarily harmful drugs are excluded. Second, they contribute to cost containment by utilizing generic drugs whenever possible. Canada, New Zealand, and the U.S. all have similar style systems for deciding if and how much coverage will be provided for prescription drugs and other

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[123] Toop et al. 16.
[124] National Institute for Health Care Management Foundation. *Prescription Drugs and Mass Media Advertising.* Washington, DC.: National Institute for Health Care Management, 2000. As cited in Toop et al. 16.
[125] Toop et al. 15.

health treatments. However, drug manufacturers employ various tactics to convince health service and benefit providers to include newly launched drugs in their formularies. The largest and most successful tactic is the "public awareness campaign," built upon DTC advertising.[126] Similarly, in Canada, the cost for new-patented drugs increased more rapidly after 1993.[127] In the U.S., DTC advertising has been responsible for higher average drug prices per prescription, a 64% increase between 1993-1998.[129]

In response to the spiralling costs of newly added drugs to the formularies, many employers, insurance companies, and health service providers have added additional tiers to their drug plans, instituted or increased cost sharing schemes, or modified the list of drugs they cover.[130] A 1999 report by the Health Insurance Association of America listed five main factors which lead to increased prescription drug expenditures:

- direct-to-consumer advertising "is placing the burden on the provider to prescribe requested medications, despite cost or efficacy;"
- an accelerated FDA approval process allowing many new, expensive drugs to enter the market;
- few incentives for health plans or providers to effectively manage cost and utilization;
- disease management programmes that rely heavily on drug therapies; and
- an increasing elderly population, needing more frequent and expensive drugs to treat chronic and acute health conditions.

Not surprisingly, DTC advertising was found to be the most significant factor leading to prescription drug expenditures.[131] In response to growing criticisms of DTC advertising and its link to drug promotion, the *Wall Street Journal* in March 2002 published an investigative report on this phenomenon. The *Journal* reported that the car manufacturer

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[126] Mintzes "An Assessment of the Health System Impacts..." 76.
[127] Mintzes "An Assessment of the Health System Impacts..." 79.
[129] Mintzes "An Assessment of the Health System Impacts..." 77.
[130] Mintzes "An Assessment of the Health System Impacts..." 79.
[131] Mintzes "An Assessment of the Health System Impacts..." 80.

General Motors (GM) spent $55 million in 2001 on the *prescription only* heartburn drug omeprazole (*Prilosec*) for its workers, a rise of 14% in one year. Of the GM employee plan members who received a prescription for *Prilosec,* 92% of them had never received a previous prescription, taken an OTC drug, made lifestyle changes, or even previously consulted a physician about gastrointestinal concerns.[132] These numbers suggest that DTC advertising played a role in increasing health care costs. As one GM executive observed, "Not everyone needs the purple pill," a reference to the trademark colour and popular slogan for *Prilosec.* It seems plausible to suggest that if this trend of over-prescribing costly "new" and possibly unnecessary drugs continues, the various health schemes currently supporting North America's fragile healthcare system may erode to the point of no return. If the media frenzy surrounding DTC advertising continues at its current pace, health consumers' current drug coverage plans may be in jeopardy. For example, the drug coverage once enjoyed by many could be severely restricted due to increasing prescription costs. As well, even if a health consumer has some form of drug coverage, he or she still may not be able to afford over-priced drugs.[133] If this situation were to occur, there would be no winners as drug manufacturers would no longer have access to a viable market.

[132] Thomas Burton. "Pushing Pills: Reining in Drug Advertising - Backlash is Brewing Among Companies Who Believe Flashy Ads Drive Up Costs." *Wall Street Journal* [New York] (13 March, 2002). As cited in Toop et al. 40.
[133] Mintzes "An Assessment of the Health Systems Impacts..." 77-80; Toop et al. 41

Potential Benefits of DTC Advertising

Role of the Health Consumer

Industry, particularly drug manufacturers, argue that DTC advertising plays a positive role in educating and empowering health consumers to take control of their own lives. As well, the American College of Physicians (1984) declared that "the patient has a right to self-determination" and the WHO held that "patient involvement in care is not only desirable but a social, economic, and technical necessity."[134] Proponents of DTC advertising argue that they are enlightening and educating their target audience—the health consumer—about their health, "better and more superior products," and conditions they "may not" even know that they are suffering from. In essence, the health marketers are granting permission to health consumers—letting them know that it is perfectly acceptable to participate in healthcare decisions since it is their lives that are at stake—to approach their physicians about what they saw, read, or heard about through DTC advertising.

The notion of autonomy[135] plays an ever increasing and predominate role in the decision making process of healthcare consumers. North American healthcare consumers have become more savvy and conscious regarding their own health, thanks in part to the increasing availability and easy access of health information, legitimate or otherwise. This newer generation of healthcare consumers are often not afraid to ask poignant

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[134] Guadagnoli and Ward 329.

[135] The word *autonomy*, derived from the Greek *autos* ("self) and *nomos* ("rule," "governance, " or "law"), originally referred to the self-rule or self-governance of independent city-states. Autonomy has since been extended to individuals and has acquired meaning as diverse as self-governance, liberty rights, privacy, individual choice, freedom of will, causing one's own behavior, and being one's own person. See Tom L. Beachamp and James Childress, *Principles of Biomedical Ethics*, 5th Ed. (New York: Oxford University Press, 2001) 57-58. The two conditions that virtually every theory of autonomy deems essential are *liberty*—independence from controlling influences—and *agency*—the capacity for understanding and intentional action. See Woodie M. Zachry III and Diane B. Ginsbury. "Patient Autonomy and the Regulation of Direct-to-Consumer Advertising" *Clinical Therapeutics*. 23.12 (2001): 2026.

questions of their healthcare providers. In their study examining patient participation in decision-making, Guadagnoli and Ward concluded that "patients want to be informed of treatment alternatives, and they want to be involved in treatment decisions when more than one effective alternative exists;" as well, they believe that patient participation is part of the patient's right to self-determination.[136] However a danger exists when the health consumer applies the tenets of autonomy, liberty and agency to the decisions they are making concerning their health. First, health consumer's liberty could be compromised when undue influences—namely biased, misleading, or erroneous information—is presented to convince them to act in a certain manner that may be to a detriment, rather than a benefit, to their health.[137] Second, the positive aspect of agency is undermined when the health consumer does not possess or comprehend the relevant information necessary to make an informed decision.[138] Although it is acknowledged that an autonomous decision making choice is often available in relation to one's health, not everyone will implement it.

Educating the Health Consumer, Public Health Benefits

The mass media, along with well chosen spokespersons, play a role in educating health consumers by encouraging them to seek medical advice for conditions some may not be aware they may have, such as, diabetes mellitus or asthma. Perhaps health consumers were too embarrassed and viewed their concerns as private maters such as sexual dysfunction, urinary incontinence, and depression, or even trivial, such as discoloured toenails, prior to seeing, hearing or reading a DTC advertisement aimed at

[136] Guadagnoli and Ward 337.
[137] Zachry III and Ginsburg 2026.
[138] Zachry III and Ginsburg 2026.

their condition. As well, advertisers may communicate warnings and the importance of screening for various conditions to the public such as the value of using sunscreen to prevent burns and skin cancer, the importance of using bug repellent, especially in areas prone to West Nile Virus, and the potential signs and symptoms of skin, colon or lung cancer for which medical attention should be sought. This type of advertising could also open a dialogue between the patient and physician in terms of conditions that may have been overlooked, or new/alternative treatment options not considered by the physicians.[139]

One of the first and most successful DTC product advertisements (launched in 1992) aimed at educating the public about a treatment available for a prevalent, highly addictive, and potentially fatal habit of smoking.[140] When the advertisement for the nicotine patch aired during the U.S. Super Bowl, the response was so great that "within weeks, demand for the patches exceeded the supply."[141] Although the nicotine patch had been available for months prior to this advertisement, health consumers who may have been interested, or had been trying unsuccessfully to quit smoking, simply were not aware of this product. This advertisement provided the opportunity and motivation for millions of health consumers to execute their personal autonomy and seek out physician assistance regarding this treatment option. However, as John Avorn, noted: "There's no detail man or pharmaceutical company or patient that puts a gun to the doctor's head to

[139] Jeffrey T. Berger et al. "Direct-to-Consumer Drug Marketing: Public Service or Disservice?" *The Mount Sinai Journal of Medicine* 68.3 (2001): 199.
[140] Alan F. Holmer. "Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians." *Journal of the American Medical Association* 281.4 (1999): 381.
[141] Holmer 381.

write a prescription. Ultimately, it isn't the patient's signature on the prescription—it's the doctor's.[142]

Even though the ability to write a prescription lies with the physician, pressure from health consumers to receive advertised medications could lead to dispensing inappropriate prescriptions. Prescribing an inappropriate drug may be easier than attempting to re-educate the health consumer as to why the drug would not be in their best interests, calling into question the principles of nonmaleficence and beneficence clearly expressed in the Hippocratic oath which reads in part: "I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them."[143] Physicians may prescribe medications at their patients' request, believing that they will neither help, or hinder their condition, although they will appease their concerns. This faulty belief system has unwittingly contributed to the growing concerns surrounding antibiotic resistant bacteria which lead to the creation of the Canadian Committee on Antibiotic Resistance (CCRA). It was not that long ago that health consumers requested, and often demanded, that their influenza be treated with antibiotics in the mistaken belief that it would effectively treat their condition. However, society is now facing a growing number of cases of antibiotic resistant conditions because of the overuse/inappropriate use of antibiotics. Knowledge and education are necessary tools to enlighten and promote autonomy amongst health consumers, but by appeasing patient demands and "misleading or influencing patients into false beliefs"[144] could result in more harm than good.

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[142] Holmer 381.
[143] Beauchamp and Childress 113.
[144] Zachry III and Ginsburg 2033.

Generally, in terms of educating the health consumer and promoting the execution of individual autonomy, the real problem occurs when industry creates DTC advertising that does not provide an accurate picture of what they are promoting. For example, one study of 207 newspaper and television news stories that focused on 3 drugs for disease prevention found that these media reports had prevalent and substantial shortcomings.[145] Of the stories that quantified the benefits of medications, only 15% presented both the relative and absolute benefits, and 83% presented information on benefits in relative terms only. In essence, half the story was missing, since noticeably absent was any explanation of the risk such as adverse events, other alternative treatments, and the cost of the drugs. The information provided in DTC advertisements is minimal at best and obviously provides limited educational value. One researcher concluded:

> There is an unmistakable conflict of interest for drug manufactures when 'educating' patients about therapeutic alternatives. The incentives for exaggeration and persuasion are great, and the patients' ability to verify promotional claims is limited by lack of technical expertise and access to unbiased information sources.[146]

Proactive Health Consumer

One of the founding and most widely accepted and applied principles of healthcare throughout the world is that of health prevention and promotion. Supporters of DTC advertising believe that these ads have a positive effect on disease management. In 1999, Lexchin examined this concept and hypothesized on both its positive and

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[145] Ray Moynihan et al. "Coverage by the News Media of the Benefits and Risks of Medications." *The New England Journal of Medicine* 342.22 (2000): 1647-1649.

[146] S. Morgan . An Assessment of the Health System Impacts of Direct to Consumer Advertising of Prescriptions Medicines (DTCA). Volume V. Predicting the Welfare and Cost Consequences of Direct to Consumer Prescription Drug Advertising. Vancouver: Centre for Health Services and Policy Research, University of British Columbia, 2001. As cited in Toop et al. 8.

negative effects.[147] Lexchin notes that proponents suggest that DTC advertising could lead to higher health consumer awareness of symptoms related to specific diseases, and to increased treatment compliance, since consumers are exposed to ads for drugs they are using on a long-term basis, a phenomenon which may help them to feel more positive about the drugs and create reinforcement for taking them as prescribed. However, one of the difficulties with this argument is that the management of disease often has an array of treatment options that fall outside of the scope of pharmacotherapy. Therefore, the advertisement is limited in its capacity to provide unbiased and useful information. Second, it is rare to see advertisements for well documented and studied diseases such as diabetes and epilepsy. Although the treatment for both of these conditions is quite specific, and a multitude of products exist, most of the drugs are reasonably priced and well past patent protection, so they would not be "worth" the effort of drug manufactures to advertise or to educate the health consumer about their use.

