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To ban or not to ban: direct-to-consumer advertising and human rights analysis

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REVIEW

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Abstract

The issues surrounding Direct-To-Consumer Advertising of pharmaceuticals are ripe for scrutiny through the lens of Human Rights analysis. Among the human rights most decisively engaged by DTCA is the right to autonomy in health-related decision making, which in turn incorporates right of access to health-related information. The latter incorporates, in part, right of access to reliable and beneficial information through the avenues of commercial speech among others. Another crucial human right is the right not to be harmed by unsafe consumer products through corporate malfeasance or negligence. The most commonly invoked policy options in the context of DTCA are either an outright ban or strengthening regulatory oversight in combination with voluntary guidelines. Banning Direct-To-Consumer Advertising risks being both over inclusive and under inclusive as a policy option. A wholesale ban risks being over inclusive in that it could deprive consumers of information about medications with a positive benefit-risk profile, ones that could enhance their quality of health and well being. Thus it risks being overly paternalistic. Banning DTCA, by itself, is under inclusive in that it is insufficient to address the ways that unadvertised drugs can pose significant risks to consumers. Other policy measures would be most optimal to deal with the very serious deficits in the processes by which prescription drugs undergo clinical trials, and garner regulatory approval prior to their promotion in the marketplace.

A more finely tuned approach to regulatory oversight is endorsed, one involving a proactive and precautionary approach reliant upon prior approval. Such an approach could help to address the very serious concerns about potential infringements of the human right not to be harmed by unsafe consumer products through corporate malfeasance or negligence

Key words: Direct-To-Consumer Advertising; Pharmaceuticals; Autonomy; Commercial Speech; Ethics; Freedom of Expression; Human Rights; Informed Consent; Paternalism; Public Policy

Introduction

The topic of Direct-To-Consumer Advertising (DTCA) of pharmaceuticals has provoked a flurry of discussion and prompted heated policy debates, appearing prominently and frequently in the pages of medical journals and newspapers around the globe. The Australian Medical Association [1] defines DTCA in its Position Statement as follows: 'advertising directed at the general public that may include any statement, pictorial representation or design, intended directly or indirectly only to promote the use of therapeutic goods as well as medical and health-related services.' The Australian Medical Association's Position Statement explicitly rejects the prospect of DTCA for prescription medicines in Australia.

At present, all of the Organization of Economic Cooperation and Development (OECD) countries, other than New Zealand and the United States, have in place prohibitions against what are known as "product claim" advertisements, i.e., ones which refer to a condition to be treated and a prescription drug treatment by name together, and make claims about the effectiveness of the named drug for that condition. Such ads must either include or make reference to sources which set out risk information.

There are two other types of Direct-To-Consumer ads: one referred to as "reminder" ads and the other as "help-seeking ads". Reminder ads provide only brand identification without mentioning conditions or diseases the product could be used to treat. Help-seeking or disease awareness ads, otherwise known as "Ask Your Doctor" ads, typically recommend that people who suffer from a condition or disease consult their physicians to

obtain further information about it. Consumers may also be invited to seek out information about a disease from other sources, and those may contain information about individual branded products. In Australia and Canada, for instance, the second and third types of ads are legally permitted, whereas the first type (product claims ads) are legally prohibited under the Therapeutic Goods Act in Australia and the Food and Drugs Act and accompanying regulations in Canada.

Persuasive speech directed at matters of health and wellness is not problematic per se. Health-related public service announcements, for instance, can be highly effective tools for health promotion. However, persuasive speech that is funded and disseminated by for-profit companies has generated significant public policy debate around the globe. The range of promotional activities undertaken by pharmaceutical companies includes those directed at physicians, such as detailing (in-person visits by pharmaceutical sales representatives), advertising in medical journals, and continuing medical education events as well as those directed at consumers through print, broadcast and online advertising. The crucial ethical issue is whether providing pharmaceutical companies with marketing opportunities targeting the ultimate consumers, i.e., patients, is more likely to empower patients or to endanger them.

Patient autonomy is a core value underpinning contemporary medical ethics, as articulated in professional codes of ethics for health care providers and in seminal court decisions.[2,3] Patient autonomy is a subset of the value of respect for persons.[2] Autonomy is often defined in contrast with paternalism; the latter is characterized as interference with the liberty or autonomy of a person in order to benefit that person directly and/ or others indirectly.[4] There has been in the past several decades a shift in medical ethics from paternalism to an emphasis on patient autonomy. The full implications of the shift from paternalism to autonomy in the health care context are matters of considerable ethical controversy and DTCA presents a striking example of the complexities.

For patients and consumers to make autonomous and thus fully informed choices, regarding their health care, they need to be able to access reliable, and especially balanced, information that is readily understood. [5] The Australian Medical Association's Position Statement implies that informed consent would be compromised by the influence of commercial considerations on the communication of health information, and a ban on DTCA is supported for that reason. Yet, there are competing concerns that blanket prohibitions of commercially-motivated persuasive speech venture too far down the path of paternalism.[6,7,8] This particular claim has been the focus of sustained debate in Canada, New Zealand and the United States [6,7,8]; that debate is discussed below in Section VII. Further contributions to those debates can be made by expanding the focus beyond freedom of commercial expression and incorporating a focus on the human right to health.

The most commonly invoked policy options in the context of DTCA are either (i) an outright ban or (ii) strengthening regulatory oversight in combination with voluntary guidelines. Other measures that can supplement and strengthen the benefits of regulatory oversight include public education campaigns (along the lines of public service announcements), media literacy training, and access to alternative, non-commercially oriented, sources of information. Whether or not DTCA is allowed, prescription drugs remain subject to government regulation to ensure that they meet requisite standards of safety as well as efficacy. A human rights analysis can help to assess the relative merits and demerits of the different policy options, with particular salience being granted to issues respecting human rights. As is elaborated below, application of human rights analysis to the topic of DTCA lends support to the position that, where a DTCA ban exists, it should not be dissolved unless and until other policy measures (as specified below in Section VIII) are instituted. Where a ban does not exist, regulatory oversight should be strengthened in combination with other policy measures, in order to ensure the fulfilment of patient autonomy, promotion of health, and avoidance of harm.

Human rights are not the only measure of the desirability of policy options, and human rights analysis will provide only a partial picture of the policy landscape. Other treatments of the broader economic context within which DTCA is situated are needed, and policy scholars and governments in Canada, New Zealand and the United States have been pursuing assessments of the economic and social costs and benefits of DTCA. [9-17] An expert advisory committee in Australia, the Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee, has specifically addressed the topic of DTCA in the Australian context [18]. Human rights are among the most widely accepted of international norms, and considered to be of paramount importance for deepening democracy, and ensuring good governance.[19,20] It is critical to assess what the human rights implications are of banning or not banning DTCA, and to do so with extensive scrutiny of a diverse selection of human rights.

Situating/ Contextualizing Human Rights Analysis

Debates over policy options for DTCA involve interaction between human rights claims of natural and artificial persons, at the intersection of moral and legal rights. Corporations have moral and legal obligations not to harm consumers by their products. Governments have moral and legal obligations not to interfere with the freedom of expression of their citizens, and to take positive measures to ensure the realization of the right to health of their citizens. The present discussion, due to space limitations and in order to maintain fidelity to the intended scope, can only provide a very brief survey of the most salient aspects of what is an enormous literature on theories of rights, generally, and human rights, specifically, as context for a human rights analysis.

Concepts of rights are prominent and influential within accounts of justified morality, and within both domestic and international law.[21] Governing rules of legal systems and moral principles recognize rights as high priority norms.[22,23] Moral rights provide the basis on which moral agents make claims to protection of their crucial interests, protection from harm and protection of their dignity. The scope or object of a right, including a human right, comprises a freedom, power, immunity or benefit. [21] The assertion of moral rights as claims by rights-holders imposes duties on moral agents who recognize the validity of those claims. [23] Familiar accounts of rights as claims distinguish between negative and positive rights. The former set out claims against others to act or refrain from acting in certain ways; the latter set out claims to positive actions to be taken by others to fulfil the rights in question. [21] Rights function as "trumps" in that they can outweigh competing considerations, including social and political goals aiming at collective benefit. [24] Legal rights are those specific rights that have been given express and explicit recognition in legal codes.

Human rights are rights that are held by natural persons, i.e., flesh and blood human beings, simply in virtue of being human, and justified by their role in constituting human dignity.[25-27] Human rights aim to secure for individuals necessary prerequisites for living a minimally good life, and in particular, an autonomously chosen and freely pursued minimally good life.[21,27] Such rights reflect the intuition that human beings are entitled to be treated in ways that promote, protect, preserve, and realize essential human attributes, capacities, or potentials.[25-27] People are entitled to protection of their human rights even if those rights are not recognized or respected by their societies.[21] Contemporary human rights are indebted to theories of natural rights, yet they go beyond older accounts of natural rights in at least three respects: (i) placing much greater significance on requirements for positive actions by states, institutions and organizations; (ii) emphasizing the importance of family and community ties in the lives of individuals; (iii) having a decidedly international and global orientation.[21]

There is widespread acknowledgement amongst human rights scholars that while rooted in moral norms, human rights have become closely identified with legislation, rulings of courts and tribunals, and especially with international norms as expressed in the International Bill of Rights.[21] That so-called International Bill of Rights includes three seminal documents: the Universal Declaration of Human Rights (UDHR)[28], the International Covenant on Civil and Political Rights (ICCPR) [29] and the International Covenant on Economic, Social and Cultural Rights (ICESCR).[30] The UDHR is not a binding legal treaty, but the two covenants are treaties binding on their members, i.e., the signatory states. Human rights do not depend upon legal enactment for their validity or justification, yet such enactment helps to ensure that there will be enhanced motivation for human rights to be upheld and given practical effect.