Industry has the belief that their DTC adverting campaigns educate the public about various health conditions which it certainly does at times, especially by way of reminder ads for vaccinations and screening tests for colon and breast cancer, for example. As well, ads aimed at non life-threatening health issues such as overactive bladders let the public know that they are not alone with this problem and that there may be help for this troublesome and sometimes embarrassing condition. However, concerns may arise when industry "overemphasizes" certain conditions. One of the most publicized campaigns over the past decade has focused on a condition that the drug industry wants the health consumer to believe is a silent and deadly disease—high

[147] Joel Lexchin. "Direct-to-Consumer Advertising: Impact of Patient Expectations Regarding Disease Management." Disease Management Health Outcomes 5.5 (1999) 273-283. As cited in Mintzes "An Assessment of the Health System Impacts..." 74.

cholesterol. In extreme cases, dangerously high levels of cholesterol may lead to an increased risk for heart attacks or strokes, but often missing in the DTC advertisements is the information that lifestyle factors—poor diet, lack of exercise, and smoking—significantly influence these elevated levels, and if modifications were made in these areas, cholesterol levels could be dramatically affected. It is not in the drug manufacturer's best interests to promote lifestyle changes, since such an endorsement would have no monetary benefit. The antilipidemic drugs, also known as statins, are some of the world's top selling drugs, specifically *Lipitor*.[148] Another troublesome aspect to the alleged purpose of educating the public about high cholesterol is the involvement of governmental bodies. In the U.S., official government-backed guidelines have surfaced recommending "that almost one in four adults should be taking statins."[149] Such unsolicited involvement has added to people's fears about their cholesterol numbers.

Although it would appear that overall the evidence in support of the benefits of DTC is limited, the fact remains that the provision of health education and promotion to consumers is of vital importance. The mass media plays an important role in conveying information to the health consumer, and the industry's utilization of DTC advertising may lead some to question the actual benefit. Television and print advertisements, especially in magazines, are the most common methods of DTC advertising of prescription and over-the-counter (OTC) drugs in North America.[150] Currently, specific research devoted to exploring how this form of advertising actually may affect health consumers is limited. Even though research into the specific affect/s of DTC advertising

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[148] Moynihan and Cassels 3.
[149] Moynihan and Cassels 15.
[150] Erica Brownfield et al. "Direct-to-Consumer Drug Advertisements on Network Television: An Exploration of Quantity, Frequency and Placement." *Journal of Health Communication* 9 (2004): 491.

of prescription and OTC drugs, as well as medical procedures, is extremely limited, it can be hypothesized that this type of advertising affects decision-making by health consumers, although to what extent is uncertain. It is highly unlikely that pharmaceutical companies would continue to report record profits on drugs if consumers did not believe these drugs were "safe" and "effective" to some degree. These same companies also spent more money on "advertisements in newspapers and popular magazines than they did in medical journals,"[151] which certainly lends itself to the notion that health consumers are playing a more active role in their health decision-making process.

In relation to the issue of "who" the target population of DTC advertising may be, Brownfield et al. examined the actual and relative frequency, time, and placement of prescription and OTC drug advertisements, which appeared during a select week of major U.S., network television. Of the 18,906 advertisements that were shown during the 504 hour sample, 907 were for OTC drugs and 428 for prescription or 4.8% and 2.3% respectively of all the ads. As well, the most common program genre in which these were shown was news programs in which 32% of all OTC and 41.4% of all prescription drug advertising appeared. The second most common genre was soap operas in which 23.6% of OTC and 27% of prescription drug advertising was shown. These two program genres accounted for close to 60% of all DTC advertising. Moreover, the study found that the target population of both prescription and OTC drugs is older health consumers or females or both.[152] This result corresponds to an earlier study that examined prescription advertisements in popular U.S. magazines finding that women are the

[151] Steven Woloshin et al. "Direct-to-Consumer Advertisements for Prescription Drugs: What are Americans Being Sold?" *The Lancet* 358 (2001): 1141.
[152] Brownfield et al. 495.

primary market target of this type of advertising.[153] According to Families USA, 2000,[154] seniors are the largest consumers of OTC and prescription drugs, and "women often are the primary decision makers on health care issues and medication purchases."[155] These findings are not indicative of gender bias but suggest women play a key role in addressing the healthcare needs of their families.

DTC advertising has and will continue to play an important role in the health consumers decision-making process until significant regulatory and legislative changes are made. Therefore this type of advertising will continue to remain a way of life for many North Americans. In a move to provide future guidance and structure as to how the pharmaceutical industry presents/portrays their products in DTC advertising, PhRMA—in a major policy speech before the American Legislative Exchange Council's 32nd Annual meeting in August 2005—announced the pharmaceutical industries' "Guiding Principles" on DTC advertising with the intention of implementing them in 2006.[156] Some of the key elements of the Guiding Principles are:

- Companies should submit all new direct-to-consumer television advertisements to the FDA before releasing them for broadcast.
- DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.
- DTC television and print advertising should be designed to achieve a balance presentation of the benefits and risks associated with the advertised prescription medicine. Specifically, risks and safety information in DTC television advertising should be presented in clear, understandable language, without distraction from the content and in a manner that supports the responsible dialogue between patients and health care professionals.

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[153] Steven Woloshin et al. 1143.
[154] Families USA. "Cost Overdose: Growth in Drug Spending for the Elderly 1992-2010." Washington, DC. (Publication No. 00-107) 2000. As cited in Brownfield et al. 495.
[155] U.S. Department of Labor. General fact on women and job based health. (2000). <http://www.dol.gov/dol/pwba/public/pubs/hlth5.htm>. As cited in Brownfield et al. 495.
[156] PhRMA Media Press Release. America's Pharmaceutical Industry Announces Guidelines on Direct-to-Consumer Advertising. 2005. 25 November, 2005. <http://www.phrma.org/mediaroom/press/releases/02.08.2005.1195.cfm>.

- Companies should spend an appropriate amount of time to educate health professionals about new medicines or new therapeutic indications before beginning the first direct-to-consumer advertising campaign. In determining "an appropriate time," companies should consider the importance of informing patients of the new medicine, the complexity of its risk-benefit profile, and health care professionals' knowledge of the condition being treated. Companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources.

However, on closer examination of these "guiding principles", there does not appear to be any significant difference from the principles that the FDA established in the 1997 *Modernization Act,* which has proven to have limited enforcement and/or sanction value. Similarly, the descriptor 'should' is used throughout the guiding principles, which again, places no onus on industry to follow through with PhRMAs guidelines. In the end, it is the health consumer who must weigh the value of advertising. They need to assert their autonomy and ensure that what they see and hear is reliable, and seek to form a mutual working relationship with their health care provider. One thing is certain—that further research is necessary to determine the true impact that DTC advertising may or may not be having on improving the health consumers.

Chapter 3

THE CREATION OF AN ILLNESS

"There's a lot of money to be made from telling healthy people they are sick."[157] With the fierce competition currently pervasive in the medical industry, what better way to tap into a new market than to "create" a new illness? Over the past 20 years alone, numerous new "illnesses" have arisen, many of which were the result of taking a normal function and implying that something was wrong. Social scientists refer to this phenomenon as "medicalization," and others simply call it "disease mongering."[158] "Medicalization" occurs when "previously non-medical problems are defined and treated as medical problems, usually in terms of illnesses or disorders.[159]

Interestingly, many of these "new" illnesses fall under the realm of psychiatry, which in part may be due to the uncertainty surrounding the diagnosis of many psychiatric illnesses. Psychiatry, unlike many other areas of medicine such as oncology and orthopedics, for example, is not as well defined in terms of overt diagnosis based on objective signs and symptoms that are uncovered through various test such as x-ray and blood tests. In this writer's experience, the diagnosing of a psychiatric condition is often based on observations of the individual's behaviour and emotional state as well as the presentation of their thought process and content. The subjective nature of this criteria, coupled with the experience and training of the psychiatrist or general practitioner making the diagnosis can vary greatly, as many psychiatric illnesses share very similar

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[157] Ray Moynihan, Iona Heath, and David Henry. "Selling Sickness: The Pharmaceutical Industry and Disease Mongering." *British Medical Journal.* 324 (2002): 886.
[158] Payer 88.
[159] Peter Conrad and Valerie Leiter. "Medicalization, Markets and Consumers." *Journal of Health and Social Behaviour* 45 (2004): 158.

features. Moreover, in psychiatry, "illnesses" are continuously being revised, modified, removed, and added due to the continuing efforts of the members of the Diagnostic and Statistical Manual (DSM) Committee.[160]

Industry also has played a significant role in promoting diagnostic imaging—specifically CT scans and MRIs—that can find all sorts of "abnormalities" for which often, no one is quite sure what should be done, if anything. As some health consumers and physicians have discovered, it may be better to leave well enough alone versus delving into the unknown, especially when the consequences could be deadly. Moynihan et al. explains: "Inappropriate medicalisation carries the dangers of unnecessary labeling, poor treatment decisions, iatrogenic[161] illnesses, and economic waste, as well as the opportunity costs that result when resources are diverted away from treating or preventing more serious diseases."[162]

Often, a health consumer is not the most reliable one to gauge his or her own subjective feelings of healthiness: "Healthy people can become more preoccupied with their bodies and their symptoms than people with serious diseases, as the hypochondriac."[163] The more that health consumers scrutinize themselves, the greater the chance that they will find something wrong. If they do not find anything wrong, they often believe something must have been missed, and they may partake in an expensive

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[160] The Diagnostic and Statistical Manual (DSM) is a classification system of mental disorders published by the American Psychiatric Association (APA). This manual is used as a diagnostic and treatment resource for a variety of clinicians, including: psychiatrists, general practitioners, psychologist, social workers and nurses, throughout the world. Since the first edition of this manual was published in 1952, the number of committee members (also referred to as, the task force) has grown exponentially from 7 members to over 25 members with some slight variations in numbers. Associated work groups have also been established to focus on specific sections of the DSM since the third edition, whose work is then reviewed by anywhere from 50-100 international advisors. However, the ultimate decision of what is published in the DSM rests with the committee members. Roger Blashfield and Kenneth Fuller. "Predicting the DSM-V." *The Journal of Nervous and Mental Disease* 184.1 (1996): 4-7.

[161] Anderson et al. 864. Iatrogenic means being caused by treatment or diagnostic procedures.

[162] Moynihan, Heath and Henry 886.

[163] Barsky 56.

and potentially dangerous journey in search of a diagnosis and subsequent treatment. Continuous exposure to DTC advertising often leaves the health consumer at the mercy of the industry, as they may never realize what Barsky refers to as the dangers "lurking in our lifestyles, diets and environment."[164]

Society's perceptions of health have changed over the years: people are more willing to "adopt the sick role more readily than they used to, perhaps in part because disability is more socially sanctioned now."[165] Today, it has become an accepted norm to discuss one's health-related issues during social settings, whereas at one time, it was as unthinkable as talking about politics or religion. In some instances, an almost competition-like mentality emerges between health consumers to see who has the most aches and pains, who is taking the greatest number of prescriptions, who has the most obscure diagnosis, or who has had the greatest number of physician visits. It would appear that the 30 year old dream of Henry Gadsden, former chief executive of *Merck* pharmaceuticals, has become a reality, and now drugs are made for everyone, including the healthy.[166]

Changing Times: The Creation of Illness

At times it is difficult to tell whether the illness or treatment came first. Dr. Rodney Jackson, professor of epidemiology at the University of Auckland in New Zealand, believes that "disease is a rare event, and physicians have run out of diseases, but you never run out of risk factors" and "when you treat risk factors, you'll never be without a

[164] Barsky 77.
[165] Barsky 188.
[166] Moynihan and Cassels xi.

job."[167] This belief has been observed time and again throughout the twentieth and twenty-first centuries. Until the mid-twentieth century, it was common practice to remove tonsils, and often adenoids, for recurrent throat infections, most specifically in children, due to the belief that it would solve this problem, since, at the time, these glands were not believed to serve a well-defined purpose.[168] However, now it is known that the tonsils and adenoids are part of the lymphatic system, which plays an important role in the immune system of children's bodies, specifically operating as gatekeepers for the lungs and intestines.[169] The tonsils and adenoids are vascular glands which potentate the chance of hemorrhage during the removal of one or both sets of these glands, even days after the procedure.[170] Nevertheless, over time, the potential risks of this once very common procedure, and its questionable necessity and benefits, has led to a dramatic drop in its frequency. Today this procedure only is considered as a last resort.

At the turn of the twentieth century, the medical profession also erroneously labeled the normally enlarged thymus gland[171] of infants and children as status thymicolymphaticus, a condition that was believed to require immediate and drastic medical attention via irradiation. At that time, the thymus gland, similar to the tonsils and adenoids, was thought to have no useful purpose. This perspective was grounded in the belief that the enlarged thymus gland was directly related to sudden infant death,

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[167] Payer 32.
[168] Payer 31.
[169] See Robert Berkow et al. *Merck Manual of Medical Information, Home Edition.* (Rahway, New Jeresy: Merck & Company Inc, 2000) 809 & 998.
[170] Lillian S. Brunner and Doris S. Suddarth. *Textbook of Medical-Surgical Nursing,* 6th Ed. (Philadelphia, Pennsylvania: J.B. Lippincott Company, 1988) 388.
[171] Anderson et al. 1710. A lymphoid organ is located in the mediastinum and functions as the primary central gland of the lymphatic system. The size of the organ relative to the rest of the body is largest when an individual is approximately 2 years old. The thymus usually attains its greatest absolute size at puberty.