Theorists of human rights posit a distinction between a "first generation" of human rights that corresponds to the civil and political rights (i.e., the ICCPR rights) and a "second generation" most closely associated with economic, social and cultural rights (i.e., the ICESCR rights).[31] Familiar examples of first generation human rights include rights to life, to vote, to free speech and to private property, as well as rights not to be arbitrarily detained or tortured or subjected to cruel and unusual punishment. Sometimes, the umbrella term "liberty rights" is used for these rights. Second generation human rights include rights to food, shelter, work, education, welfare, and health. They are sometimes characterized by the umbrella term of "welfare rights", although they encompass a much wider array of entitlements than welfare strictly understood. [32] Such rights are a necessary condition for liberty rights to be of value.[27,32] Although it can be more difficult to specify the duty-bearers corresponding to welfare rights than is the case typically for liberty rights, welfare rights deserve the same status as human rights.[27,32]

The distinction between the generations of rights is affiliated with qualitative and quantitative differences in the forms and modes of protection, differences that arise from wording in Article 2 for each document. Article 2 of the ICCPR ensures that the rights contained therein are to be given immediate effect, and obliges states to develop possibilities of legal remedies. [29] The parallel provision in the ICESCR, Article 2, uses strikingly different words in key passages.[30] The rights contained therein are to be realized progressively, and steps toward their fulfilment are subject to resource constraints (with reference to maximum of available resources on the part of a state). The phrase "legislative measures" is used rather than legal remedies.[30] The ICCPR provides for states and/ or individuals to present their complaints to a reviewing body, whereas there is no similar complaint procedure anticipated in the ICESCR.

A highly significant conceptual and practical matter of contemporary concern is the issue of the human rights obligations of companies or corporations. The Special Representative of the Secretary-General has advocated a framework that rests upon three core principles, or pillars: (i) the State Duty to Protect against human rights abuses by third parties, including business, through appropriate policies, regulation, and adjudication; (ii) Corporate Responsibilities to Respect human rights, which means to act with due diligence to avoid infringing on the rights of others; and (iii) greater access to Remedies, judicial and non-judicial.[33] The framework builds on well established norms of international law that ensure that States have duties to protect their citizens from abuses and violations of human rights, including those for which businesses are responsible. It is recommended that states and corporate entities undertake human rights impact assessment (HRIA), especially in relation to proposed development projects or privatization initiatives, in order to identify, prevent, and ameliorate

potential human rights abuses.[34,35,36,37] A first step towards the undertaking of a comprehensive human rights impact assessment could be the type of human rights analysis pursued here.

The most fundamental of human rights is the right to life, a foundational right without which other human rights cannot be exercised or fulfilled. Article 3 of the Universal Declaration of Human Rights guarantees that "everyone has the right to life, liberty and security of the person".[28] The right can be construed to incorporate the right not to be harmed by unsafe consumer products through corporate malfeasance or negligence, especially the right not be killed thereby. Two other core human rights at stake in the policy debates over DTCA are the human right to health and the right to freedom of commercial expression, or commercial speech. The right to freedom of expression, like the right to life and the right to health, is a right held by natural persons (i.e., flesh and blood human beings), but extended by association to artificial persons (i.e., companies and corporations), for reasons of strategy and logistics.

Human rights can be characterized in terms of the basic capabilities that make a life fully human and support our powers as moral agents.[38,39] Of exceptional importance amongst basic capabilities is the ability to live to the end of a normal life span, and the ability to have good health.[38] The human right to health is found in Article 12 of the ICESCR, and its content and contours have been articulated by the United Nations Committee on Economic Social and Cultural Rights (CESCR) and the World Health Organization (WHO).[40,41] Article 12 guarantees everyone the right to enjoyment of the highest attainable standard of physical and mental health. The World Health Organization has characterized health as a state of complete physical, mental and social wellbeing, and not just an absence of disease or infirmity.[42] The human right to health clearly encompasses an aspirational goal, given the exigencies of resource constraints facing all nations to greater or lesser degrees. Philosophers have criticized the overly idealistic construction of the right to health, while still recognizing the crucial contributions of health to human functioning and flourishing.[27,43,44] Health policy scholars have linked proposals for health care reform, both domestic and global, to human rights, as well as to social justice more broadly conceptualized.[45]

In the General Comment Number 14, the UN CESCR elaborates on the legal obligations resting on states under international law to respect, protect and fulfil the human right to health. Those obligations include preventing the marketing of unsafe drugs (paragraph 34), and avoiding limitations on people's access to health-related information and services due to the activities of third parties (paragraph 35).[40] State actions or policies or laws that are likely to result in bodily harm, unnecessary morbidity and preventable mortality will contravene Article 12 of the ICESCR (as per paragraph 50), as will state failures to properly regulate the activities of corporations.[40] State failure to protect consumers from the products of manufacturers of medicines is presented as one of several examples of violations of the obligation to protect the right to health (paragraph 51).[40]

Article 19 of the ICCPR provides that: "Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice."[29] The wording of the ICCPR is echoed in section 14 of the New Zealand Bill of Rights Act.[46] The Canadian Charter of Rights and Freedoms, section 2(b) guarantees "freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication".[47] The right to freedom of expression, as with many in the Canadian Charter, is subject to "such reasonable limits prescribed by law as can be reasonably justified in a free and democratic society" (as per section 1).[47] The First Amendment of the United States Constitution ensures that "Congress shall make no law… prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press".[48]

DTCA is a type of corporate speech or commercial expression. The European Court of Human Rights has defined commercial expression as the dissemination of information for the purpose of inciting the public to purchase a particular product.[49] Philosophers and legal scholars have stressed that it can be difficult to justify the extension of the moral right to freedom of expression to commercial and corporate speech.[50,51] It is important to highlight the fact that legal systems in liberal democratic societies, such as Australia, Canada, New Zealand and the United States, provide legal status to companies and corporations, as notional "legal persons" with separate juristic personhood, in order that they may sue and be sued, have legal privileges and legal responsibilities. In the implementation of human rights as legal rights, some "human" rights can be designated as ones that can be held by all legal persons, including companies and corporations. The right to freedom of expression, or free speech, is such a right.

The human right to freedom of expression is justified on the basis of core values, or rationales, including: (i) the argument from truth; (ii) the argument from democracy; and (iii) individual self-development.[52,53,54] Other rationales thought to support the right include: (iv) stimulus to tolerance; (v) flourishing of pluralism; (vi) intrinsic worth of communicative experiences; and (vii) contributions to public policy goals regarding the efficient allocation of resources.[53] Philosophers and legal scholars typically recognize the need for limitations on the right to freedom of expression, and those limitations are motivated by similar concerns that underlie the rationales in favour of freedom of expressions. Such concerns include: (a) harm avoidance (physical and other types of harm); (b) prevention of detriment to the interests of individuals through invasion of privacy or damage to reputation; and (c) other public policy considerations (for

instance, dealing with hate speech, pornography, or threats to national security).[53]

The truth rationale starts from the premise that rooting out the suppression of ideas, opinions and expressions increases the likelihood that truth will prevail. [55] Truth is more probable since a supposed falsehood (that we may be tempted to stamp out through censorship) may turn out to be true, or at least contain some portion of the truth.[55] We cannot assume that we are infallible. Moreover, it can be said that truth is better served by the power of ideas to get them accepted in the competition of the marketplace. [56] This particular argument has garnered sceptical responses from philosophers and legal scholars, who point out that success in the market does not itself provide proof of truth, but it has had considerable sway on jurists in many liberal democratic societies. [50, 52, 53, 54]

The argument from democracy views freedom of expression as necessary for the sustenance and flourishing of democracy, which is a form of government that depends upon an engaged and informed citizenry. Underpinning a democratic vision of society is the notion of the sovereign power of the democratic electorate.[54,57] The people, who in effect rule through the delegated activities of their political representatives, need access to the widest possible range of information and ideas in order to scrutinize, assess, criticize, and propose reforms in matters of public policy. Restrictions on speech would impair the deliberative process, and prevent voters from knowing enough about the substance and process of the workings of government.[54,57] Unconstrained communication ensures that citizens can hold their governments to account, take steps to prevent and control potential abuses of power, and safeguard and enhance democratic discourse. The argument from democracy is not invulnerable to criticism, since it is not insulated from the objection that the majority might conceivably choose to restrict expression as an exercise of popular sovereignty. [54]

Of the three core rationales, the third argument, with its focus on individual development, lends most support for the expansion to commercial speech. It, like the other two, is inextricably connected to the needs and interests of natural persons, with its emphasis on the contributions of expression and communication to the development of the human personality. Free expression is crucially important for the exercise of human autonomy, self-realization and self-fulfilment, as well as for public validation and public recognition of diverse “ways of life”. [58] Freedom of commercial expression can be defended on the basis that individual development and individual autonomy can be furthered through the free flow of commercial information. The profit motive alone should not disqualify communicative acts from protection. While many, if not most, media entities active in liberal democratic societies are for-profit companies, they frequently pursue objectives and convey communicative content that furthers the interests of individuals in seeking after truth, engaging in democratic deliberation, and enhancing their autonomy.

Three distinct strands of argument in favour of commercial speech as valuable speech are the following: (a) a consumer may have an interest as keen, if not even keener, in the free flow of commercial information than in the political issues of the day; (b) society has an interest in the unimpeded flow of commercial information in order to ensure the proper working of a market economy; and (c) arguments in favour of restricting commercial speech may be tantamount to paternalism.[59] As to the latter point, specifically, it is wrong to deprive people of information simply because they might use it improperly, or in the eyes of others, foolishly.[52] There are important public policy interests than can justify governmental controls on commercial expression, but the means used to do so should be properly designed to ensure optimal balancing. Regulatory measures could be seen to be best suited to protect consumers from potential harms represented by commercial speech, whereas broad and sweeping bans on commercial speech risk being viewed as more extensive than necessary.

Courts in liberal democratic societies have provided varying levels of recognition to commercial speech under the rubric of freedom of expression. Courts in the United States, for instance, have frequently granted protection to commercial speech, albeit with a lower (i.e., less strict) standard of scrutiny of restrictions than that accorded to content based restrictions of political speech (which get the strictest scrutiny).[50,52] Canadian courts, in the application of the Charter, have determined that commercial speech conveys meaning and has expressive content, and thus deserves protection.[50,52] Commentators from New Zealand and the United States contend that the existing protections for commercial speech should be deemed to cover DTCA, although the issues have not specifically been addressed by courts in either country.[7,8] The current restrictions on DTCA in the Canadian context have not been tested in the courts, but commentators have speculated that the prohibition on DTCA may not withstand a constitutional challenge.[9]

The human rights potentially at stake in the context of DTCA are threefold. First is the right to life, which has particular salience in conjunction with the duty to avoid intentional harm (or the duty of non-maleficence). Second is the right to health, which incorporates the right of access to health related information and which generates an obligation on government to regulate business in order to protect consumers from risks posed by the products of manufacturers of medicines. Third is the right to freedom of expression, which is conceptually and practically affiliated with the right of companies to communicate with the public, provided that the public is properly protected from harm.

It should be noted that debates about the epistemological status of human rights, about whether preference should be given to accounts of human rights based on social contract theory, or capabilities theory, or other contenders is beyond the scope of the present

discussion.[21,27,38,39,60] So are the debates about whether there needs to be greater levels of government intervention to address concentrations of corporate power in the media sector.[50] The discussion will turn to an examination of pervasive and influential arguments in favour of, and in opposition to, DTCA after the introduction of a simple assumption about information.

A Simple Assumption About Information

The application of a human rights analysis to the topic of DTCA should begin with a simple assumption. That assumption is that, other things being equal, more information is better than less information. The autonomy of patients is enhanced when they have more information about potential treatments for conditions they may have. The autonomy of consumers is enhanced when they have more information about the availability of products and their respective features, including their functionality. The analysis will begin with a few arguments in favour of DTCA, ones which rely upon the simple assumption. Next, the objections to DTCA will be examined in order to demonstrate that the simple assumption cannot be sustained. Then, an analysis of the human rights implications of banning DTCA will be provided.

Arguments in Favour of DTCA

The Right to Health and Access to Health Information

Access to health information is a crucial component of the human right to health. A plausible case can be made out that on the basis of the human right of access to health information, natural persons (i.e., human beings) are entitled to be informed about the availability of potential drugs, the risks and benefits, and other salient details, in order to enable them to make decisions, with the input of their health care providers, about what is best for their health. Moreover, since natural persons are not able to generate sufficient information by themselves, and due to the unparalleled knowledge and experience of their products held by pharmaceutical companies [61], the freedom of commercial expression for artificial persons (i.e., companies and corporations) could be thought to serve the interests of natural persons.

Increased Awareness and Compliance Among Health Care Consumers

There have been positive assertions trumpeted in defence of DTCA, which also function as counter-arguments to redress the perception that there are insufficiently weighty or worthy moral reasons for allowing direct to consumer advertising of pharmaceuticals. A familiar argument valorizes consumer autonomy and consumer empowerment, with specific variants that tailor the argument to highlight the needs of vulnerable groups such as women.[62] Types of patients most likely to benefit from DTCA include the following: (i) those of low socioeconomic status who are difficult to reach by other means of imparting health information; (ii) those who conditions are minor and/ or temporary, and who would prefer easily accessible information, and perhaps less rather than more of it; (iii) those with extensive experience managing chronic, long-term conditions or recurring illness.[63]

Defenders of DTCA insist that campaigns concentrate on particular therapeutic classes. These include drugs to treat conditions for which the symptoms are readily recognized by consumers (such as allergies, arthritis and obesity) or drugs for treatment of previously undiagnosed conditions (osteoporosis, cholesterol, diabetes, and depression). In addition, campaigns target conditions, such as hair loss or skin conditions, that consumers perceive treatments to enhance quality of life.[64] Such conditions, while some might view them as part of the normal vicissitudes of life, can be genuinely health-detracting for others.[65]

In general, consumers who are adults with presumed decision making capacity are entitled to be well informed about available products, goods, and services, and about their qualities, features and prices. The Pharmaceutical Research and Manufacturers of America, representing the brand name drug companies, insists that Direct-To-Consumer Advertising has as its overarching purpose informing and educating consumers about symptoms for conditions that are treatable. [66] As PhRMA states on its website: “Studies show DTC advertising brings patients into their doctor's office and starts important doctor-patient conversations about health that might otherwise not have happened.”[66] An executive of PhRMA suggests that by increasing the likelihood that advertising will prompt patients to seek help, and then receive safe and effective medication, it could play a valuable role in enhancing public health. [67]

Surveys undertaken by the United States Food and Drug Administration [68] and Prevention Magazine [69, 70, 71] found that DTCA leads patients to talk to their physician, including about previously undisclosed conditions. Some commentators have noted that DTCA could potentially trigger a positive response in a person who is currently enduring a condition, but who has previously held back from telling her or his doctor. Some chronic conditions are said to especially prone to being under diagnosed and undertreated. Examples include depression and hyperlipidemia. [72, 73, 74]

One third of respondents to the Prevention Magazine 1999 study reported that DTCA had reminded them to fill a prescription.[70] In Prevention Magazine’s 2000 study, just over a fifth of respondents said DTCA made it more likely that they would take medicine regularly, while 3 percent said DTCA made it less likely they would do so.[69] In the US FDA (1999) study, about half of respondents said that their doctor recommended a different medicine or even a nondrug option.[68] One study of physician experiences recounted that 67 percent of physicians felt DTCA helped them have them to have to

have better discussions with their patients, and 46 percent agreed that it helped to increase compliance.[75] Another study of consumers found there to be notable spill over effects to DTCA's impact, including attentiveness to side effects, and increased information seeking from other sources.[76]

Thus, far from potentially putting patients in greater jeopardy, some argue, DTCA could potentially increase opportunities for wellness and well being, for those people who have heretofore abstained from seeking out medical advice and help. In particular, patient health could be enhanced through greater compliance with treatment regimens, provided that advertising is sufficiently informative in order to serve as a reminder and a prompt to compliance. It should be noted that the argumentation strategy relies upon characterizing a side-effect of DTCA (i.e., prompting patients to visit their physicians) as a benefit of DTCA.

Benefits to Health Care Systems

Industry based defenders tend to make two claims. One is that DTCA can actually generate benefits to patients of the sorts discussed just above. Another claim is presented as a counter to the charges that DTCA generates economic harms; that argument is discussed briefly below in Section VI. In response to that charge, defenders of DTCA insist that DTCA will not significantly increase costs overall. [61, 64, 67, 77] They argue that outpatient drug treatment can substitute for more costly therapies and hospitalizations. Ultimately, if properly used, prescription drugs could be less costly and more effective than other medical interventions. Thus, the argumentation strategy is to characterize the absence of additional costs as a form of benefit.

Thus far, the discussion has been very general. It is now time to make distinctions between different clusters of drugs that can be advertised directly to consumers, and evaluate the respective merits and demerits of information about those clusters. There are four distinct categories of prescription drugs relevant for the purposes of this analysis, each of which has two subcategories. The subcategories are divided on the basis of the presence or absence of DTCA for those drugs.

Categories of Drugs

Group A: Drugs which have proven safety and efficacy, over the longer term, and which are designed to treat life-threatening and/or debilitating conditions. These drugs include antiretroviral therapies, antibiotics, and numerous drugs for cancer, heart disease, stroke, diabetes, and more. These drugs work to save lives, and have a risk-benefit profile which is not problematic.
Group A.1: Drugs Not-Advertised to Consumers
Group A.2: Drugs Advertised to Consumers
NOTE: These drugs will be generally safe, when used as prescribed, as substantiated by the available adverse events information. There is clearly a risk if such drugs are prescribed improperly (to patients who should not be taking them), or are taken for "off label" uses, or if overdoses occur. These drugs may still cause significant side effects.

Group B: Drugs which have proven safety and efficacy, over the longer term, which are designed to treat non-life-threatening, non-debilitating conditions. Such conditions can include post-nasal drip (caused by rhinitis or sinusitis), restless legs, baldness, or skin conditions. These drugs do not pose undue risks, in terms of patient safety, although they are blamed for increasing health care costs overall, and they are part of a problem known as the "medicalisation of normal human experience".[78-80]
Group B.1: Drugs Not-Advertised to Consumers
Group B.2: Drugs Advertised to Consumers
NOTE: See note above for Group A.

Group C: Drugs designed to treat life-threatening and/ or potentially debilitating conditions, which receive marketing approval from the regulatory authorities, but which turn out to have a problematic risk-benefit profile. Either the drugs turn out to be not genuine medical advances (i.e., no better than existing drugs, as with the proverbial "me-too drugs"), or the drugs turn out to be much less safe than was initially recognized by the regulatory authorities (as, for example, with rofecoxib and rosiglitazone).
Group C.1: Drugs Not-Advertised to Consumers
Group C.2: Drugs Advertised to Consumers

Group D: Drugs designed to treat non-life-threatening conditions (see examples above), which receive marketing approval from the regulatory authorities, but which turn out to have a problematic risk-benefit profile. Either the drugs turn out to be not genuine medical advances (i.e., no better than existing drugs, as with the proverbial "me-too drugs"), or the drugs turn out to be much less safe than was initially recognized by the regulatory authorities (as with decongestants containing phenylpropanolamine that posed a possible risk of stroke). [81]
Group D.1: Drugs Not-Advertised to Consumers
Group D.2: Drugs Advertised to Consumers

In order to apply a human rights analysis to the topic of DTCA, it is critical to survey the objections that have been levelled against DTCA, and situate both the defences and the objections in the context of these categories.

Interlocking Arguments Against DTCA

There are several strands of argument against DTCA that are typically relied upon to support prohibitions. These arguments, although distinguishable, intersect in intriguing and important ways. The strands include: (i) concerns about patient safety and drug efficacy; (ii) concerns about negative impact on physician prescribing practices and patient-physician relationships; and (iii) concerns about the detrimental effects on the fiscal viability of health care systems. At root of the arguments

are assumptions which in turn rest upon empirical evidence.