"crib death," or sudden infant death syndrome (SIDS) as it is commonly called today.[172] Autopsies performed on infants and children found enlarged thymus glands which were believed to have caused sudden death by compressing their airways.[173] Since the thymus gland was known to be sensitive to radiation, it was extensively used as a treatment: "The first patient [diagnosed with status thymicolymphaticus] was treated with a total of 96 minutes of x-rays."[174] Between the early 1900s and the late 1950s, tens of thousands of infants and children were treated with massive doses of radiation for this perceived "deadly" condition. Unknown to physicians at the time, this "treatment" contributed to a significantly high level of thyroid, breast, and other forms of cancer in these patients. In 1945, Dr. John Caffery stated: "Destroying the thymus myth was one of his field's [radiology] most important contributions to medicine [...] most mistakes I've seen were not because one didn't know some disease but because he didn't know he was looking at normal."[175] The medicalization of this "normal" condition and its subsequent treatment illustrate how harm was intentionally introduced to a non-problematic condition, with potentially fatal outcomes.

The continued quest for health and wellness also was the basis for the introduction and widespread marketing of two pharmaceutical drugs—diethylstilbestrol (*DES*) in the 1940's and thalidomide in the late 1950s. In 1938, *DES* was the first synthetic estrogen to enter the market and originally was prescribed for reproductive health problems, most notably menopause.[176] However, in the 1940s, researchers recommended the use of this

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[172] Tood Jacobs, Donald Frush, and Lane Donnelly. "The Right Place at the Wrong Time: Historical Perspective of the Relation of the Thymus Gland and Pediatric Radiology." *Radiology* 210 (1999): 12.
[173] Jacobs, Frush and Lane 13.
[174] Jacobs, Frush and Lane 14.
[175] Jacobs, Frush and Lane 14.
[176] Susan Bell. Reader's Companion to U.S. Women's History: Diethylstilbestrol (DES) 6 August, 2005.<http://college.hmco.com/history/readerscomp/women/html/wh_009900_diethylstilb.htm>.

drug to prevent miscarriages. Millions of women throughout North America were prescribed this drug, even though it was never officially approved for use during pregnancy. In the 1950s controlled clinical studies cast doubt on the safety and efficacy of *DES*, specifically during pregnancy. The studies indicated that *DES* actually appeared to increase the chances of miscarriages.[177] However, it was not until 1971, some 33 years after its introduction to the North American market, that *DES* was finally removed after being confirmed to be a transplacental carcinogen. The daughters of the women who took *DES* during pregnancy were found to have a greater risk of developing vaginal or cervical cancer as a teenager or young adult. As well, these "*DES* daughters" also have had a greater risk of ectopic pregnancies, miscarriages, premature births, and stillborns.[178] Compared to non-exposed men, the "*DES* sons" have been found to have an increased risk of infertility and genital abnormalities.

Thalidomide was introduced in 1956 as a sedative, but became a popularly prescribed drug for morning sickness in the late 1950s and early 1960s. The U.S. FDA never approved this drug for the U.S. market, since questions were raised as to its safety for humans; nevertheless, it was readily available in Canada and several European countries.[179] Thalidomide was not removed from the world market until 1961 when severe teratogenic[180] birth defects were directly linked to its use during pregnancy.[181] Even a single dose, a 50 mg capsule, could cause birth defects. Unfortunately, before this drug's removal more than 10,000 children were born with severe limb malformations and

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[177] Bell "Reader's Companion..."
[178] Bell "Reader's Companion..."
[179] Anthony Perri III and Sylvia Hsu. "A Review of Thalidomide's History and Current Dermatological Applications." *Dermatology Online Journal* 9.3 (2003): 1. 7 August, 2005. <http://dermatology.cdlib.org/93/reviews/thalidomide/hsu.html>.
[180] Anderson et al. 1690. Teratogenic means the development of physical defects in the embryo.
[181] Perri and Hsu 3.

other physical defects around the world. Moreover, it has been estimated that approximately 40% of exposed fetuses died during or shortly after birth, with bowel atresia being the most common cause of death.[182]

The key issue that arises in relation to these conditions and their subsequent treatments is how both the medical profession and industry make mistakes. It is acknowledged that there must be a distinction made between adverse events that appear during the trial phase of a new drug or procedure which subsequently is marketed and promoted to the health consumer versus adverse events that may arise years after taking a drug or having had a medical procedure as noted in the aforementioned examples. However, the more serious concern arises when various drugs, medical products and procedures that have ominous trial data make it to market. As well, when evidence mounts as to the negative long-term effects of medical products and procedures once deemed safe and effective, the concerns may be downplayed or even ignored. One would like to believe that logic would dictate that past mistakes would be the catalyst for learning, and as a result, safety mechanisms would be put in place to prevent such incidents from happening again. Yet, time and again, unnecessary medical mistakes occur, most recently with the drug *Vioxx*.[183]

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[182] Perri and Hsu 3.

[183] See A. Mark Fendrick. "COX-2 Inhibitor Use After Vioxx: Careful Balance or End of the Rope." editorial, *The Journal of Managed Care* 12.11 (2004): 740-741; "Risky Business: The need to establish improved drug-safety measures after the withdrawl of Vioxx is paramount, but setting up such systems will be far from easy." editorial, *Nature Reviews* 4 (2005): 793 and "The 'file drawer' phenomenon: suppressing clinical evidence." editorial, *Canadian Medical Association Journal* 170.4 (2004): 437. For or greater detail into the world of medical mistakes see: Atul Gawande. *Complications: A Surgeon's Notes on an Imperfect Science*. (New York: Henry Holt and Company, 2002) and Robert M. Wachter and Kaveh Shojania. *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes.* (New York: Rugged Land, 2004).

One critic of what he sees as "the medicalization of life and the expansion of patienthood" has stated: "an alliance of advertisers, manufacturers, entrepreneurs, and advocacy groups has discovered that medicalization is lucrative."[184] The industry, most notably through their effective usage of DTC advertising over the past 20 years, has demonstrated the powerful role it plays in relation to the creation of illness. For example, the record profit that many of the large pharmaceutical companies are posting is evidence of the strong hold they have over both the medical profession and the health consumer. The same trend holds true for the private medical industry as the number of private diagnostic and cosmetic surgery centres continues to increase. In 2005, Moynihan and Cassels examined the intricacies the pharmaceutical industry uses to make health consumers believe they are sick.[185] One strategy shared by Vince Parry—an advertising expert —is how medical experts are gathered to "create new ideas about illnesses and conditions" with the goal of providing the health consumer around the world "a new way to think about things" and to provide a link between illness and medication to maximize sales.[186] Over the years, the industry has been quite creative and extremely successful in their use of DTC advertising to get the message out about illnesses and their subsequent treatments. Some of most successful strategies incorporated into the DTC advertising machine involve the use of product champions, thought-leaders, key opinion leaders,[187] and patient advocacy groups.

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[184] Barsky124.
[185] For more detail see Moynihan's and Cassel's *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All Into Patients.*
[186] Moynihan and Cassels xiv.
[187] See Moynihan and Cassels 6. These key opinion leaders are the senior physicians who write the guidelines, conduct the sponsored research, educate colleagues at sponsored conferences, and publish papers in medical journals kept afloat financially by carrying drug company advertisements. At the same time as being on the drug company payroll as advisors and paid speakers, many of these physicians hold positions at prestigious academic institutions.

Leaders of Illness

"Cultivating a stable of thought-leaders is a key part of the industry's marketing strategies."[188] The recruitment and grooming of future thought-leaders is a precise science. The right match is essential to ensure that the message the industry wishes to convey is effective and convincing: "Prominent doctors are enlisted to publicly affirm the malady's ubiquity, then public-relations firms launch campaigns to promote the new disease, using dramatic statistics from corporate-sponsored studies."[189] The most successful members of this elite group are able to work the crowd and "sell without selling."[190] For these select few consultants, benefits may range from lucrative consulting fees, stock ownership, appearances at high profile events, and research grants to conduct clinical trials.

One of the most prominent thought-leaders of the 1990s was Dr. Jack Gorman, a well-respected and esteemed psychiatrist and professor at Columbia University. During this time, he led the campaign promoting an obscure psychiatric condition known as General Anxiety Disorder (GAD). During one of his frequent television appearances he stated: "It is our hope that patients will now know that they are not alone, that their disease has a name, and it is treatable."[191] The treatment Dr. Gorman was advocating was paroxetine (*Paxil*), a selective serotonin reuptake inhibitor (SSRI). However, at the time, a little known fact of this disease awareness campaign was that Dr. Gorman served as a paid consultant to at least 13 pharmaceutical firms including *SmithKline Beecham*,

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[188] Moynihan and Cassels 38.
[189] Brendan Koerner. "Disorders Made to Order. July/August 2002." 20 March, 2005 <http://www.motherjones.com/news/feature/2002/07/disorders.html>.
[190] Moynihan and Cassels 39.
[191] Koerner "Disorders Made to Order"

(now known as *GlaxoSmithKline*) the manufacturer of *Paxil.*[192] Dr. Gorman's work on this campaign helped propel this obscure disease and its treatment into a multi-billion dollar enterprise.[193]

The latest thought-leader to enter the arena of disease awareness and promotion is Dr. Irwin Goldstein, a urologist and professor of urology and gynecology at the Boston University School of Medicine.[194] Acting as the keynote speaker at several national and international industry sponsored gatherings, Dr. Goldstein has been an outspoken advocate of a 'disorder' that has recently garnered significant public attention—female sexual dysfunction (FSD)[195]. By all accounts, he is a "consultant and lecturer for every pharmaceutical company,"[196] leaving open to question his ability to provide an objective view of the disorder.

A strong correlation appears to exist between the promotion of newly created and obscure illnesses (and their subsequent treatment) and the funding and other fringe benefits that thought-leaders such as Drs. Gorman and Goldstein—as well as numerous other high profile physician/researchers—receive for their part in "educating" health consumers and other health practioners. Most of the relationships forged between industry and health professionals create a potential for conflict of interest, especially when characterized by financial ties. Moreover, in this context, conflicts of interest raise

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[192] Koerner
[193] Moynihan and Cassels 120.
[194] Moynihan and Cassels 178.
[195] Sexual dysfunction is defined as a problem with sexual responding that causes a person mental distress; examples are erectile dysfunction in men and anorgasmia in women. William Masters and Virginia Johnson were the first researchers to explore the physiological sexual response beginning in the mid 1950's and culminated in 1966 with the publication of Human Sexual Response. In response to the lack of understanding and treatment of sexual dysfunctions these researchers published their book, Human Sexual Inadequacy in 1970. For more information on sexual dysfunction see Janet Shibley Hyde's and John DeLamater's book: Understanding Human Sexuality, 8th Ed.
[196] Ray Moynihan. "The Making of a Disease: Female Sexual Dysfunction." *British Medical Journal* 326 (2003): 46.

many ethical issues especially in terms of the fiduciary role physicians undertake as part of their profession vis-à-vis the Hippocratic Oath and Professional Codes of Conduct. As noted earlier, both health consumers and physicians rely on the credibility of information presented in medical journals and other sources such as conferences: the latter are, more often than not, industry sponsored.[197]

Often, thought-leaders, or at least their names, are linked to key clinical trials of the drug they are promoting. When prominent physicians permit their names to be linked to clinical studies in which they had limited or no actual participation, concerns are raised, especially since their names alone often are important factors in the studies reaching publication status, and in their perceived reliability. This phenomenon, known as medical "ghostwriting", has been garnishing wider attention in the past decade.[198]

The ghostwriting trend was brought to the public attention in 1999 in a case involving the diet drug fen-phen produced by *Wyeth-Ayerst Laboratories*. It was found that:

> Wyeth-Ayerst had commissioned ghostwriters to write ten articles promoting fen-phen as a treatment for obesity. Two of the ten articles were actually published in peer-reviewed medical journals before studies linked fen-phen to heart valve damage and often fatal lung disease forcing the company to pull the drugs from the market.[199]

The drug fen-phen is actually a combination of two separate drugs (fenfluramine and phentermine) which are both classified as anorectics—drugs used to suppress appetite in

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[197] William B. Weeks, Amy E. Wallace and B.C. Surott Kimberly. "The Changing Face of Pharmaceutical Advertising: A look a medical journals reveals a new era in advertising. *Marketing Health Services* 21.3 (2001): 30, Clifford 18 and Davidoff et al. 786-788.

[198] Troyen A. Brennan, M.D., J. D. addressed the growing trend of industry purchasing tailored editorials for publication in both peer and non-peer reviewed medical journals from well known and respected physicians who had no connection with the clinical trials. Troyen A. Brennan. "Buying Editorials." *The New England Journal of Medicine* 331.10 (1994): 673-675.

[199] Sheldon Rampton and John Stauber. "Research Funding, Conflicts of Interest, and the 'Meta-methodology' of Public Relations." *Public Health Reports* 117 (July-August 2002): 331-339.

obese individuals. Both of these drugs have been on the market for decades, with phentermine gaining FDA approval in 1959 and fenfluramine in 1973.[200] However, the FDA never approved these drugs to be used in combination or for long-term use, but published studies suggested significant weight loss would result if this combination were used for an extended period of time. In 1996, more than 18 million Americans were prescribed this combination of drugs.[201] It was not until 1997 that concerns were raised by physicians at the Mayo clinic in Minnesota when a significant number of patients developed heart valve disease after taking fen-phen. This finding lead to the issuance of a Public Health Advisory, and subsequently lead the FDA to withdraw fenfluamine and another anorectic, dexfenfluramine from the U.S. market on September 15, 1997.[202] This incident highlighted the serious consequences ghostwriting may have on both the unsuspecting treating physician and their patients.