Background Conditions

Assumption I: Existing systems for regulating drug safety do not ensure that unsafe drugs will not reach the market. The process of clinical trials is fraught with opportunities for commercial considerations to impact negatively on the pursuit of scientific knowledge, and for conflicts of interest to jeopardize the fully accurate dissemination of research results.[82-92] Government agencies such as the Food and Drug Administration in the United States, the Therapeutic Goods Administration in Australia, Medsafe (within the Ministry of Health) in New Zealand, and the Therapeutic Products Directorate (within Health Canada) in Canada, lack adequate resources, necessary capacity, and sufficient political will to do the job they have been tasked with properly.[93-97]

Assumption II: Pharmaceutical companies are so determined to market their products that they engage in a range of deceptive and misleading practices, with respect to the reporting of clinical trial results, including duplicate publication, selective publication and selective reporting, as well as ghost-writing. [98, 99] These practices tend to produce the impression that certain prescription medications are safer than they actually are. [90,100]

Assumption III: DTCA lacks sufficient quality of information in terms of content; it is not balanced or accurate.[101,102] In a survey undertaken by the Henry J. Kaiser Family Foundation, substantial proportions of survey respondents (70 percent) recount that they learned little or nothing more from ads about a health condition requiring treatment.[103] DTC Ads tend to be superficial in their coverage of conditions, and to rely upon emotional appeals.[104] Consumers may not understand efficacy claims made in DTCA. A study providing respondents with “benefit box” information (standardized table with published data on the chances of various outcomes with and without the drug) found that respondents would pay a lot of attention to that kind of information, and that they would trust that kind of information more than what was actually found in the ads scrutinized.[105] Many ads neglect to inform potential patients about basic matters such as risk factors, prevalence of a condition or subpopulations at greatest risk. Ads for prescription drugs seldom educate about the mechanisms by which they work, necessary duration of use, their success rates, or alternative treatments or behavioural changes that could supplement or even supplant treatment. [106,107,108,109,110] DTC ads were found to give consumers 30 percent less time to absorb facts about risks than about benefits, and to leave out important contextual information for risk statements that were included.[111]

For adults with limited literacy, in particular, DTCA relies too heavily on medical terms that could be hard to decipher.[111] The average reading difficulty scores of the text materials that are intended to fill in the gaps from broadcast ads were found to be well above the reading ability of average adult Americans.[111] It should be noted that some critics of DTCA highlight the special vulnerability of women.[112] In general, consumers lack adequate knowledge of medicine or pharmacology to be able to assess for themselves the relative merits and demerits of advertised prescription medicines. There is evidence that consumers are labouring under misperceptions about the level or extent of protection provided by the regulatory system. One study found that 43 percent of respondents believed that only completely safe drugs could be advertised directly to consumers, 22 percent believed that advertising of drugs with serious side effects had been banned, and 27 percent believed that only extremely effective drugs could be marketed directly to consumers. [108] Consumers are at a substantial informational disadvantage vis-à-vis the marketers of prescription drugs. [111-119]

Assumption IV: Physicians are besieged by an onslaught of promotional activities undertaken by pharmaceutical companies, including advertising in medical journals, detailing (in-person office visits by pharmaceutical sales representatives, or PSRs), and free samples of drugs, “gifts”, and continuing medical education (CME) events.[120-128] In addition to the pressures posed by those activities, patients who have their expectations raised of benefit from an advertised drug represent additional pressures on the physician to prescribe that drug. IMS Health gathered survey data indicating that two thirds of Americans recalled being exposed to DTCA, and about one tenth asked for a prescription for the advertised drug. [129] Of those asking, 73 percent obtained a prescription for the advertised drug.[129] Numerous studies have found that physicians have mixed feelings, at best, about DTCA.[130-140]

Physicians have expressed concerns about the impact of DTCA on patient satisfaction, patient trust in their doctor, and also about the “hassle” factor. Physicians stressed that exaggerated perceptions of drug benefits was the most significant problem with DTCA in one study [130]; addressing those exaggerated perceptions can potentially waste valuable time in visits.[75] In one study, 30 percent of physician respondents reported that DTCA made patients less confident in their doctor’s judgment.[75] When asked about their perceived likelihood of reacting to non-fulfilment of a prescription, 46 percent of respondent patients forecast disappointment, one fourth anticipated that they would resort to persuasion and seeking the prescription elsewhere, and 15 percent said they would consider terminating their relationships with their physicians.[131] When asked about the efficacy of an advertised drug that had been prescribed to patients, 46 percent of physician respondents felt it was the most effective, while 48 percent felt it was no more effective than other drugs, and 12 percent predicted that there would be no effect on symptoms.[75] In that same study, 20 percent predicted there would be no effect on the patient’s overall health, and 5 percent thought other options may have been more effective than the advertised drug that was prescribed.[75]

Critics worry that the cumulative effects of the promotional activities and desires to achieve patient satisfaction can lead to improper or excessive prescribing, which has implications for patient safety (discussed just below).[117-119,134,135] Commentators may make the assumption that general practitioners can be deficient in their knowledge of pharmacology (as are consumers in general), and thus that some physicians will also be at an informational disadvantage vis-à-vis the marketers of prescription drugs.[141]

Implications: Threats to Patient Safety

Several high profile and much publicized cases starkly illustrate the implications in terms of threats to patient safety. One case is that of Merck's blockbuster drug rofecoxib (Vioxx), the use of which was found to increase the risk of serious coronary heart disease when compared with celecoxib use. [142-145] The drug was approved by the FDA in May 1999, and epidemiological studies highlighted problems during 2002 and 2004. [146] The drug was not taken off the market until September 2004. Subsequently, officials from Merck admitted to an error in interpretation in a crucial statistical test, in 2006, and ultimately agreed to one of the largest civil litigation settlements for class action lawsuits in 2007.[146,147] Critics of the company charged that officials had been aware of the potential risks from the drug, prior to 2004, but had continued to aggressively market it (spending over $100 million US a year, and more than $160 million US in 2000 [148,149] and irresponsibly downplay the risks.[150,151] The drug rosiglitazone (Avandia), used to treat diabetes, has been associated with a significant increase in the risk of myocardial infarction.[152] It has been the focus of controversies over internal government reports that connect the drug to increased risk of death, and the subject of a US Senate investigation.[153,154]

A drug that is not as safe as promised that is promoted through DTCA may bring harm to greater numbers of people. A survey sponsored by the FDA found that 22 percent of general practitioners and 13 percent of specialists indicated that they felt "somewhat" or "very" pressured to prescribe drugs to patients who had seen DTC advertising.[130] One study was designed to track prescribing behaviour of doctors in geographically close cities, one American and one Canadian (to test the effects of DTCA, legal in the former but illegal in the latter).[134,135] The researchers reported that patients in the US city were more than twice as likely to request drugs advertised directly to consumers.[134,135] With the Vioxx drug specifically, there are indications that Merck's very hefty advertising budget translated into greater numbers of patient requests acquiesced to by physicians.[155,156]

Detriment to Health Care Systems

Assumption V: Due to the impact DTCA has on escalating demand for "me-too" drugs (i.e., pseudo innovations), and for the newest and most expensive medications that may be no more effective than older, cheaper alternatives, the overall effect of DTCA is to substantially increase costs to health care systems. In addition, critics of DTCA object to its contributory role in the "medicalisation" of normal human experience, by "selling sickness", "disease mongering", and flogging a "pill for every ill", a role that further increases costs.[78,79,80,110,157] Considerable evidence has been accumulated that DTC can be associated with increased health care costs.[9,15,16,158-161]

It should be emphasized that this is an issue over which the defenders and the detractors of DTCA are in striking disagreement. As noted above, proponents of DTCA insist, in light of proper interpretation of the relevant data, that DTCA will not prove to be inefficient from a societal perspective.[162-164] It has been emphasized that spending on DTCA tends to be concentrated on a relatively small number of brands, and that it amounts to a small proportion of overall spending on promotion of pharmaceuticals.[165,166] The impact of DTCA on a product's market performance may be tempered or even negated by the formulary status or price or copayment of the advertised drug.[140] It has been suggested that drug spending increases attributed to the effects of DTCA should more properly be attributed to patients' insulation from paying the full costs of drugs, a problem that could be addressed through other policy options, such as consumer cost-sharing and the formulary status of drugs.[163,167]

The opponents of DTCA insist that proper interpretation of the data shows just the opposite. There is, policy analysts have argued, sufficient evidence to indicate that DTCA increases consumer demand for advertised medicines, typically newer drugs that are more costly than older treatments (and especially than non-treatment options), and that leads to expenditures that are not cost-effective overall.[9,11,117-119] Critics contend that the trajectory of the expected continuing increases in costs will ultimately put the viability of health care systems at risk, for no net benefit in terms of patient well being, and potentially net detriment.[9,11,117-119]

Human Rights Analysis: Underinclusivity and Overinclusivity

The primary issue to be addressed is that of patient safety. It is without doubt that patient wellbeing counts among the desiderata of policy goals for any health care system. There are clear connections between the right to health and avoidance of morbidity and mortality due to unsafe medications, as was noted above (in Section II). It should be emphasized that the charge about increased risk to safety will only hold against drugs falling within Group C and Group D, but would not apply to drugs falling within Group A and Group B. Recall that Group A and B did not have a problematic risk-benefit profile, and thus those two clusters of drugs do not pose particular risks to patient safety. Of course, it bears repeating that the caveats mentioned above apply: provided the drugs are

prescribed properly and not given for off-label uses, and if overdoses are avoided.

For the drugs in Category C (C.1 and C.2) and D (D.1 and D.2), it is clear that such drugs may pose risks to consumers in ways to which they could not be presumed to consent, if fully informed about the risks. It is helpful to conceive of a right not to be harmed by unsafe consumer products through corporate malfeasance or negligence, especially the right not be killed thereby.

The challenge is that a ban on Direct-To-Consumer Advertising by itself, as a prophylactic for human rights abuse is underinclusive, since it would only remedy the potential harm posed to consumers of drugs in Subcategories C.2 and D.2. The consumers of drugs in those two categories are the "additional" patients who receive those drugs due to exposure to DTCA and willingness of their physicians to prescribe in accordance with patient expectations. It is important to emphasize that improper prescribing goes well beyond advertised drugs. Research indicates that elderly patients especially are subjected to levels of improper prescribing that are alarming.[168] Consumers who receive drugs in Subcategories C.1 and D.1 are still put at risk, even though DTCA is not implicated.

The fundamental issue is that unsafe drugs, i.e., ones that have an inherently problematic risk-benefit profile, should not be allowed to get on the market in the first place. If they do sneak out, they need to be tracked down and dealt with promptly. There has been sustained and intense focus upon the larger topic of drug approval, ushering in many focal points for reform. Examples include the pre-registration of all clinical trials, the adoption by medical journals of a policy of only publishing articles pertaining to pre-registered clinical trials, as well as toughening up the policies and procedures concerning disclosures of potential conflicts of interest. [169] Medical journals can adopt a policy requiring data from clinical trials written up in submissions to be subjected to independent analysis, in order to substantiate the results. Other calls for reform have focused on the need for more rigorous oversight through improvements in post-approval adverse event monitoring. [170]

Other policy measures can address the potentially problematic influence of sales-related activities of pharmaceutical corporations upon physicians. These include legislative reform to require companies to disclose all expenditures on gifts to physicians, and medical school policies that ban or limit marketing-related interactions between physicians and industry. Still others try to reduce the risk of adverse events going undetected, through, for instance, provision of a toll free number for patients and physicians to report adverse events and other side effects of prescription medication directly to regulatory authorities. Regulatory and other reforms that directly fix the gaps in the processes for drug testing and approval will have the effect of remedying risks to consumers posed by drugs in subcategories C.1 and D.1, drugs that are not the focus of DTCA campaigns. Reforms such as these have the merit of being sufficiently inclusive to cover all four subcategories of C and D types of drugs.

If the focus shifts to drugs in Categories A and B, the challenge is a different one. Now, the ban on DTCA risks being overinclusive. Drugs in subcategories A.1 and B.1 are drugs about which consumers would benefit from having access to accurate, balanced, and comprehensive information. A ban on DTCA for drugs in those categories risks being a way to constrain demand and ration services, as has been suggested as a rationale for the ban in the European context.[115] Such a policy rationale (i.e., cost containment) can be justified on economic grounds, but not necessarily on grounds of respecting human rights. A wholesale ban prevents information about those drugs from reaching consumers directly, and potentially jeopardizes a fuller exercise of their autonomy.

Policy Recommendations

Policy recommendations following from a human rights analysis are in keeping with the differentiated approach to the human rights obligations of corporations, as articulated by the United Nations Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises. [33] Under that framework, for-profit entities have responsibilities to respect human rights, whereas states have responsibilities for protection of human rights. Pharmaceutical companies are morally required to avoid harming their customers through malfeasance and negligence. Governments are morally required to ensure that the human rights of their citizens are not abused or violated, and they are obliged to take action to prevent abuses or violations by third parties.

The fatal flaw in the line of reasoning presented to defend DTCA is that the simple assumption cannot be sustained. The simple assumption posits that, other things being equal, more information is better than less information. The serious deficits in information quality that have been the focus of the empirical research surveyed above mean that more information is not necessarily better. If the information being provided by DTCA is significantly compromised in terms of balance, and educational value, as many studies have suggested, a permissive approach to DTCA may be an idea whose time should not come, for those jurisdictions in which a ban already exists.[116,117,118,119,171] Governments in countries that currently prohibit DTCA would be unwise and imprudent to rush to dissolve the prohibition unless and until the other policy measures outlined above are in place to ensure protection of the public.

Some commentators have called for a ban even in the circumstances where DTCA is legally allowed, at present, on the grounds that respect for autonomy demands it. [141,172] Or a ban has been seen as a last resort, out of despair that the current system of company self-monitoring and regulatory oversight is not working, and

fear that commercial considerations have come to compromise the quality of health care.[173,174]

Numerous commentators take a considerably more optimistic stance on the potential for significant improvements in the regulatory regime. What is needed, they argue, are regulatory measures to ensure that advertising contains specific content, with details about who may be at risk for the condition, what nonpharmacological treatment options are available, when behaviour modification is likely to be effective, as well as the likely efficacy of alternative treatments. [104,107,111] It is most likely that some kind of "pre-review" or "prior approval" of DTCA would be necessary to achieve those policy goals. It is telling that a substantial proportion of survey respondents in the US incorrectly believed that regulatory authorities were already exercising that kind of proactive and precautionary oversight. [108]

With the shift to autonomy, health care is a partnership between patients and health care providers, albeit a partnership in which physicians, serving as learned intermediaries, perform a gatekeeping role.[175,176] Physicians can take the initiative to remind their patients that DTCA is simply "advertising", and as such reflects "unabashed attempts" to get them to buy something (in the words of a former editor of the New England Journal of Medicine).[177] Physicians should advocate for better quality information to be generated, so that they will have at their disposal ready sources of "counter-detailing" in order to stimulate more balanced conversations with their patients.[108,178] Health care professionals and members of the general public alike should advocate for improved sources of health information of all kinds from many different sources.[115,179]

Pharmaceutical companies should embrace the myriad possibilities for optimizing their efforts towards corporate social responsibility, particularly in relation to the United Nations Global Compact Principles, the first principle of which reads as follows: "businesses should support and respect the protection of internationally proclaimed human rights".[180] The drug industry has a tremendous opportunity to address the concerns of its critics, and to redeem its credibility and its public reputation.

Conclusion

If there can be sufficient assurance in the quality of data obtained from clinical trials, and if quality assurance can be effected in the production of promotional materials, then it could be said that allowing DTCA, with proper oversight by regulatory authorities, could be the most autonomy preserving policy option. It could potentially be the policy option least fraught with the afflictions of paternalism. However, the "ifs" relating to quality assurance are very substantial ifs, and we seem to be rather a long way from those concerns being adequately addressed.

Human rights are not the only measure of the desirability of policy options, and human rights analysis will provide only a partial picture of the policy landscape. Other treatments of the broader economic context within which DTCA is situated have great value. [9-17] Yet, human rights are in many ways a common currency of value in our contemporary globalized world, and an evaluation of policy options would be remiss without taking the measure of their respective implications for human rights.

The merits of the approach taken here include the differentiation of types of drugs into categories based on features of the targeted conditions, and respective risk-benefit profiles, in addition to whether the drugs are or are not advertised directly to consumers. That differentiation makes clear that not all drugs are equal with respect to the impact of DTCA upon patient well being.

The core argument is that banning Direct-To-Consumer Advertising risks being both overinclusive and underinclusive as a policy option. A wholesale ban risks being overinclusive in that it could deprive consumers of information about medications with a positive benefit-risk profile (i.e., those in subcategories A.1 and B.1), ones that could enhance their quality of health and well being. Thus it risks being overly paternalistic and could potentially infringe the human right of access to reliable and beneficial information through the avenues of commercial speech among others. Banning DTCA, by itself, is underinclusive in that it is insufficient to address the ways that unadvertised drugs (i.e., those in subcategories C.1 and D.1) can pose significant risks to consumers. Other policy measures would be most optimal to deal with the very serious deficits in the processes by which prescription drugs undergo clinical trials, and garner regulatory approval prior to their promotion in the marketplace. A more fine tuned approach to regulatory oversight is endorsed here, one involving a proactive and precautionary approach reliant upon prior approval, and working in tandem with generation of alternative and high quality sources of information. Such an approach could help to address the very serious concerns about potential infringements of the human right not to be harmed by unsafe consumer products through corporate malfeasance or negligence.

References

1. Australian Medical Association. AMA Position Statement on Direct-To-Consumer Advertising – 2007 [Internet] Canberra, ACT: 2007. Available from: <http://ama.com/au/node/2931>
2. Beauchamp T, Childress J. Principles of biomedical ethics, Sixth Edition. Oxford: Oxford University Press; 2008.
3. Faden R, Beauchamp T. A history and theory of informed consent. Oxford: Oxford University Press; 1995.
4. Dworkin, G. Paternalism. The Monist, 1972; 56(1):64-84.

5. Zachry WM III, Ginsburg DB. Patient autonomy and the regulation of direct-to-consumer advertising. Clin Ther 2001 Dec; 23(12):2024-2037. doi: 10.1016/S0149-2918(01)80155-7.
6. Gold JL. Paternalistic or protective? Freedom of expression and direct-to-consumer advertising policy in Canada. Health Law Rev. 2003; 11(2):30-6. Available from: <http://www.law.ualberta.ca/centres/hli/userfiles/goldjfrm.pdf>
7. Lau, Y. Is banning direct to consumer advertising of prescription medicine justified paternalism? J Bioeth Inq. 2005; 2(2):69-74.
8. Shuchman M. Drug risks and free speech – can Congress ban consumer drug ads? N Engl J Med. 2007 May 31; 356(22):2236-9.
9. Mintzes, B. Direct-to-consumer advertising of prescription drugs in Canada: what are the public health implications? Health Council of Canada, 2006 Jan. [cited 2010 Oct 10] Available from: <http://healthcouncilcanada.ca/docs/papers/2006/hcc_dtc-advertising_200601_e_v6.pdf>
10. Health Canada. Legislative Renewal - Issue Paper: Direct to consumer advertising (DTCA) of prescription drugs. Ottawa 2003 August 11.
11. Toop, L., D. Richards, T. Dowell, M. Tilyard, T. Fraser, B. Arroll. 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. Christchurch, Dunedin: New Zealand Departments of General Practice, Wellington and Auckland Schools of Medicine; 2003.
12. New Zealand Ministry of Health. Direct-to-consumer advertising of prescription medicines in New Zealand: A discussion paper. Wellington, New Zealand: Ministry of Health (NZ); 2000.
13. Calfee, JE. What do we know about direct-to-consumer advertising of prescription drugs? Health Aff (Millwood). 2003 Feb 26; W3:116-119. Available from: <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.116v1>
14. Calfee, J. Public policy issues in direct to consumer advertising of prescription drugs, [Internet] 2002 Jul 8. [cited 2010 Oct 10] Available from: <http://www.ftc.gov/ogc/healthcare/calfeedtcjppm.pdf>
15. Kaiser Family Foundation. Understanding the effects of direct-to-consumer prescription drug advertising. 2001 Nov. Available from: <http://www.kff.org/rxdrugs/upload/Understanding-the-Effects-of-Direct-to-Consumer-Prescription-Drug-Advertising-Report.pdf>
16. United States. General Accountability Office. FDA oversight of direct-to-consumer advertising has limitations. Report to Congressional Requesters. Washington (DC): GAO; 2002 October. Report: GAO-03-177.
17. United States. General Accountability Office. Prescription drugs: Improvements needed in FDA's oversight of direct-to-consumer advertising. Washington (DC): General Accountability Office; 2006 November. Report: GAO-07-54.
18. Australian Government Department of Health and Ageing. Direct to consumer advertising (DTCA) of prescription medicines and the Quality use of medicines (QUM). Pharmaceutical health and rational use of medicines (PHARM) Committee; [Internet] 2004 April. [cited 2010 Oct 10] Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/6D64F5D246ED8FDBCA256F9A00146902/$File/dtca.pdf>
19. Beetham, D. Democracy and human rights. Cambridge: Polity Press, 1999.
20. Donnelly J. Universal human rights in theory and practice. Second Ed. Ithaca: Cornell University Press, 2003.
21. Nickel JW. Making sense of human rights. Second Edition. Malden: Blackwell Publishing; 2007.
22. Campbell T. Moral dimensions of human rights. In Campbell T, Miller S, editors, Human rights and the moral responsibilities of corporate and public sector organizations. Dordrecht: Kluwer Academic Publishers; 2004, 11-30.
23. Feinberg J. The nature and value of rights. J Value Inq. 1970; 4(4):243-257. doi: 10.1007/BF00137935.
24. Dworkin R. Taking rights seriously. Cambridge: Harvard University Press; 1977.
25. Donnelly J. Human rights as natural rights. Hum Rts Q. 1982 Autumn; 4(3):391-405.
26. Gardner J. 'Simply in virtue of being human': The whos and whys of human rights. J. Ethics Soc. Phil. 2008 Feb; 2(2): 1-22.
27. Griffin J. On human rights. Oxford: Oxford University Press, 2008.
28. Universal Declaration of Human Rights, G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948).
29. International Covenant on Civil and Political Rights, G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171.
30. International Covenant on Economic, Social and Cultural Rights, G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3.
31. Vasak K. Human rights: a thirty-year struggle: the sustained efforts to give force of law to the universal declaration of human rights. UNESCO Courier 30 (11). Paris, FR: United Nations Educational, Scientific, and Cultural Organization. 1977 Nov.
32. Archard D. Welfare rights as human rights. In Campbell T and Miller S, editors, Human rights and the moral responsibilities of corporate and public sector organizations. Dordrecht: Kluwer Academic Publishers; 2004, 45-62.
33. Ruggie J. Special Representative of the secretary-general on the issue of human rights and