David Healy of the University of Wales has been instrumental in bringing national and international attention to the ghostwriting phenomenon, so much so that his teaching position at the University of Toronto was suspended and an offer of employment by the Centre for Addictions and Mental Health was withdrawn because of his criticism of the pharmaceuticals industry and the medical profession for allowing this type of publication bias.[203] Dr. Healy estimates that as much as 50 percent of the literature on

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[200] Eric Colman. "Anorectics on trial: a half century of federal regulation of prescription appetite suppressants." *Annals of Internal Medicine* 143.5 (2005): 381.
[201] Heidi M. Connolly et al. "Valvular heart disease associated with fenfluramine-phentermine." *The New England Journal of Medicine* 337.9 (1997): 581.
[202] U.S. Food and Drug Administration. "FDA announces withdrawal fenfluramine and dexfenfluramine (fen-phen)." 30 September, 2005. <http://www.fda.gov/cder/news/fenphenpr81597.htm>.
[203] Steven Lewis et al. "Dancing with the porcupine: rules for governing the university-industry relationship." *Canadian Medical Association* 165.6 (2001): 784.

drugs is ghostwritten.[204] Jerome Kassirer—past editor of the NEJM—responded to the Wyeth-Ayerst acknowledgment of this style of research:

> The whole process strikes me as egregious [...] The fact that Wyeth commissioned someone to write pieces that are favourable to them, the fact that they paid people to put their names on these things, the fact that people are willing to put their names on it, the fact that the journals published them without asking questions.[205]

What Healy and Kassirer have exposed is a lack of professional integrity and ethics in both the industry and some medical professionals. In light of their work, it seems apparent that some physicians are willing to stake their careers on studies that they have had limited or no actual participation in and, most tragically, are also willing to put unsuspecting health consumers' lives at risk. This being said, there is no reason to believe that all thought-leaders partake in the unscrupulous activities just addressed, but doubt has been cast on the reliability, safety, and efficacy of some of the drugs they are promoting in their industry-sponsored roles.

Advocacy, But For Whom?

Patient advocacy groups can play a powerful role in conveying a message or educating others about health conditions in which they have an interest, and often, media outlets are their voice of choice. One of the earliest and most successful patient advocacy groups was the March of Dimes founded in 1938 by former U.S. President Franklin D. Roosevelt to raise money to find a cure for polio and care for those suffering from the illness. Through this group's hard work and determination, a vaccination for the disease

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[204] Produced and reported by Erica Johnson and Colman Jones "Inside the Business of Medical Ghostwriting," *CBC Marketplace*, CBC Television, 25 March 2003.
[205] Rampton and Stauber 117.

was developed in 1955.[206] Rather than disbanding after an effective cure was found, the group turned its attention to improving the health of infants by preventing premature birth, birth defects, and infant mortality. Today, two of the most well known patient advocacy groups supporting breast cancer are the American Cancer Society and the Canadian Breast Cancer Foundation. Through their pink ribbon campaign, these advocacy groups have raised millions of dollars to support educational awareness and research for breast cancer. Patient advocacy groups play an important role in creating illness awareness, although a problem arises when they are sought out, or even created, by industry to advocate new or obscure illnesses.

The direct sponsorship of patient advocacy groups by industry has become "a key element of marketing strategies for every major medical condition, and with virtually every major drug company."[207] A recent U.K. survey found that almost two-thirds of patient advocacy groups and global health charities now accept support from pharmaceutical or device manufacturers.[208] On the surface, this may seem a reasonable practice, since many patient advocacy groups are constantly struggling financially to keep their organizations afloat so they can support their members and continue to spread their message. However, this alliance comes at a cost. Pubic relations practitioner Teri Cox in 2002, quoted a senior pharmaceutical company PR experts as saying:

> "Gone are the days when companies just handed out big checks to groups with no discussion afterwards, now we seek opportunities with groups that not only help them achieve their goals and objectives, but also help us move our business along."[209]

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[206] For more information on the history and role the March of Dimes go to <www.nationmaster.com/encylopedia/March-of-Dimes>.
[207] Moynihan and Cassels 62.
[208] Moynihan and Cassels 62.
[209] Teri P. Cox. "Forging alliances, advocacy partners", supplement to *Pharmaceutical Executive*, September (2002):8 as cited in Moynihan and Cassels 75.

Cox in her report notes that patient advocacy groups become members of the pharmaceutical companies 'marketing' team and that "accepting commercial sponsorship almost always ties the recipient, whether they like it or not, into the sponsor's marketing machinery."[210] It would appear as though many patient advocacy groups 'unwittingly' hand over the direction, and at times the voice of their organization to that of their corporate (pharmaceutical) sponsor.

Certainly, industry is well aware that advocacy groups have a rich supply of real people with various illnesses, and that a strong public relations team can make these illness, and most importantly their "treatment," a virtual financial success by focusing on people's emotions about being sick and the desire to be well. Cox (2002) further pointed out that: "Advocacy groups help companies provide the media with patients for their stories, they help defuse the arguments of industry critics by offering positive messages about drug companies, they even help influence the decisions of policy-makers and regulators."[211] A question can be raised that if advocacy groups feel they are promoting positive messages sponsored by financial backing from the drug companies, why do so few openly disclose these ties? Patient relations have become powerful tools in moving the pharmaceutical industries "political and financial agenda forward".[212]

Patient advocacy groups are not always the product of grass roots organizations. In some cases, large corporations have used public relations professionals to create fake

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[210] Teri P. Cox. "Forging alliances, advocacy partners", supplement to *Pharmaceutical Executive*, September (2002):8 as cited in Moynihan and Cassels 74-75.
[211] Moynihan and Cassels 74.
[212] Greg Critser, *Generation Rx: How Prescription Drugs Are Altering American Lives, Minds and Bodies* (New York, New York: Houghton Mifflin Company, 2005) 28.

grassroots campaigns, a concept known as "astro-turfing."[213] This strategy was used to support the release of the drug *Lipitor* when a newly created patient advocacy group—the Boomer Coalition—emerged as part of Pfizer's (the manufacturer of *Lipitor*) public relations firm.[214] What made this campaign unique as well as successful was the involvement of several well-known movie and television stars, recruited as part of the new group to encourage health consumers to get their cholesterol levels checked. Pfizer's role in the campaign was never mentioned by any of the group's members.[215]

More recently, astro-turfing has been used to aggressively promote GAD, a little known anxiety disorder at the time, purportedly treatable by *Paxil* as discussed above. Coincidentally, on the date *Paxil* was released on the open market, a new patient advocacy group known as Freedom From Fear surfaced to share their story with health consumers. Their GAD campaign involved releasing the results of a telephone survey that indicated "people with GAD spend nearly 40 hours per week, or a full-time job, worrying."[216] Similar to the Boomer Coalition, this advocacy group failed to mention any ties with the drug industry, or any "treatment" for this condition. However, the contact person listed for this group and their survey was an account executive at Cohn & Wolfe, *Paxil*'s manufacturer's public relations firm.[217]

Following the success of their GAD campaign, *Paxil*'s manufacturer and its public relations firm Cohn & Wolfe were now ready to put their expertise to work for the latest new disorder to materialize—Social Anxiety Disorder (SAD)—another disorder requiring a new patient advocacy group to promote awareness. The Social Anxiety

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[213] Moynihan and Cassels 9.
[214] Moynihan and Cassels 9.
[215] Moynihan and Cassels 9
[216] Koerner.
[217] Koerner.

Disorder Coalition was formed with the support of three nonprofit members: the American Psychiatric Association, the Anxiety Disorders Association of America, and Freedom from Fear. The slogan "Imagine Being Allergic to People" became the catch phrase of this group.[218] During the height of this public awareness campaign, the coalition had a toll-free number to provide information to health consumers; however, those who call this number today receive a recorded message that simply states: "This program has successfully concluded."[219] This action (the shutting down of an information hot-line) by an advocacy group, that played such an integral part in making health consumers aware of this "potentially life altering" condition, is an illustration of the creative and exceeding powerful marketing practices the industry engages as part of their financial agenda.

The commercialization of medicine is big business for industry. With the right public relations machinery, lax regulation and legislation surrounding DTC advertising and an endless supply of health consumers, the creation of illness and its subsequent treatment is a very lucrative business. Concerns have been raised by various organizations including the WHO regarding many of these seemingly back door industry marketing tactics but to no avail. The following chapter will address the medicalization of several conditions and how DTC advertising will likely influence the future of healthcare in North America.

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[218] Koerner.
[219] Koerner.

Chapter 4

DISORDERS MADE TO ORDER

In the late 1980s, a new classification of drugs, selective serotonin re-uptake inhibitors (SSRI) entered the market, and originally, they were prescribed for the treatment of depression. *Prozac* (fluoxetine), the first to enter the arena, was a marketing sensation from the start, initiating what has been called the *Prozac* era. However, as with all regulated drugs, patent protection eventually comes to an end, and *Prozac* and its successors were no exception. Over the years, pharmaceutical companies have developed creative solutions to protect their investments when patent protection concludes. One strategy is to market the drug for a secondary use in the treatment of existing conditions. This is what Merck was attempting to do with *Vioxx* prior to its recall. Another tactic involves the utilization of a current drug to treat mysterious new syndromes such as premenstrual dysphoria disorders (PMDD). Using this strategy, *Prozac* which no longer had patent protection was packaged under a new name—*Sarafem*—as the only current treatment for this new "disorder."[220] IMS Health has recognized this technique as a strategy to "combat generic erosion" and believes that if pharmaceutical companies are to sustain growth and market share, they have to find ways "to extend the life of their patents, to receive FDA approval for new indications of existing products, and to create new, improved versions of existing products."[221] Such strategies make perfect marketing sense, since "a new indication can be obtained in less

[220] Nathon Greenslit. "Pharmaceutical Branding: Identity, Individuality, and Illness." *Molecular Interventions* 2.6 (2002): 344.
[221] Greenslit 344.

than 18 months, compared to the eight years it takes to bring a drug from the lab to the pharmacy."[222]

A movement is growing to medicalize natural processes such as menopause and more recently menstruation itself by converting them into diseases or conditions that require treatment. With female life expectancy continually increasing, more women will reach the menopause phase of their lives, thereby creating a potentially large market population. In terms of targeting large populations, industry is trying to encourage women to reconsider whether there is a need or reason to have as many menstrual cycles when drugs exist that can suppress them. Discussions surrounding menstrual suppression are targeting younger women who have numerous reproductive years ahead. These two "conditions" may some day soon make it difficult to separate natural bodily states from abnormal ones.

Of course it must be acknowledged that new specifically diagnosable diseases requiring specific and sometimes immediate medical attention have arisen over the past twenty years, for example, Acquired Immunodeficiency Syndrome (AIDS) and West Nile Virus, but the difference is in how the label of "illness" emerged. The majority of the marketing of drugs and imaging services is accomplished through the mass media and is aimed at capitalizing on a range of consumer emotions and potential motivations—from "fear about disease to promises of health."[223] With this in mind, how can society be protected from falsely believing that people are suffering from an "illness" or "disorder" that requires medical attention, when in truth they are not?

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[222] Koerner.
[223] Illes et al. 2415.

The Changing Face of Psychiatry

To this day, the brain remains the least understood aspect of the human design giving psychiatry an air of uncertainty. The causes, and sometimes treatments, for many psychiatric illnesses such as schizophrenia and Electro Convulsive Therapy (ECT), used primarily in the treatment of major depression, remain speculative to this day. However, in 1948, the responsibility of the *International Statistical Classification of Diseases and Health Related Problems* (ICD)—then in its 6th edition—was transferred to the newly formed WHO. At this time, the knowledge about and understanding of mental disorders was fairly limited, and the ICD had inadequately addressed mental disorders as a whole, for example, offering no codes for personality disorders or dementia.[224] As a result of these shortcomings, the WHO explored ways in which to standardize psychiatric diagnosis and mental health statistics.[225] While the attempt to standardize mental disorders was taking place at an international level, the United States through the American Psychiatric Association (APA) was working on their own manual, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM). The first edition of the DSM was published in 1952 and has undergone several editions and revisions since. Over the course of the last 50 years, this manual has added numerous new conditions, made changes in diagnostic criteria, merged conditions, and removed some conditions. One of the most infamous "conditions" ever to be given a psychiatric label was homosexuality. This category was added to the DSM II in the late 1960s. However, this condition was de-listed from the revised edition of the DSM II in the early 1970s after

[224] David Healy, *The Creation of Psychopharmacology* (Cambridge, Massachusetts: Harvard University Press, 2002) 298.
[225] Healy 298.

intense debate and pressure from within the psychiatric community and other interest groups. Nevertheless, to this day, the DSM remains an influential tool in the diagnosing of mental disorders in North America and abroad.