transnational corporations and other business enterprises. Business and human rights: Further steps toward the operationalization of the "protect, respect and remedy" framework. A/HRC/14/27 [Internet] 2010 Apr. 9. [cited 2010 Oct 10] Available from: <http://198.170.85.29/Ruggie-report-2010.pdf>
34. Ruggie J. Special representative of the secretary-general on the issue of human rights and transnational corporations and other business enterprises. Human rights impact assessments – resolving key methodological questions. A/HRC/4/74, [Internet] 2007 Feb 5. [cited 2010 Oct 10] Available from: <http://www2.ohchr.org/english/issues/globalization/business/reports.htm>
35. Aim for human rights. Guide to corporate human rights impact assessment tools. Aim for Human Rights. [Internet] Utrecht, The Netherlands, January 2009. [cited 2010 Oct 10] Available from: <http://www.humanrightsimpact.org/fileadmin/hria_resources/Business_centre/HRB_Booklet_2009.pdf>
36. Business leaders' initiative on human rights/ UN global compact and United Nations High Commissioner for Human Rights. A guide to integrating human rights into business management. [Internet] 2006 Nov 4. [cited 2010 Oct 10] Available from: <http://www.humanrightsimpact.org/fileadmin/hria_resources/Business_centre/HRB_Booklet_2009.pdf>
37. Rights and Democracy. Getting it right: A step by step guide to assess the impact of foreign investments on human rights. [Internet] 2008 Nov [cited 2010 Oct 10] Available from: <http://www.dd-rd.ca/site/_PDF/publications/Getting-it-right_HRIA.pdf>
38. Nussbaum M. Capabilities and human rights. In Hayden P, editor, The philosophy of human rights, St Paul: Paragon House; 2001, 212-240.
39. Sen A. Elements of a theory of human rights. Philos Public Aff. 2004 October; 32(4): 315-356.
40. United Nations Committee on Economic, Social and Cultural Rights. The right to the highest attainable standard of health. General comment No. 14 (2000). E/C.12/2000/4, 2000 Aug 11. [cited 2010 Oct 10] Available from: <http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/40d009901358b0e2c1256915005090be?Opendocument>
41. Office of the High Commissioner for Human Rights/ World Health Organization. The right to health. Fact sheet number 31. [cited 2010 Oct 10] Available from: <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>
42. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.
43. Bok S. Rethinking the WHO definition of health. Working Paper Series, Volume 14(7), October 2004.
44. Callahan D. The WHO definition of 'health'. Hastings Center Studies, Volume 1(3),1973: 77-87.
45. Chapman A, editor. Health care reform: a human rights approach. Georgetown: Georgetown University Press; 1994.
46. New Zealand Bill of Rights Act 1990, Public Act No 109. Available online: <http://www.legislation.govt.nz/act/public/1990/0109/latest/DLM224792.html>
47. Canadian Charter of Rights and Freedoms, s. 1, s. 2(b), Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, c.11. Available online: <http://www.canlii.org/en/ca/const/const1982.html>
48. U.S. Const. Amendment 1. Available online: <http://www.usconstitution.net/xconst_Am1.html>
49. Emberland M. The human rights of companies: Exploring the structure of ECHR protection. Oxford: Oxford University Press; 2006.
50. Barendt E. Importing United States free speech jurisprudence? In Campbell T, Sadurski W, editors, Freedom of communication. Aldershot: Dartmouth; 1994, pp.57-75.
51. Shiner RA. Freedom of commercial expression. Oxford: Oxford University Press; 2003.
52. Barendt E. Freedom of speech. Second Edition. Oxford: Oxford University Press; 2005.
53. Campbell T. Rationales for freedom of communication. In Campbell T, Sadurski W, editors, Freedom of communication. Aldershot: Dartmouth; 1994, pp.17-44.
54. Schauer F. Free speech: A philosophical enquiry. Cambridge: Cambridge University Press; 1982.
55. Mill JS. On liberty. Penguin; 1859.
56. Justice Holmes in US v. Abrams 250 US 616, 630-631 (1919).
57. Meiklejohn A. Free speech and its relation to self-government. In Political freedom: the constitutional powers of the people. NY: Oxford University Press; 1965.
58. Raz J. Free expression and personal identification. In Raz J. Ethics in the public domain: Essays in the morality of law and politics, Revised Edition. Oxford: Clarendon Press, 1994, pp.146-169.
59. Justice Blackmun in Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council 425 US 748, 763, 764-765, 769-770 (1976)
60. Rawls, John. The law of peoples. Cambridge: Harvard University Press; 1999.
61. Jones T. Should drug companies be allowed to talk directly to patients? Yes. BMJ, 2003 Jun 14;326:1302 doi: 10.1136/bmj.326.7402.1302

62. Shirreff, R. For them to know and you to find out: challenging restrictions on direct-to-consumer advertising of contraceptive drugs and devices. University of Toronto Faculty of Law Review. 2000 Spring; 58:121-155.
63. Hasman A, Holm S. Direct-to-consumer advertising: Should there be a free market in healthcare information? Camb Q Healthc Ethics. 2006 Winter;15(1):42-9.
64. Holmer AF. Direct-to-consumer advertising – strengthening our health care system. N Engl J Med 2002 Feb 14;346(7):526-528.
65. Bonaccorso S, Sturchio JL. Direct to consumer advertising is medicalising normal human experience (against). BMJ 2002 Apr 13;324:908 doi: 10.1136/bmj.324.7342.908
66. PhRMA Website, Direct to Consumer Advertising. [cited 2010 Oct 10] Available from: <http://www.phrma.org/taxonomy/term/97>
67. Holmer AF. Direct-to-consumer prescription drug advertising builds bridges between patients and physicians. JAMA. 1999 Jan 27;281(4):380-382.
68. United States Government, Food and Drug Administration. Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs: Main survey results. 1999. Rockville, MD. [cited 2010 Oct 10] Available from: <http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf>
69. Prevention Magazine. International survey on wellness and consumer reactions to DTC advertising of RX drugs. Emmaus, PA: Rodale Press; 2000.
70. Prevention Magazine.Year two: a national survey of consumer reactions to direct-to-consumer advertising. Emmaus, PA: Rodale Press; 1999.
71. Prevention Magazine and the American Pharmaceutical Association. Navigating the medication marketplace: how consumers choose. Washington, DC: Joint Survey; 1997.
72. Donohue JM, Berndt E. Effects of direct to consumer advertising on medication choice: the case of antidepressants. JPP&M. 2004 Fall; 23(2):115-127.
73. Kravitz RL, Bell RA. Direct-to-consumer advertising of prescription drugs: balancing benefits and risks, and a way forward. Clin Pharmacol Ther. 2007 Oct; 82(4):360-362. doi:10.1038/sj.clpt.6100348
74. Kravitz RL, Epstein RM, Feldman MD, Franz CE, Azari R, Wilkes MS, Hinton L, Franks P. Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized controlled trial. JAMA. 2005 Apr 27;293(16): 1995-2002.
75. Weissman JS, Blumenthal D, Silk AJ, Newman M, Zapert K, Leitman R, and Feibelmann S. Physicians' reports on patient encounters involving direct-to-consumer advertising. Health Aff (Millwood). 2004 Apr 28. doi: 10.1377/hlthaff.w4.219
76. Weissman JS, Blumenthal D, Silk AJ, Zapert K, Newman M, and Leitman R. 2003. Consumers' reports on the health effects of direct-to-consumer drug advertising. Datawatch: Drug Ads, Web Exclusive. 2003 Feb 26. doi: 10.1377/hlthaff.w3.82
77. Kelly P. DTC advertising's benefits far outweigh imperfections. Health Aff (Millwood). 2004;W4: 246-248. doi: 10.1377/hlthaff.W4.246
78. Mintzes, B. For and against: direct to consumer advertising is medicalising normal human experience (for). BMJ 2002 Apr 13;324:908-911 doi:10.1136/bmj.324.7342.908
79. Moynihan R, Heath I, Henry D. Selling sickness: the pharmaceutical industry and disease mongering. BMJ. 2002 Apr 13;324:886-891 doi:10.1136/bmj.324.7342.886
80. Moynihan R, Savage R. Too much medicine? Almost certainly. BMJ. 2002 Apr 13;324:859-860 doi:10.1136/bmj.324.7342.859
81. Horwitz RI, Brass LM, Kernan WN, Viscoli CM. Phenylpropanolamine and risk of hemorrhagic stroke: final report of the hemorrhagic stroke project.[Internet] 2000 May 10. [cited 2010 Oct 10] Available from: <http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3647b1_tab19.doc>
82. Angell, M. 2000. Editorial: Is academic medicine for sale? N Engl J Med 2000 May; 342(20):1516-1518. doi: 10.1056/NEJM200005183422009
83. Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. JAMA, 2003;289(4):454-465 doi:10.1001/jama.289.4.454
84. Bodenheimer T. Uneasy alliance: clinical investigators and the pharmaceutical industry. N Engl J Med 2000; 342:1539-1544. doi:10.1056/NEJM200005183422024
85. Curfman GD, Morrissey S, Annas GJ, Drazen JM. Peer review in the balance. N Engl J Med 2008 May 22;358(21):2276-2277. doi: 10.1056/NEJMe0803516
86. DeAngelis CD. The influence of money on medical science. JAMA. 2006 Aug 23/30; 296:996-998. doi:10.1001/jama.296.8.jed60051.
87. Lexchin, J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. BMJ 2003 May 29;326:1167-1170 doi:10.1136/bmj.326.7400.1167
88. Melander H, Ahlqvist-Rastad J, Meijer G, Beermann B.Evidence b(i)ased medicine - selective reporting of studies sponsored by pharmaceutical industry: review of studies in new drug applications, BMJ 2003 May 29;326:1171-1173 doi:10.1136/bmj.326.7400.1171
89. Roberts W. The tangled web of medical and commercial interests. Health Expect. 2007 Feb 27;10:1-3. doi: 10.1111/j.1369-7625.2007.00432.x