David Healy, Ray Moynihan, and others have alluded to and even suggested that over the years some of the DSM committee members may have permitted personal or perhaps outside interests guide them in their support of changes to the DSM, most specifically the addition of new and sometimes controversial conditions. Since psychiatry is not an exact science, it is not uncommon for different psychiatrists to diagnose the same patient with a different condition based upon their interpretation of the DSM criteria. The American Psychiatric Association itself in 1987 acknowledged that there were "many instances in which the criteria [in the DSM] were not entirely clear, were inconsistent across categories, or were even contradictory."[226] Healy noted that the disorder categories between the DSM-II to that of the DSM-IV have almost doubled, from 180 to over 350 categories, making it possible and even quite likely those individuals could be diagnosed with different several mental disorders at the same time resulting in a multitude of treatments.[227]

However where the potential problems arise is when the DSM committee and advisory members have links to industry and could use their influence to make changes to the diagnostic criteria without having reliable scientific justification for these revisions. The DSMs of the past have moved beyond "an almost sole reliance on expert consensus

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[226] Thomas Widiger and Anna Clark. "Towards DSM-V and the Classification of Psychopathology." *Psychological Bulletin, the American Psychological Association Inc.* 126.6 (2000): 947.
[227] David Healy. The Antidepressant Era (Cambridge, Massachusetts: Harvard University Press, 1997) 175.

to a greater reliance on reviews of published literature"[228] for example, which, as already addressed, poses concerns in relation to issues of conflicts of interests, specifically publication bias. The implications of such changes may result in the application of inappropriate or perhaps unnecessary medical treatment that could in turn lead to the stigma often associated with the label of a mental disorder.

Studies conducted in both North America and Australia have found that the majority of diagnosing and subsequent treatment of minor depressive disorders for example are carried out by general practitioners (GPs) versus psychiatrists.[229] As well, these studies indicated that GPs might not be as capable, comfortable or confident with appropriately diagnosing and treating possible psychiatric conditions, especially if these physicians do not have appropriate education and training regarding these disorders. A 1999 report presented to the United States Surgeon General found,

> stigmatization with people with mental disorders has persisted throughout history. It is manifested by bias, distrust, stereotyping, fear, embarrassment, anger, and/or avoidance. Stigma leads others to avoid living, socializing or working with, renting to, or employing people with mental disorders, especially severe disorders such as schizophrenia.[230]

An extensive MEDLINE (Ovid) literature review utilizing the key words: stigma and mental illness, uncovered hundreds of articles from across the globe that addressed various facets of what was presented in the U.S. Surgeon General's report. A common

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[228] Michael First et al. "Clinical Utility as a Criterion for Revising Psychiatric Diagnosis." *American Journal of Psychiatry* 161.6 (2004): 952.

[229] Heather McGarry, Kelsey Hegarty and Jane Gunn. "How do Victorian GPs Manage Patients with Depression?" *Australian Family Physician* 34.7 (2005): 603, Peter McManus et al. "Use of Antidepressants by General Practitioners and Psychiatrists in Australia." *Australian and New Zealand Journal of Psychiatry* 37 (2003): 184 and Ramin Mojtabai. "Diagnosing Depression and Prescribing Antidepressants by Primary Care Physician: The impact on practice style variations." *Mental Health Services Research* 4.2 (2002): 109.

[230] D. Satcher. Mental Health: A Report of the Surgeon General. Washington. D.C.: Office of the U.S. Surgeon General, 1999. As cited in Patrick W. Corrigan. "Target-Specific Stigma Change: A strategy for impacting mental illness stigma." *Psychiatric Rehabilitation Journal* 28.2 (2004):113.

theme throughout the literature was that, a diagnosis of a mental disorder would overwhelmingly result in the stigmatization of the individual to varying degrees. Consequently, if physician's misdiagnose/over-diagnose individuals with a mental disorder based on questionable diagnostic information, for example, may result in unforeseen and virtually treatment resistant condition, known as stigmatization.

Robert Spitzer—a prominent New York State psychiatrist, past editor of the DSM III and III-R, and a leading recipient of industry grants to conduct research into drug treatments for anxiety disorders—has been an instrumental force behind the expansion of the DSM criteria since it's second edition.[231] The DSM III under the leadership of Spitzer has been "widely regarded as marking a revolution in American and world psychiatry" as it "satisfied the needs of the insurance and pharmaceutical industries as well as the requirements of regulators.[232] Spitzer during an interview with Ray Moynihan confessed to having been teased by some younger colleagues "as someone who never saw a disorder he didn't like" and believes that the lack of knowledge to substantiate various "new conditions" is all the more reason to place them in the DSM, since this would "facilitate more research on [...] causes and treatment."[233] Over the past decade, this line of reasoning has lead to the creation and expansion of several conditions both in the DSM and in other standardized classification systems.

One addition to the DSM that has received substantial media attention is Generalized Anxiety Disorder (GAD), a once rare, poorly recognized and little studied

[231] Koerner 144.
[232] Healy "The Creation of ..." 304.
[233] Moynihan and Cassels 108-109.

condition[234], falling under the heading of Anxiety Disorders. The media and industry success with the promotion of GAD contributed to the launching of a new condition known as Social Anxiety Disorder (SAD). Unlike GAD, SAD is not even a recognized condition in the DSM but an extension of another rare condition known as Social Phobia. The most recent psychiatric condition to garner the health consumers' attention is specifically aimed at the female population—female sexual dysfunction (FSD). As with SAD, FSD has not yet found its own place in the DSM but is described as encompassing several vague categories found under the heading of Sexual and Gender Identity Disorders (in the DSM), namely, hypoactive sexual desire disorder, female sexual arousal disorder, sexual pain disorder (dyspareunia and vaginismus), and female orgasmic disorder. What these aforementioned conditions have in common is their strong support from industry, some DSM committee members, patient advocacy groups, and other prominent physicians (thought leaders), making them all well known and subsequently diagnosed and treated conditions.

Generalized Anxiety Disorder

At the beginning of the new millennia, millions of people in North America experienced what was touted as a "hidden epidemic," a feeling of suffering from an unrecognized disease.[235] Consumers are exposed to TV and print advertisements urging them to watch for symptoms, such as, restlessness, fatigue, irritability, difficulty concentrating, and sleep disorders. The disease—Generalized Anxiety Disorder

[234] Hans-Ulrich Wittchen, Ron C. Kessler, Katja Beesdo, Petra Krause, Michael Hofler, and Jurgen Hoyer. "Generalized Anxiety and Depression in Primary Care: Prevalence, Recognition and Management." *Journal of Clinical Psychiatry* 63. suppl 8 (2002): 24.
[235] Koerner 144.

(GAD)—according to some reports, left individuals paralyzed with irrational fear often to the extent that they were unable to leave their homes and complete normal activities of daily living. Prior to the media hype, little attention was given to this disorder even though it was classified in DSM III, the hallmark of modern day North American psychiatry. David Healy notes that the inclusion of GAD in the DSM III was almost by default, when "floundering somewhat, members of the anxiety disorders subcommittee stumbled on the notion of generalized anxiety disorder" and "consigned the greater part of the rest of the anxiety disorders to this category."[236] Since this disorder was introduced,

> it has been one of the least successful diagnosis in the manual. With each iteration of the system, the criteria for this disorder has undergone additional changes in an effort to increase its reliability, clarify its boundaries, reduce heterogeneity, and help to predict treatment response.[237]

Since the issuing of the DSM III, attempts have been made to separate this condition from the more easily definable condition known as a Panic Disorder. Several symptoms more characteristic of Panic Disorder were deleted from the DSM III-R GAD criteria and placed in the DSM IV and current DSM IV-TR version. Contrary to Spitzer's belief, GAD has facilitated little evidence based research into its cause and effective treatment, and thus the classification validity of this disorder remains questionable.[238]

Nevertheless, the timing could not have been better for industry to enlighten the consumer as to what GAD was and how to treat it, since the FDA had just approved the

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[236] Koerner 144.
[237] Allen Frances and Ruth Ross. *DSM-IV Case Studies: A Clinical Guide to Differential Diagnosis* (Washington, DC: American Psychiatric Press Inc. 1996) 187.
[238] Frances and Ross 188-189.

SSRI drug paroxetine (*Paxil*) for the treatment of this little known disorder.[239] GlaxoSmithKline, the manufacturers of *Paxil*, hoped to capitalize on this new indication, by strong—and what could be seen as unethical or at least biased—marketing practices. For example, they used corporate-sponsored studies[240] to demonstrate the efficacy of *Paxil* on GAD, enlisting prominent doctors (thought leaders) to publicly promote the disorder, and recruiting patient advocacy groups to serve as the "public face" for the condition.[241]

Social Anxiety Disorder

GlaxcoSmithKline's DTC advertising strategies for GAD were a tremendous success. *Paxil* became the *Valium* of the 1990s for the treatment of anxiety. Although *Paxil* is an SSRI, industry managed to distinguish it from its predecessor *Prozac* and other competitors by focusing on a different disease—GAD. *Paxil*'s success for the treatment of GAD led to a significant share of the anxiety market. Then, in 1998, the company applied once again to the FDA for approval to market *Paxil* for an "extremely

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[239] Koerner.

[240] Corporate-sponsored studies are a reality of scientific research. However some organizations have set forth 'doctrines' for researchers to adhere to in an attempt to quash issues related to publication bias. Currently, some journals subscribe to the publications ethics outlined in the "Uniform Requirements of Manuscripts Submitted for Biomedical Journals: Writing and Editing for Biomedical Publication", a document that was developed by the International Committee of Medical Journal Editors (ICMJE). Part of the reporting requirement of this document is that authors are routinely required to disclose details of their own and their sponsor's role in the study. In many instances, the author will be required to sign a statement indicating that he/she accepts full responsibility for the conduct of the trial, had access to the data and controlled the decision to publish. See Davidoff 787. In 2004, Canada via the Canadian Institute of Health Research (CIHR) instituted a policy in which "all new CIHR-funded randomized controlled trials (RTCs) must be registered with an International Standard Randomized Controlled Trial Number (ISRCTN)" The rational behind this registry is that a set of values held by the CIHI will be subscribed to, namely: public interest, sound ethical principles, excellence, public transparency, accountability and collaboration. See David Moher and Alan Bernstein. "Registering CIHI-funded randomized controlled trials: a global public good." *Canadian Medical Association* 171.7 (2004):750.

[241] Koerner.

rare" debilitating form of shyness known as Social Anxiety Disorder (SAD).[242] As noted earlier, SAD is not even mentioned in the DSM and is not a condition that has gained recognition in healthcare texts or journals. Yet, SAD is portrayed as a stand-alone condition linked to Social Phobia, which *is* characterized by the DSM. With FDA approval, the company and their advertising agency (Cohn & Wolfe) set to work to "create" a new severe disorder that could be managed with medical treatment.[243] According to IMS Health, *Paxil* ranked in ninth place of the most dispensed drugs in Canada in 2003, behind anti-hypertensive and anti-inflammatory drugs. It would appear that DTC advertising has had a tremendous success in Canada, when disorders which were given little attention prior to GlaxcoSmithKline's marketing campaign were associated with treatments provided by the top ten most dispensed drugs.

The slogan "Imagine being allergic to people" helped to make this obscure condition a marketing sensation. The Social Anxiety Disorder Coalition, an advocacy group created by Cohn & Wolfe, developed a massive public awareness campaign. Journalists were provided with packets stating that SAD affects just over 13 % of the population, or 1 in 8 Americans, and is the third most common psychiatric disorder in the United States after depression and alcoholism.[244] However, the DSM cites studies indicating that between 3-13% of people may suffer from this condition at some point in their lives, but in fact only 2% "experience enough impairment or distress to warrant a diagnosis of social phobia."[245] The selective use and interpretation of numbers and

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[242] Koerner.
[243] Koerner
[244] Koerner.
[245] Koerner.

percentages helped to create a well received public awareness campaign, and more health consumers were being diagnosed and treated for SAD than ever before.

However, as with almost any success there comes a downside as GlaxcoSmithKline soon discovered. Many research studies, mostly non-industry sponsored, that began to surface in the mid 1990s indicated that SSRIs produced withdrawal and dependence problems and *Paxil* was one of the worst offenders.[246] Placebo-controlled clinical trials also indicated that SSRIs led to increased behavioural and emotional changes, including suicidal tendencies, particularly in the pediatric population.[247] The term "SSRI discontinuation syndrome"[248] was affixed to a cluster of psychological and somatic symptoms resulting from the discontinuation or tapering down of the dosage of SSRIs. Fortunately, in recent years, the notion of discontinuation syndrome has been receiving greater support in terms of public awareness and research. Yet, many patients "have been treated inappropriately for other problems following the mistaken diagnosis made in good faith by physicians unaware of the possibility of SSRI withdrawal problems."[249]

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[246] Kathy Black, Cathy Shea, Serdar Dursun and Stanley Kutcher. "Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: Proposed Diagnostic Criteria." *Journal of Psychiatry & Neuroscience* 25.3 (2000): 255-262; and David Healy. "SSRIs & Withdrawal/Dependence." Briefing Paper, 2003, 16 August, 2005. <http://www.socialaudit.org.uk/58092-DH.htm>.

247 David Gunnell and Deborah Ashby. "Antidepressants and Suicide: What is the Balance of Benefit and Harm." *British Journal of Medicine* 329 34-38.

[248] See Kathy Black, Cathy Shea, Serdar Dursun, and Stanley Kutcher. "Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: Proposed Diagnostic Criteria," *Journal of Psychiatry & Neuroscience* 25.3 (2000): 255-262. Proposed Diagnostic Criteria for SSRI Discontinuation Syndrome:
Criteria A—Discontinuation of or reduction in dose of a SSRI after a period of at least one month
Criteria B—Two (or more) of the following, developing within 1-7 days of criterion A: Dizziness, light-headedness, vertigo or feeling faint; Shock-like sensations or paresthesia; Anxiety; Diarrhea; Fatigue; Gait instability; Headache; Insomnia; Irritability; Nausea and/or emesis; Tremor; Visual disturbances.

[249] Healy "SSRIs Withdrawal/Dependence..."

Historically, much of the original popularity of SSRIs was based on the belief that they were not addictive or dependent forming like the benzodiazepines, which were the standard treatment for anxiety disorders at the time. Physicians actively switched patients from the benzodiazepines, and newly diagnosed patients were automatically prescribed SSRIs as the first line of treatment.[250] With so much media attention focused on the positive aspects of educating health consumers about GAD and SAD, the concerns being raised by physicians and their patients about withdrawal and dependence issues were slow to receive attention.

Through the action of various researchers, physicians, law firms, and governmental bodies, the negative and potentially deadly effects of *Paxil* and other SSRIs were finally recognized. Since 2003, the United Kingdom has banned the use of most SSRIs in children, and in the spring of 2004, the U.S. FDA required that warning labels—known as black boxes—be affixed to all antidepressants to outline the potential problems associated with taking these drugs.[251] In the summer of 2004, Health Canada strengthened its warnings regarding SSRIs and newer antidepressants by issuing advisories outlining concerns regarding the potential for behavioural and/or emotional changes that may put patients at an increased risk of self-harm, or harm to others. A disclaimer also was issued stating that these drugs have not been fully evaluated in patients less than 18 years of age and recommended against their use in this age group.[252] Certainly, the negative media attention SSRIs have been receiving will reduce the profit

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[250] Healy "SSRIs Withdrawal/Dependence..."
[251] Moynihan and Cassels 134-135.
[252] Health Canada. *Advisory, Health Canada Advises Canadians of Stronger Warnings for SSRIs and Other Newer Anti-Depressants.* June 3, 2004. 20 January, 2005. available at <www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2004/2004_31_e.html>.

margin of their drug manufacturers. It is possible that the loss suffered by health consumers taking these drugs is only beginning to surface.

Changing Times: Sexual Dysfunctional Disorders

It may be the changing times, societal and cultural, that have made possible an openness and willingness to share what many once considered taboo, namely, sexual dysfunctional disorders. For almost a decade, a media frenzy has been swirling around *Viagra* (sildenafil citrate), the first drug to enter the market as an "effective" treatment for male erectile dysfunction. Pfizer, the manufacturer of *Viagra*, reported sales of $1.7 billion in 2002, an increase of 14% over the previous year.[253] With the continued success of this treatment for male sexual dysfunction, the question being asked by the pharmaceutical industry was how to build a similar market for women?[254] What was needed was "a clearly defined medical diagnosis with measurable characteristics to facilitate credible clinical studies."[255]

Ray Moynihan, an Australian freelance journalist and author who has had numerous publications in the *British Journal of Medicine* and recently co-authored *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All Into Patients*, has followed the evolution of what has become known as "female sexual dysfunction." To establish credibility for this new disorder, clinicians, researchers, and drug companies worked together to direct clinical trials and define what

[253] Pfizer. Annual Report 2002. 9 April, 2005 <http://www.pfizer.com/are/investors_reports/annual_2002/p2002ar24_25_26_27a.html>.
[254] Ray Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder Being Identified to Meet Unmet Needs or to Build Markets for New Medications?" *British Medical Journal* 326 (2003): 45.
[255] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 45.

female sexual dysfunction (FSD) would mean.[256] As with GAD, the DSM along with other classification systems were used as guides for creating the definition and subsequently for setting forth the overlapping categories that would make up this dysfunction, namely, hypoactive sexual desire disorder (HSDD), female sexual arousal disorder (FSAD), female orgasmic disorder, and sexual pain disorder. Today, these categories or derivatives of them are routinely utilized in health care settings and found throughout medical literature.

Moynihan continued to follow this growing phenomena from internationally held conferences to the founding of the Female Sexual Function Forum, and also paid close attention to the increasing role the pharmaceutical industry played, particularly Pfizer, in the expansion of this dysfunction. In a 1999 publication, concerns were raised by the earliest figures available regarding the prevalence of this dysfunction.[257] This study was based on a reanalysis of a 1992 survey in which approximately 1500 women responded yes or no to "whether they had experienced any of seven problems, for two months or more during the previous year, including a lack of desire for sex, anxiety about sexual performance and difficulties with lubrication."[258] The results of this reanalysis of data estimated that 43% of females over the age of 18 experience sexual dysfunction.[259] To be included in this 43% category, the women only had to answer yes to just one of the seven questions posed. This percentage number has been widely cited in both the scientific and lay media since the journal's publication.[260] However, according to Moynihan, the

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[256] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 45.
[257] Edward Laumann, Anthony Paik and Raymond Rosen. "Sexual Dysfunction in the United States. Prevalence and Predictors." *Journal of the American Medical Association* 281.6 (1999): 537.
[258] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 46.
[259] Laumann, Paik and Rosen 537.
[260] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 46.

study's authors—Ed Laumann and colleagues—never intended this number to equate to a clinical diagnosis, even though it has become synonymous with female sexual dysfunction. Moreover, when the research methodology and design of the original study are examined, it is apparent just how deceptive the results would be. Nevertheless, this study is still cited and has become an effective marketing tool in DTC advertising.

Sandra Leiblum, professor of psychiatry at Robert Wood Johnson Medical School, believes that "real dysfunction is much less prevalent than 43%, and that this figure has contributed to an overmedicalization of women's sexuality, where changes in sexual desire are the norm."[261] Leiblum went on further to state that "there is dissatisfaction and perhaps disinterest among a lot of women, but that doesn't mean they have a disease."[262]As well, John Bancroft of the Kinsey Institute of Indiana University is highly critical of the term "dysfunction" he argues that the term is misleading and is a creation of corporate design. Bancroft believes that:

> An inhibition of sexual desire is in many situations a healthy and functional response for women faced with stress, tiredness, or threatening patterns of behaviour from their partners. [...] The danger of portraying sexual difficulties as a dysfunction is that it is likely to encourage doctors to prescribe drugs to change sexual function when attention should be paid to other aspects of a woman's life.[263]

Leonore Tiefer, clinical associate professor of psychiatry at New York University, has been a vocal force against the medicalizing of sexual difficulties. Like Bancroft she believes that "women's sexual problems and satisfactions have far more to do with relationship difficulties, life stressors, and cultural expectations than with clitoral blood

[261] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 45.
[262] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 46.
[263] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 46.

flow or testosterone levels."[264] However, it is important to note that Tiefer is not opposed to the development and marketing of proven medications for genuine female sexual problems. Tiefer's concern lies with the trivialization of the complex nature of female sexual problems, which may result in inappropriate labeling and treatment.[265]

When comparing male erectile dysfunctions to that of female sexual dysfunctions, it is apparent that it is much more difficult to quantify how to pharmacologically treat women, especially when the data results are suspect and fail to consider the normal aging processes of women physiologically, physically, and psychologically. Currently, the only physiological studies in support of FSD are based on the results of "sexual function studies" conducted on rabbits. Results from these studies are the theoretical basis for the possible cause/s of FSD, namely, "vaginal engorgement insufficiency and clitoral erectile insufficiency."[266] Even though FSD appears to have no quantifiable basis to support the cause or diagnosis of this condition, Goldstein, the current thought leader for FSD, notes that "the pharmaceutical industry's role in helping build the science of this new disorder has been 'paramount'."[267] This statement suggests that the role of industry in relation to this disorder is much more than finding an effective treatment, and includes building of a diagnostic criteria for this previously unknown condition.

The results of the Lauman et al. study provided the necessary foundation to target as widespread a population as possible by encouraging women over the age of 18 to believe that they could be suffering from a "disease" requiring treatment. FSD could easily be described as a "threshold disease" like high blood pressure and high cholesterol,

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[264] Moynihan and Cassels 185.
[265] Moynihan and Cassels 180.
[266] Moyihan and Cassels 184-185.
[267] Moynihan. "The Making of a Disease: Female Sexual Dysfunction: Is a New Disorder..." 47.

where the line between normal and diseased is arbitrary.[268] The key advantage of DTC advertising for FSD is that a drug could be marketed to a large proportion of the female population, a strategy which could significantly increase profits faster and higher than promoting a drug for a disease only affecting a small number of individuals. Unfortunately, this common tactic increases the likelihood that women will believe they have a condition requiring a treatment that could potentially create more harm than benefits. Also, they may forgo other more beneficial treatment options that could address the root cause of their problem.

Business ethicist David Holley notes that for a sale to be mutually beneficial to the buyer and seller, the purchase decision must be well informed, unforced, and rational. If promotional tactics interfere with any of these three decision-making conditions, they are unethical. Furthermore, advertisements that are untruthful or deceptive also are unethical because they induce consumers to make poorly informed decisions.[269] A characteristic strategy of disease mongering is taking a commonly occurring symptom and exaggerating its seriousness. It could be argued that most of the symptoms set forth by these disorders may be situational and solely dependent on what is happening in the consumer's life at the time he or she is exposed to DTC advertising.

What Was Once Natural

Menopause always has been seen as a right of passage for women in one form or another, since it signaled the end of their reproductive capabilities. Some women have

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[268] Payer 89.

[269] David Holley. "A Moral Evaluation of Sales Practices." *Business and Professional Ethics Journal* 1 (1987): 3-21. As cited in Steven Latham. "Ethics in the Marketing of Medical Services." *The Mount Sinai Journal of Medicine.* 71.4 (2004): 247.

embraced this passage, while others have dreaded it, but the fact remains that it is a natural part of life. However, "through false analogy, this natural process is being treated as a hormone deficiency disease 'like diabetes' or 'like hypothyroidism'."[270]

The hormonal effects of menopause may produce symptoms such as hot flushes, insomnia, and poor concentration. However, no certainty exists as to the degree and nature of any symptom(s) a woman may experience that necessitate(s) medical treatment. Half of almost every population in every country is female, and as women age, they are likely to experience menopause. In terms of numbers, this is staggering amount of potential patients for the pharmaceutical industry. As with GAD, SAD and FSD, a huge market is awaiting the right "product." All that is necessary is to convince women that menopause is a condition which will lead to unbearable symptoms necessitating treatment, and without it they may increase their chances, for example, of developing osteoporosis and heart disease related to hormone deficiency.

Margaret Lock, a medical anthropologist has studied and written several works that explore the notion of menopause in a cultural context, with a specific emphasis on comparing the Japanese culture to that of the West. She also looked beyond the biological variables surrounding this state and examined social and psychological variables.[271] What Lock found in her studies was

> "the experience of menopause in Japan can certainly not be described as one which is strongly associated with ill-health, on the contrary, it is viewed as a part of the natural process of aging. Perhaps we should begin to examine some of the assumptions which are often made in connection with menopause and female aging in the West, namely, that it is

[270] Payer 190.
[271] Margaret Lock. *"Hot Flashes in Cultural Context: the Japanese case as a cautionary tale for the West."* In E. Schonbaum (Editor) Progress in Basic Clinical Pharmacology, volume 6, The Climacteric Hot Flush. (Basel, Switzerland: Karger, 1991) 40.

> debilitating time for the majority of women which is best managed through medication."[272]

She also felt that menopause has become highly medicalized in the West and suggested that the reasons for this related to "the aggressive marketing of estrogen replacement therapy and its adoption by gynecologists in their belief that it is an effective cure for symptomatology at menopause."[273]

Over the past 25 years, by using DTC advertising, the pharmaceutical industry has done a fantastic job of informing the public, specifically women in industrialized and developing nations, that there is no reason to suffer with the symptoms of menopause and no reason to potentially increase the chances of developing osteoporosis or heart disease, especially when a treatment is available, namely, hormone replacement therapy (HRT). In North America in particular, it is difficult for any woman to isolate herself from the mantra that one day she will experience the "unpleasant" symptoms of menopause and as a result the increased risks for other health conditions. In part, this unfortunate situation exists due to the continuous media attention devoted to the problems of menopause. In essence, women are pre-programmed to believe that when they enter the change of life, their life will in fact change drastically if they do not seek medical intervention.[274]

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[272] Lock 57.