90. Safer D. Design and reporting modifications in industry-sponsored comparative psychopharmacology trials, J Nerv Ment Dis. 2002;190(9):583-592. doi: 10.1097/01.NMD.0000030522.74800.0D
91. Stelfox HT, Chua G, O'Rourke K, Detsky AS. Conflict of interest in the debate over calcium-channel antagonists. N Engl J Med 1998 Jan8;338:101-106 doi: 10.1056/NEJM199801083380206
92. Wynia M, Boren D. Better regulation of industry-sponsored clinical trials is long overdue. J Law Med Ethics. 2009 Fall;37(3):410-9. doi: 10.1111/j.1748-720X.2009.00402.x
93. Abramson, J. Overdosed America: The broken promise of American medicine: How pharmaceutical companies distort medical knowledge, mislead doctors, and compromise your health. New York: Harper Collins; 2004.
94. Angell, M. The truth about drug companies: how they deceive us and what to do about it. New York: Random House; 2004.
95. Angell, M. Excess in the pharmaceutical industry. CMAJ 2004 Dec;171(12):1451-1453. doi:10.1503/cmaj.1041594.
96. Avorn, J. Powerful medicines: the benefits, risks and costs of prescription drugs. New York: Vintage/Random House; 2007.
97. Bremner, JD. Before you take that pill: why the drug industry may be bad for your health. New York: Avery/Penguin; 2008.
98. Singer, N. Medical papers by ghostwriters pushed therapy. The New York Times [Internet] 2009Aug5. [cited 2010 Oct 10] Available from: <http://www.nytimes.com/2009/08/05/health/research/05ghost.html>
99. Wilson, Duff. 2008. Drug maker said to pay ghostwriters for journal articles. The New York Times [Internet]. December 12, 2008 [cited 2010 Oct 10]. Available from: <http://www.nytimes.com/2008/12/12/business/13wyeth.html>
100. Herxheimer, A., Lundorg, C.S., Westerholm, B. Advertisements for medicines in leading medical journals in 18 countries: a 12-month survey of information content and standards. Int J Health Serv. 1993; 23:161-172.
101. Stryer, D, Bero LA. Characteristics of materials distributed by drug companies: an evaluation of appropriateness. J Gen Intern Med. 1996 Oct;11(10):575-83.
102. Bero, LA.'Educational' advertisements – I haven't seen one yet!. West J Med. 2001 Jun;174(6):395.
103. Henry Kaiser Family Foundation. Understanding the effects of direct-to-consumer prescription drug advertising. Menlo Park, CA. November 2001.
104. Frosch, DL, Krueger PM, Hornik RC, Cronholm PF, Barg FK. 2007. Creating demand for prescription drugs: a content analysis of television direct-to-consumer advertising. Ann Fam Med. 2007, Jan-Feb;5(1):6-13. doi: 10.1370/afm.611
105. Woloshin S, Schwartz LM, Welch HG. The value of benefit data in direct to consumer drug ads. Health Aff (Millwood) Web Exclusive, 2004;W4:234-245. doi: 10.1377/hlthaff.w4.234
106. Bell RA, Wilkes MS, Kravitz RL. The educational value of consumer-targeted prescription drug print advertising. J Fam Pract. 2000 Dec;49(12):1092-98.
107. Bell RA, Kravitz RL, Wilkes MS. Direct-to-consumer prescription drug advertising, 1989-1998: a content analysis of conditions, targets, inducements and appeals. J Fam Pract. 2000 Apr; 49(4):329-335.
108. Bell RA, Kravitz RL, Wilkes MS. Direct-to-consumer prescription drug advertising and the public. J Gen Intern Med 1999;14:651-657.
109. Wilkes, MS, Doblin, BH, Shapiro, MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. Ann Intern Med. 1992 Jun1;116:912-919.
110. Wilkes S, Bell RA, Kravitz RL. Direct-to-consumer prescription drug advertising: trends, impact, and implications. Health Aff (Millwood), 2000 Apr;19(2):110-128. Available from: <http://content.healthaffairs.org/cgi/reprint/19/2/110>
111. Kaphingst KA, DeJong W. The educational potential of direct-to-consumer prescription drug advertising. Health Aff (Millwood). 2004 Jul/Aug;23(4):143-150. Available from: <http://content.healthaffairs.org/cgi/reprint/23/4/143>
112. Ford AR, Saibil, D, editors. The push to prescribe: Women and Canadian drug policy. Toronto, ON. Women's Press, 2010.
113. Brownfield ED, Bernhardt JM, Phan JL, Williams MV, Parker RM. Direct-to-consumer drug advertisements on network television: an exploration of quantity, frequency, and placement. J Health Commun. 2004;9(6):491-497. doi:10.1080/10810730490523115
114. Day R. Direct-to-consumer drug ads: what do people understand and remember? [Internet] Testimony to the U.S. Congress House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 2008 May 8; [cited 2010 Oct 10] Available from: <http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.050808.Day-testimony.pdf>
115. Detmer DE, Singleton P, Ratzan SC. The need for better health information: advancing the informed patient in Europe. In Santoro M, Gorrie T, editors, Ethics and the pharmaceutical industry. Cambridge: Cambridge University Press; 2005, 196-205.
116. Hoffman JR, Wilkes M. Direct to consumer advertising of prescription drugs: an idea whose time should not come. BMJ. 1999 May 15; 318: 1301-1302.

117. Mansfield P. Banning all drug promotion is the best option pending major reforms. J Bioeth Inq. 2005;2(2):75-81.
118. Toop L, Mangin D. Industry funded patient information and the slippery slope to New Zealand. BMJ. 2007 Oct;335:694. doi: 10.1136/bmj.39346.525764.AD
119. Toop L, Richards D. New Zealand deserves better. Direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand: for health or for profit? N Z Med J. 2003 Aug 22;116(1180):U556.
120. Avorn J, Milton C, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. Am J Med. 1982 Jul;73(1):4-8.
121. Moynihan, R. Who pays for the pizza? Redefining the relationships between doctors and drug companies: Part 1 – Entanglement. BMJ 2003 May 29;326:1189-1192 doi:10.1136/bmj.326.7400.1189
122. Moynihan, R. Who pays for the pizza? Redefining the relationships between doctors and drug companies: Part 2 – Disentanglement. BMJ 2003 May 29;326:1193-1196 doi:10.1136/bmj.326.7400.1193
123. Moynihan, R.Drug company sponsorship of education could be replaced at a fraction of its cost. BMJ 2003;326:1163 doi:10.1136/bmj.326.7400.1163
124. Relman, A. Defending professional independence: ACCME's proposed new guidelines for commercial support of CME. JAMA. 2003 May 14;289(18):2418-2420.
125. Sade, R. Introduction: Dangerous liasons? Industry relations with health professionals. J Law Med Ethics. 2009 Fall;37(3):398-400. doi: 10.1111/j.1748-720X.2009.00400.x
126. Tsai, A. Policies to regulate gifts to physicians from industry. JAMA. 2003 Oct 1;290(13):1776 doi:10.1001/jama.290.13.1776
127. Wager, E. 2003. How to dance with porcupines: Rules and guidelines on doctors' relations with drug companies. BMJ. 2003 May31; 326:1196-98. doi: 10.1136/bmj.326.7400.1196
128. Ziegler M, Lew P, Singer BC. The accuracy of drug information from pharmaceutical sales representatives. JAMA. 1995 Apr 26;273(16):1296-1298.
129. IMS Health reports direct to consumer advertising increases prescription pharmaceutical brand requests and awareness: majority of physicians have negative view toward DTC advertising. September 15, 1998. <http://www.imshealth.com/html/news_arc/09_15_1998_104.htm>
130. Aikin, K, Swasy J, Braman A. Patient and physician attitudes and behaviors associated with promotion of prescription drugs.[Internet] 2004 Summary of FDA survey research results, executive summary. 2004 Nov 19.[cited 2010Oct 10] Available from: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm109877.pdf>
131. Bell RA, Wilkes MS, Kravitz, RL. Advertisement-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses. J Fam Pract. 1999 Jun;48(6):446-452.
132. Hamm RM., Hicks RJ, Bemben DA. Antibiotics and respiratory infections: are patients more satisfied when expectations are met? J Fam Pract. 1996 Jul;43(1):56-62.
133. Keitz S, Stchuchak K, Grambow S, Koropchak C, Tulsky C. Behind closed doors: management of patient expectations in primary care practices. Arch Intern Med. 2007 Mar 12;167:445-452.
134. Mintzes B, Barer ML, Kravitz RL, Bassett K, Lexchin J, Kazanjian A, Evans RG, Pan R, Marion SA. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. CMAJ 2003 Sept 2;169(5):405-412.
135. Mintzes, B, Barer ML, Kravitz RL, Kazanjian A, Bassett K, Lexchin J, Evans RG, Pan R, Marion SA. Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: Two site cross- sectional survey. BMJ 2002 Feb 2;324:278-279. doi:10.1136/bmj.324.7332.278
136. Murray E, Lo B, Pollack L, Donelan K, Lee K. Direct-to-consumer advertising: public perceptions of its effects on health behaviors, health care, and the doctor-patient relationship. J Am Board Fam Pract. 2004 Jan-Feb;17(1):6-18.
137. Murray E, Lo B, Pollack L, Donelan K, Lee K. Direct-to-consumer advertising: physicians' views of its effects on health behaviors, health care, and the doctor-patient relationship. J Am Board Fam Pract. 2003 Nov-Dec;16(6):513-524.
138. Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct to consumer advertisements for prescription drugs: What are Americans being sold? Lancet. 2001 October 6;358(9288):1141-1146.
139. Young, D. Studies show drug ads influence prescription decisions, drug costs. Am J Health Syst Pharm. 2002 Jan 1;59(1):14,16. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/11813459>
140. Zachry WM III, Shepherd MD, Hinich MJ, Wilson JP, Brown CM, Lawson KA. Relationship between direct-to-consumer advertising and physician diagnosing and prescribing. Am J Health Syst Pharm. 2002 Jan 1;59(1):42-49.
141. Hubbard JE. The dangers of detailing: how pharmaceutical marketing threatens health care. In: Arnold D, editor, Ethics and the business of biomedicine. New York: Cambridge University Press, 2009:pp.103-130.
142. Bombardier C, Laine L, Reicin A. et.al. Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. VIGOR study group. N Eng J Med 2000;343:1520-8.

143. Graham DJ, Campen D, Hui R, Spence M, Cheetham C, Levy G, Shoor S, Ray WA. 2005. Risk of acute myocardial infraction and sudden cardiac death in patients treated with Cyclo-Oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: Nested case-control study. Lancet, 2005 Feb 5:365(9458): 475-481. doi:10.1016/S0140-6736(05)17864-7
144. Juni P, Rutjes AW, Dieppe PA. Are selective COX 2 inhibitors superior to traditional non-steroidal anti-inflammatory drugs? BMJ 2002;324:1287-8.
145. Mukherjee D, Nissen SE, Topol EJ. Risk of cardiovascular events associated with selective COX-2 inhibitors. JAMA. 2001 Aug 22;286(8):954-959.
146. Berenson, A. Merck admits a data error on Vioxx. New York Times [Internet]. 2006 May 31[cited 2010 Oct 10]. Available from: <http://www.nytimes.com/2006/05/31/business/31drug.html>
147. Berenson, A. Merck agrees to settle Vioxx suits for $4.85 billion. New York Times [Internet]. 2007 Nov 9. [cited 2010 Oct 10] Available from: <http://www.nytimes.com/2007/11/09/business/09merck.html>
148. National Institute for Health Care Management. Prescription drug expenditures in 2001: another year of escalating costs. 2002 May 6. [cited 2010 Oct 10] Available from: <http://www.nihcm.org/pdf/spending2001.pdf>
149. National Institute for Health Care Management Research and Educational Foundation. 2000. Prescription drugs and mass media advertising. 2000 Sept. [cited 2010 Oct 10] Available from: <http://www.nihcm.org/~nihcmor/pdf/DTCbrief.pdf>
150. Topol EJ. Failing the public health – rofecoxib, Merck and the FDA. N Engl J Med 2004 Oct 21;351(17):1707-9. doi: 10.1056/NEJMp048286
151. Topol EJ. Good riddance to a bad drug. The New York Times [Internet]. 2004 Oct 2 [cited 2010 Oct 10] Available from: <http://www.nytimes.com/2004/10/02/opinion/02topol.html>
152. Nissen SE, Wolski K. Effect of Rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. N Engl J Med 2007 Jun 14;356:2457-2471. doi: 10.1056/NEJMoa072761
153. Harris G. 2010. Research ties diabetes drug to heart woes. The New York Times. [Internet] 2010 Feb 20. [cited 2010 Oct 10] Available from: <http://www.nytimes.com/2010/02/20/health/policy/20avandia.html>
154. Harris G. 2010. FDA to restrict Avandia citing heart risk. The New York Times. [Internet] 2010 Sep 23. [cited 2010 Oct 10] Available from: <http://www.nytimes.com/2010/09/24/health/policy/24avandia.html>
155. Bradford WD, Kleit AN, Nietert PJ, Steyer T, McIlwain T, Ornstein S. How direct-to-consumer television advertising for osteoarthritis drugs affects physicians' prescribing behavior. Health Aff (Millwood). 2006 Sept-Oct; 25 (5): 371-1377. doi: 10.1377/hlthaff.25.5.1371
156. Spence MM., Teleki S, Cheetham TC, Schweitzer SO, Millares M. Direct to consumer advertising of cox-2 inhibitors: effect on appropriateness of prescribing. Med Care Res Rev. 2005Oct; 62(5):544-559. doi: 10.1177/1077558705279314 9
157. Hollon M. Direct-to-consumer marketing of prescription drugs: creating consumer demand. JAMA1999 Jan 27;281(4):382-384.
158. Rosenthal M, Berndt E, Donohue J, Epstein A, Frank R. Demand effects of recent changes in prescription drug promotion. [Internet] The Henry J. Kaiser Family Foundation, 2003 June. [cited 2010 Oct 10] Available from: <http://www.kff.org/rxdrugs/upload/Demand-Effects-of-Recent-Changes-in-Prescription-Drug-Promotion-Report.pdf>
159. Kessler DA, Levy DA. Direct-to-consumer advertising: is it too late to manage the risks? Ann Fam Med. 2007 Jan/Feb;5(1): 4-5.
160. Lurie, P. Testimony before the Senate Special Committee on Aging on the impact of direct-to-consumer drug advertising on seniors' health and health care costs (HRG Publication #1751). [cited 2010 Oct 10] Available from: <http://www.citizen.org/publications/print_release.cfm?ID=7402>
161. Morgan, S. An assessment of the health system impacts of direct-to-consumer advertising of prescription medicines (DTCA). Health Policy Unit Research Reports, Vancouver, Canada. University of British Columbia (HPRU 02:5D), 2001 Aug. [cited 2010 Oct 10] Available from: <http://www2.itssti.hc-sc.gc.ca/hpb/hcpd/pchcd/projectc.nsf/ExecSum/NA250/$File/execsum-eng.pdf>
162. Saunders B. Direct-to-consumer advertising--where does the public interest lie? N Z Med J. 2003 Aug 22;116(1180):U557.
163. Calfee JE. An assessment of direct-to-consumer advertising of prescription drugs. Clin Pharmacol Ther. 2007 Oct; 82(4):357-60.
164. Dubois R. Pharmaceutical promotion: Don't throw the baby out with the bathwater. Health Aff (Millwood), 2003 February 26;W3:96-103.
165. Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. N Engl J Med 2002 Feb 14;346(7):498-505.
166. Donohue JM, Cevasco M, Rosenthal M. A decade of direct-to-consumer advertising of prescription drugs. N Engl J Med 2007 August 16;357(7):673-681. doi: 10.1056/NEJMsa070502
167. Rosenthal M, Donohue J. Direct-to-consumer advertising of prescription drugs: A policy dilemma. In Santoro M, Gorrie T, editors, Ethics and the pharmaceutical industry. Cambridge: Cambridge University Press; 2005:169-183.

168. Newcomer, LN. 2000. Medicare pharmacy coverage: ensuring safety before funding. Health Aff (Millwood). 2000 Mar/Apr:59-62. Available from: <http://content.healthaffairs.org/cgi/reprint/19/2/59.pdf>
169. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Updated 2010 April. [cited 2010 Oct 10] Available from: <http://www.icmje.org/urm_full.pdf>
170. Chen JY, Carter M. Bioethics and post-approval research in translational science. AJOB 2010 Aug;10(8):35-36. doi:10.1080/15265161.2010.494220
171. Garlick W. Should drug companies be allowed to talk directly to consumers? No. BMJ 2003 June 14; 326(7402): 1302–1303. doi: 10.1136/bmj.326.7402.1302-a.
172. Arnold, D. The ethics of direct-to-consumer pharmaceutical advertising. In: Arnold D, editor, Ethics and the business of biomedicine. Cambridge. Cambridge University Press; 2009. pp. 131-149.
173. Stange, KC. Time to ban direct-to-consumer prescription drug marketing. Ann Fam Med. 2007 Mar/Apr; 5(2):101-104. doi: 10.1370/afm.693
174. Stange, KC. In this issue: doctor-patient and drug company-patient communication: drug-to-consumer advertising. Ann Fam Med. 2007 Jan/Feb;5(1):2-3. doi: 10.1370/afm.670
175. Coulter A. Paternalism or Partnership? BMJ. 1999 September 18; 319(7212): 719–720.
176. Drazen JM. The consumer and the learned intermediary in health care. N Engl J Med. 2002 Feb 14; 346(7): 523-524.
177. Ingelfinger FJ. Advertising: informational but not educational. N Engl J Med. 1972 Jun 15; 286(24):1318-1319.
178. Wolfe SM. Direct-to-consumer advertising - education or emotion promotion? N Engl J Med. 2002Feb 14;346(7): 524-526
179. Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: Is the information good enough?. BMJ. 1999 January 30; 318: 318-322.
180. United Nations Global Compact Website. <http://www.unglobalcompact.org/Issues/human_rights/>

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