[273] Edward Norbeck and Margaret Lock. *"Health, Illness and Medical Care in Japan: cultural and social dimensions."* (Honolulu, Hawaii: University of Hawaii Press, 1987)14.

[274] Dr. Robert Wilson, in his 1952 bestselling monograph, *Feminine Forever* attempted to persuade modern society that menopause was a disease, a hormone deficiency disease that required/mandated a cure. Throughout his book he referred to menopause as a horrendous fate, that "instead of being condemned to witness the death of their own womanhood during what should be their best years, they will remain fully feminine- [with hormone replacement therapy] physically and emotionally-for as long as they live. He did acknowledge that not all women are affected by or to the same degree by menopausal symptoms but noted "no woman can be sure of escaping the horror of this living decay. Every woman faces the threat of extreme suffering and incapacity." The words of Dr. Wilson rang true for decades, spreading the word of the unnecessary transformation awaiting women as they aged. Dr. Wilson's words lead to a substantial rise in the sale of hormone replacement by his pharmaceutical sponsor.

In 1999, a study was conducted in northeast Thailand to investigate perceptions about menopause.[275] What makes this study unique is that in Thailand a large distinction exists between the educational/value system of rural versus urban women. Rural women who participated in the study did not see menopause has having any change on their lives in terms of new roles or status. They remained valued members of society. Moreover, many rural women reported no symptoms related to menopause (dizziness, irritability, or tiredness) and were barely able to recall when their last menstruation occurred. However, for educated urban women, fear of menopause was common. These women saw the change of life as distressing and the beginning of old age. Moreover, they perceived menopausal women as irritable, unattractive, and depressed. Even when symptoms of menopause were minimal, such as hot flashes and sweating, they were perceived negatively. Not surprisingly, these urban women believed that television, magazines, newspapers, and advertisements helped shape their attitudes about menopause.

This study is an illustration of the role and effect that mass media has on individual perceptions, especially in relation to this naturally occurring condition. Those women that had limited or no exposure to mass media, and specifically to DTC advertising for HRT, did not perceive menopause with fear. Subsequently, the potential symptoms of this condition were all but absent or not associated with menopause itself. In contrast, women exposed to DTC advertising about HRT shared many of the same fears held by North American women, including the sense of dread about the menopause experience itself.

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[275] Siriporn Chirawatkul, Kalaya Patanasir, and Choosri Koochaiyasit. "Perceptions About Menopause and Health Practices Among Women in Northeast Thailand." *Nursing and Health Sciences* 4 (2002): 113-121.

In 2005, a study was published which examined how women's attitudes towards menopause correlated to the severity of their menopausal symptoms.[276] Women who were taking HRT were included in both the participant and control group. The study found that those women who held a more negative attitude towards menopause experienced a greater the severity of menopausal symptoms. However, through participation in educational and physical programs, the women in the study reported significant improvements in attitude, which helped to reduce the severity of their symptoms (hot flushes, nocturnal perspiration, fatigue, and insomnia). Nevertheless, the authors of the study found that "physicians still emphasize medical treatment instead of promoting a healthy lifestyle, behavioral changes, and positive attitudes toward this period of life."[277] The philosophy of some physicians, DTC advertising's promotion of drugs for menopausal symptoms, and the mass media's negative portrayal of menopause in general may make it more difficult for women to make informed decisions as to how to best deal with this stage of life.

In North America, menopause has become a condition encapsulated in dread and fear due in part to the pharmaceutical industries' desire to take advantage of a growing market through its aggressive DTC advertising and other marketing strategies. Yet, even though hormone estrogen therapy has been available on the market for more than 60 years primarily as means to relieve menopausal related symptoms, the enthusiasm for its

[276] Mina Rotem et al. "A Psycho-Educational Program for Improving Women's Attitudes and Coping With Menopausal Symptoms." *Journal of Obstetric, Gynecologic & Neonatal Nursing* 34.2 (2005) 233-240.
[277] Rotem et al. 234.

use—either by itself or in combination with progesterone—has fluctuated dramatically over the years.[278]

Until 2002, many women were requesting, or following the recommendation of their own physicians, to take HRT as a means of addressing menopausal symptoms. A recent study conducted by the *Journal of the North American Menopause Society* found that 92% of the 400 physicians surveyed routinely offered HRT to their menopausal patients.[279] In addition, it has been reported that in the United States, hormone therapy prescriptions increased from 58 million in 1995 to 90 million in 1999, and this number has remained stable until 2002.[280] However the industry marketing and growing media coverage given to the alleged benefits of HRT came to a halt when a longitudinal study (with a planned duration of 15 years) commissioned by the National Institutes of Health in 1991—known as the Women's Health Initiative (WHI) to study the preventative effects of HRT on chronic diseases—was halted in 2002 due to concerns of increased rates of breast cancer, heart disease, and strokes among study participants being treated with a combination of estrogen and progesterone HRT.[281] The outcome of this report resulted in a dramatic drop in the prescription sales of HRT. IMS Health reported a double-digit drop (26.8%)—approximately 3.1 million HRT prescriptions in Canada during 2003. The decrease was directly related to the findings in the WHI study,

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[278] Elizabeth Barrett-Connor, Deborah Grady and Marcia Stefanick. "The Rise and Fall of Menopausal Hormone Therapy." *Annual Review of Public Health* 26 (2005): 115-140.
[279] Boris Kaplan et al. "Gynecologists' Trends and Attitudes Toward Prescribing Hormone Replacement Therapy During Menopause." *The Journal of the North American Menopause Society* 9.5 (2002): 354.
[280] Adam Hersh, Marcia Stefanick and Randall Stafford. "National Use of Postmenopausal Hormone Therapy: Annual Trends and Response to Recent Evidence." *Journal of the American Medical Association* 291.1 (2004): 47-53.
[281] Beverly Lawton et al. "Changes in Use of Hormone Replacement Therapy After the Report From the Women's Health Initiative: Cross Sectional Survey of Users." *British Medical Journal* 327 (2003): 845.

specifically the estrogen-progestin combined therapy.[282] Similarly, as a result of this study, HRT sales in the United Status also dropped dramatically. This phenomenon is one more example of how the medicalization of a condition, especially a naturally occurring one, has resulted in potentially serious health risks.

Menstrual Suppression

Just as with menopause, menstruation is a naturally occurring event in females that may begin as early as the pre-teen years and continue until the 50s, and in rare instances the 60s, amounting to a significant number of cycles during the reproductive years. With the advent of the birth control pill (BCP) in the 1960s, women have been able to suppress their natural menstrual cycle by taking these pills continuously without the standard 7-day break in every 28-day artificial cycle as this regime demanded. Menstrual suppression also is also common with the more long-term methods of birth control such as the 3-month injection *Depo-Provera* and the 5-year implant *Norplant.* However, in these latter more invasive measures, menstrual suppression is more of a side effect than as a specific reason for taking them.

Barr Pharmaceuticals, one of the leading manufactures of BCPs, has been actively promoting its latest product *Seasonale* through advertisements in several popular women's magazines. This drug reduces the number of menstrual cycles a woman experiences to only four a year. Leslie Miller, an assistant professor at the University of Washington Medical Centre and proponent of this new drug, defends its use by arguing that women never were meant to have 13 cycles/year, since pregnancy and breast-feeding

[282] IMS Health. A Health Information Update From IMS Health: Hormone Replacement Therapy 2003. 20 March, 2005 <www.imshealthcanada.com/htmen/3_1_37.htm>.

made this highly unlikely prior to BCPs.[283] The real concern with this new drug and the message it is promoting lies in how the natural occurrence of menstrual cycles is being portrayed to young women. If women choose to have more than four cycles/year, will they soon face stigmatization? Without understanding the long term consequences of tampering with natural body processes, industry is trying to medicalize natural menstruation as it did with menopause to capitalize on the potentially large population afflicted with this "condition."

Cosmetic Considerations: The Quest for Perfection

The history of plastic surgery[284] dates back over 4000 years to the time of ancient Egypt, and, more recently, to the Sanskrit texts of ancient India some 2600 years ago, which describe nose, ear, and lip reconstruction using skin grafts.[285] This particular medical skill is thought to be one of the oldest healing arts, with the aim to improve and restore form and function. As with most areas of medicine, plastic surgery progressed gradually over hundreds of years. It was not until "the 19th and 20th centuries that this specialty forged ahead both scientifically and within the medical establishment in both Europe and the United States,"[286] with the greatest developments happening during the World Wars. However, over time, the skill and continuing advances in plastic surgery

[283] "Medicine or Market Driven: Menstrual Suppression." Narr. Margaret Taylor. *The National. CBC Television.* 9 August 9, 2005.
[284] Anderson et al. 1353. The word "plastic" is derived from the Greek word plastikos, meaning "to mold" or "to give form." Plastic surgery includes both the reconstructive and aesthetic subspecialties.
[285] Michael Ciaschini and Stephan Bernard. "History of Plastic Surgery." *emedicine.* (January, 2005) 14 August, 2005 <http://www.emedicine.com/plastic/topic433.htm>.
[286] Paul Schnur and Pamela Halt. "The History of Plastic Surgery, the American Society of Plastic Surgeons (ASPS) and the Plastic Surgery Educational Foundation (PSEF)." American Society of Plastic Surgeons. 2000. 21 August 2005. <http://www.plasticsurgery.org/overview/pshistry.html>.

moved beyond the reconstruction of traumatic injuries and congenital deformities, for example, cleft lips and palates into what now is known as cosmetic surgery.

In the 1960s, the notion of "cosmetic surgery" entered the minds of health consumers, as a new substance—silicone—emerged as the newest tool for cosmetic surgeons. Originally, silicone was used to treat skin imperfections but soon was utilized in breast implant devices.[287] Over the years, progress in cosmetic surgery continued. Media outlets and brochures produced by the American Society of Plastic Surgeons (ASPS) outlining the specialty and the latest plastic surgery techniques (e.g., liposuction, face lifts, and rhinoplasty) kept health consumers informed.

Over time, in the eyes of health consumers, the term cosmetic surgery became a separate specialty from plastic surgery. Plastic surgery is synonymous with reconstructive procedures, whereas cosmetic surgery tends to refer to personal improvement procedures. Cosmetic surgery has evolved from strictly surgical procedures to less invasive non-surgical treatments such as Botox injections, laser hair removal, microdermabrasion, and collagen injections. As well, many non-medically trained staff in private-for-profit settings perform many of these non-surgical procedures. In 2003, the American Society for Aesthetic Plastic Surgery (ASAPS) noted a 20% increase in total cosmetic procedures done between 2002-2003, with surgical procedures accounting for a 12% increase and non-surgical procedures 22%. Currently, women constitute the majority of those seeking out these procedures at 87%, although gender difference appears to be evening out as time passes.[288] Robert Bernard, president of the

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[287] Ciaschini and Bernard..

[288] The American Society for Aesthetic Plastic Surgery "Cosmetic Plastic Surgery Research: Statistics and Trends for 2001, 2002 and 2003" page 5 of 20. 21 August 2005 <http://www.surgery.org/press/statistics-2003.php>.The American Society for Aesthetic Plastic Surgery.

ASAPS, believes that a strengthening economy means more people are willing to invest in things that improve their quality of their lives, and "feeling good about the way they look is high on the list of priorities for many Americans."[289]

The concern with cosmetic procedures, both surgical and non-surgical, is influencing many health consumers to choose to undergo potentially dangerous and expensive procedures. Recently, several television shows have gained popularity by focusing on correcting what many people believe/perceive to be cosmetic defects. For example, "The Swan," "Extreme Makeovers," and "SkinDeep" have attracted huge television audiences by spotlighting the procedures to correct the physical "flaws" that their participants believe they possess. In the case of "The Swan," women compete by means of a series of surgical procedures to win a beauty pageant at the end of the series. What message are these shows sending? The sponsors and producers of these shows appear to want their viewers to believe that if they do not have a perfect smile, dancer's legs, or prominent cheek bones, something is physically wrong. Moreover, consumers of these shows are assured that these flaws or imperfections could be corrected through cosmetic procedures.

Writer Lynn Payer comments that "if you cannot convince people they are sick, you can convince them that they are ugly-and perhaps that their ugliness qualifies as "disease."[290] Cosmetic clinics, both surgical and non-surgical, take out full-page ads in newspapers, advertise on billboards, and place colourful brochures (with before and after pictures of patients) in medical clinics first, to convince people that they have flaws, and second, to tell them the good news—the flaws can be corrected. Moreover, often these

[289] The American Society for Aesthetic Plastic Surgery 5-20.
[290] Payer 221

ads minimize the risks involved with many of the procedures. In the end the question remains, who ultimately decides the criteria for this new "disease" that industry is trying to create?

Cosmetic surgery is not the only way to deal with the physical flaws that health consumers believe they may have. For example, recently, the drug xenical (*Orlistat*)—an antiobestiy agent—has been in the media spot light as the newest treatment for North Americans' growing problem with obesity. Yet, in most of the advertisements, the name *Orlistat* was not even mentioned. Instead, throughout Canada, the advertisements appearing as pamphlets in physicians' offices and in national newspapers, magazines, billboards, and television told the story of "Julie" in different scenarios. The ads asked the question: "What would you do with a few pounds less?" and suggested you speak to your doctor about weight loss options.[291] What made this specific advertising so unique and potentially deceptive was the manner in which it was presented, especially the latest ad in which "Julie," dressed in lingerie, commented: "Last night, I did a striptease for my husband." This ad offended a range of people from physicians, women's groups, to the general population.[292] Nevertheless, in terms of drug promotion, the public outcry did more for Roche, the manufacturer of *Orlistat*, than its own paid advertisements.

Health consumers now are acutely aware that there is a drug that "may" help with both their actual and perceived weight problems. Yet, even though studies have indicated that *Orlistat* does help, diet alone can be responsible for at least half of any weight

[291] June Thompson. "Shaping UpSource: The Gazette Who is Julie? And why is she appearing in print ads barely clothed?" *Montreal Gazette* (March 29, 2005): D 4.
[292] Thompson D 4.

loss.[293] Furthermore, approximately 25% of study participants withdrew from the *Orlistat* trials during the first year because of the side effects related to decreasing fat absorption, namely, oily spotting, flatus with discharge, fecal urgency, and oily stools. *Orlistat*—as a supplement to dieting—resulted in an additional weight loss of 3.3 kg over 12 months with an average cost of $2040 New Zealand per year or $618 per kilogram. The loss of 3 kilograms per year will have only nominal, if any, real effects on an obese person's life. As well, many drug plans will not cover or subsidize this medication, making it an extreme expenditure for what appears to be limited results. Informing health consumers about ways to reduce their weight may be helpful, but focusing on a drug versus more natural processes such as proper diet and exercise is sending a dangerous message—that a pill can cure or at least significantly assist in treating this mounting societal problem. Tragically, in the 1990s, fen-phen, another anti-obesity drug, was aggressively promoted until it was linked to the morbidity and mortality of thousands of health consumers suffering from heart value damage and fatal lung disease.[294]

The most troubling aspect of DTC advertising is how industry often "creates" a condition or disease requiring a treatment or procedure that the have made available. By means of creative and sometimes aggressive DTC advertising, a patient market is effectively produced. Originally, the medical industry developed products to treat existing conditions. Now, disease mongering tactics are utilized as standard practice to

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[293] Michael Davidson et al. "Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 years With Orlistat." *Journal of the American Medical Association* 281.3 (1999):235-242 and James Hill et al. "Orlistat, a Lipase Inhibitor, For Weight Maintenance After Conventional Dieting: a 1-y Study." *American Journal of Clinical Nutrition* 69.6 (1999):1108-1116 and Therapeutics Initiative. "New drugs V. Orlistat (xenical)." *Therapeutics Letter 2000*; Issue 34. As cited in Toop et al. 24.

[294] Rampton and Stauber 332.

increase market share. The creation of illness has become a multi-million dollar industry involving industry-funded public relations firms, thought leaders, and patient advocacy groups. Nevertheless, it is ultimately up to the individual health consumer to ask questions and seek answers if there exists an uncertainty regarding the possible diagnosis and subsequent treatment or procedures options recommended for these 'disorders'. No longer can society rely on physicians, the former gatekeepers of medical knowledge, to protect them from what is seen and heard through DTC advertising. As well, government legislation and regulations have been demonstrated to have numerous flaws and shortcomings, leaving the individual susceptible to the notion of, health consumer beware.

Conclusion

The evolution of medicine has been marked by great tragedies and triumphs of diagnosis, treatment, and, in some cases, cures. Moreover, the "healer" also has undergone a multitude of changes in terms of level of education, training, experience, responsibilities, and roles (from individual healthcare providers to corporate entities such as pharmaceutical companies and diagnostic imaging clinics). In the past century in North America, this progression of medical advances has been guided by various organizations such as the Canadian and American Medical Associations. Their goal and function is to ensure that health consumers receive prudent, appropriate, and safe care from their members who must adhere to the high and stringent standards outlined in the organization's constitution. Governmental legislation and regulations also have evolved to regulate, inform, and protect health consumers. For example, Health Canada and the U.S. Food and Drug Administration have issued advisory and black box warnings to alert health consumers about potentially harmful drugs and treatments. At first glance, it may appear that the medical industry, healthcare providers, and governmental bodies all share a common goal of providing optimum care for health consumers. However, the present study has shown that the specific financial interests of the medical industry have tended to trump other concerns, in particular, patient safety and health.

The practices of industry—specifically, Direct-to-Consumer advertising—have played a pivotal role in the commercialization of disease. Currently, the United States and New Zealand are the only industrialized nations which openly permit DTC advertising of medical treatments, diagnostic services, and medical procedures to health

consumers. What is certain is that the industry has unearthed an extraordinarily profitable means to enlighten both health care providers and consumers about newly available products and services.

A host of ethical considerations come into play when examining the positive and/or negative consequences that DTC advertising has had or may have on interested parties, namely individual health consumers, healthcare providers, governmental bodies and the medical industry. The positive view of DTC advertising suggests that empowering health consumers through education, health promotion, awareness and reminder advertisements leads to greater autonomy in making responsible health care decisions. Furthermore, the empowerment of individuals to assert their autonomy will encourage them to ask their physicians about new/alternative treatment options or possible medical conditions that may have been overlooked. However, when comparing the possible positive benefits to the potential negative costs, a grey area emerges which challenges and in some instances negates any potential benefit.

The negative consequences of DTC advertising present a multitude of concerns including questionable research data on various treatment modalities that industry promotes and physicians utilize, which in turn raises questions regarding health safety and conflict of interest. For example, many of the new products and services promoted through DTC advertising are no more effective than older and cheaper ones, and their safety and efficacy too often are uncertain as seen with *Vioxx* and CT scans. As well, the affects on the physician/patient relationship also have been questioned. Barbara Mintzes et al. conducted a comparison study (between the U.S. and Canada) to look at the impact

of DTC advertising for pharmaceuticals on prescribing decisions in primary care.[295] Their results indicated that more advertising leads to more requests for advertised medicines (prescriptions) and that DTC advertising may open a dialogue between physicians and patients resulting in a prescription, "often despite physician ambivalence about treatment choice."[296] Concerns also exist that patients' self-diagnosis based on advertisements—combined with insufficient assessment and subsequent follow-up care from heavily burdened healthcare professionals—may result in prescriptions for conditions for which patients are not afflicted.

Although strong and at times very persuasive ethical arguments have been made for both sides in the ethical debate surrounding DTC advertising, the fact remains that more research is necessary to provide a greater level of objectivity to this ongoing concern. The lack of substantive and verifiable evidence makes it difficult to effectively challenge or support the merits of DTC advertising. Until this happens health consumers will have to rely on government bodies and their subsequent legislation and regulations to provide some element of safety through a system of checks and balances. As well, physicians will continue to play a pivotal role in providing health consumers with the best and most reasonable care possible in light of the constantly changing health environment. Nevertheless, the ultimate responsibility of disseminating and choosing how to use and apply the health information provided through DTC advertising is in the hands of the health consumer.

No doubt DTC advertising vis-à-vis the advent of mass media has a tremendous impact on the health consumer in terms of providing health information and

[295] Mintzes et al. "How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing..." 405.
[296] Mintzes et al. "How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing..." 405.

enlightenment. However, when DTC advertising is not regulated, or sanctions to prevent misrepresentation and abuse are not strictly enforced, the health consumer may be in danger of being harmed. As demonstrated throughout this thesis, if the drug and medical industry are given free reign to create new diseases and syndromes, problems—and sometimes tragedy—can occur. In the end, the industry is accountable to its shareholders, not the general public. Pharmaceutical companies are not altruistic in nature, and when an opportunity arises that could potentially yield greater profits, they are bound to focus on their bottom line. This statement is not meant to discount the past or current work the industry has done, and is doing, toward the treatment of many diseases, disorders, and conditions, although the fact remains that drug companies are a capitalist creation. When clever advertising suggests that one may be suffering from a little known condition, questions should and must be asked, especially when the industry professes to have a new effective treatment or cure. However, the health consumer should not have to stand alone in raising questions about the suspect claims of disease mongering. Health professionals, policy makers, and those involved in the mainstream media must also address these concerns.

Furthermore, the promotion of often obscure and poorly defined disease criteria—for example, Generalized Anxiety Disorder and Social Anxiety Disorder—the creation of disorders such as Female Sexual Dysfunction and the suggestion that naturally occurring process such as menopause and the menstrual cycle are unnecessary and potentially deadly diseases must be challenged. In addition, the media and industry have been involved in persuading people to question the adequacy of their physical being and have promoted potentially risky and expensive treatments (e.g., cosmetic procedures) to "cure"

conditions that are non-consequential to a normal existence. When advertisements and even complete television programs are designed to emphasize physical "imperfections," questions need to be asked about who determines what is the status quo of our current body image. These are essential questions to ask, especially when medical treatments and procedures have been promoted (through advertising) for dealing with conditions that most often are the result of lifestyle choices.

Millions of North Americans now take a pill for a "condition" they believe they are suffering from based on criteria often established by individuals and groups who have vested financial interest in providing treatment. Industry also has focused on specific gender based conditions, which often are natural and age-related processes such as male erectile dysfunction. After the incredible success of *Viagra*, industry turned its attention to the relatively untapped female market, and thus the condition Female Sexual Disorder was created. Moreover, industry not only sets its sights on "illnesses" that can be treated with medication but on the means to diagnose them, for example, on procedures such as CT scans and MRIs. As well, industry has discovered the powerful role of vanity and self-esteem in the human psyche and, in light of this knowledge, has played an intricate role in increasing society's quest for perfection through cosmetic surgery and other quick fixes such as medical weight loss treatments.

As most Canadians will seek out medical attention and services at some point, the medical industry must continue to play an integral role in their everyday lives. Although up until now, Canada has resisted significant changes to legislation governing the prohibition of DTC advertising; this easily could change. In fact, in 1996, Canada's firm stance on prohibiting DTC advertising eroded when an amendment to the existing

legislation permitted DTC help-seeking and reminder ads. The experiences of the U.S. and New Zealand regarding the negative consequences of DTC advertising should serve as a warning as to the potential disastrous impact that this type of advertising could have on Canada's already fragile healthcare system.

The American Medical Association's recent rejection of the proposed ban on the advertising of prescription drugs is a disconcerting indication of just how difficult it may be to regulate or institute changes once industries practices have become entrenched in healthcare practices. The relaxation of the U. S. regulations governing DTC advertising of pharmaceutical drugs has permitted this industry to become one of the most profitable in the country. However, this success has come at a cost for individual health consumers in terms of increased insurance plan premiums to cover these expensive new drugs, and the potential for an increased risk of morbidity and mortality related to unsafe and inappropriate treatment regimes. As well, physicians are spending more time and resources educating patients about alternative treatments and measures that the patient has "learned" about from DTC advertisements, even though he or she may or may not have the condition described.

Although Canada has not yet joined the U.S. in amending regulations and legislation openly permitting DTC advertising of prescription drugs, Canadians are not immune or protected from the cross border onslaught of mass media DTC advertisements. Thanks in part to Canada sharing U.S. cable programs, conducting free trade with the U.S., and having lax enforcement of its advertising laws, Canadians already are exposed to television commercials, magazines, and newspapers advertising various conditions and drugs, or making thinly veiled suggestions to health consumers to

seek out their physician for more information about a drug or condition. If the Canadian government were to introduce legislation permitting DTC advertising, and more importantly, chose to eliminate the list of serious diseases for which manufacturers currently cannot advertise treatment, preventions, or cures, the already fragile state of publicly funded health care in the country could be weakened even further by "sick" individuals demanding access to additional services and treatments. Persuaded by the promises and fears raised by DTC advertising, health consumers may forego the established standard of care in favour of demanding they receive treatments seen on television or read about in magazines. Moreover, these cures and treatments may involve greater health risks and cause a greater strain on healthcare resources, especially when additional tests and procedures are needed to rule out false-positives results.

However, in Canada, the opportunity still exists not only to protect the current legislation governing DTC advertising but to create new legislation aimed at protecting the health consumer against misleading DTC advertising. Canada is in a unique position in that we can learn from the U.S. and New Zealand experience and potentially avoid many of the negative effects of DTC advertising. As well, Canadians are fortunate in that they have powerful lobbying groups such as the Canadian Pharmacists Association, Canadian Medical Association, Canadian Health Coalition, and the Consumer's Association of Canada to rally against proposed changes to the Canadian legislation on DTC advertising. Nevertheless, it is uncertain how these groups will fair in continuing to dissuade the Federal government from instituting proposed changes. Healthcare consumers also must take an active role to prevent changes that could negatively affect the fragile state of the Canadian healthcare system. In a democratic society, social unity

is paramount to protect the well being of all. If Canada continues to downplay the negative implications that DTC advertising has had on the U.S. and New Zealand, and to a certain extent some Canadians, and further chooses to consider proposed changes to existing legislation governing DTC advertising, Canadians may be destined to become a nation of "healthy invalids, crippled not by disease but by the idea of disease."[297]

[297] Barsky 17.

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