

Direct-to-Consumer Advertising for Prescription Drugs in Canada: Beyond Good or Evil

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Canadians have always had a hard time reconciling health and mercantilism. The publicly-funded system is, in part, responsible for nourishing this collective position, as Canadians rarely have to pay physicians and hospitals directly for the health care and services they receive. Direct-to-Consumer-Advertising (DTCA) is a particularly controversial issue for Canadians, as it not only involves commercial interests in health, but also allows for the appealing possibility of greater involvement for patients in decisions related to their health.¹

DTCA for prescription drugs is, in principle, forbidden in Canada. Pharmaceutical companies are limited to aiming their advertisement solely to health professionals. However, discussion surrounding the DTCA issue remains relevant, as the federal government has indicated its interest in revising the *Food and Drug Act*. Key changes with respect to the advertising of health care products are being seriously considered, notably regarding the introduction of DTCA for prescription drugs.²

Even though the legislation restricts most DTCA, the truth is that Canadians, whether they want to be or not, are aware of it. The current loopholes in Canadian legislation and policies, combined with the fact that advertising from the United States reaches Canada via magazines, television and the Internet, make DTCA an already-existing reality for Canadians³. Therefore, in this article I propose stepping away from the traditional binary debate about whether DTCA is good or not in order to focus on some practical issues and solutions. I will first discuss the legislation and policies surrounding DTCA in Canada. Secondly, I will

underline the lack of involvement by certain key actors in the debate. Finally, I will propose some potential solutions (should DTCA be further implemented in Canada) that would notably provide for greater involvement of these actors.

The Status of DTCA Under Canadian Law

The responsibility for interpreting and enforcing drug-advertising regulations lies with Health Canada. It seems that Canada, through current Canadian law on the subject, has put its foot in the door with respect to DTCA, but now doesn't know if it should step in or slam the door shut again. While DTCA is allowed for non-prescription drugs, it is, in principle, restricted for prescription drugs.⁴ The Canadian *Food and Drugs Act* mentions that, "No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventive or cure for any of the diseases, disorders or abnormal physical states [...]"⁵ The Act defines advertisement as including any representation by any means whatsoever for the purpose of directly or indirectly promoting the sale or disposal of any food, drug, cosmetic or device.⁶

Whereas the applicable regulation seems quite broad on the definition of advertisement, a policy statement made by Health Canada in 1996 indicated a distinction between advertising and "information dissemination".⁷ This statement had the impact of allowing "help-seeking" advertisement, which describes the condition the drug treats, but not



the name, price, or quantity.⁸ As well, “reminder” advertisement, which provides the name, price, or quantity of the drug without stating its use, is permitted in Canada.⁹ The type of advertisement that is presently not allowed in Canada is that which links both categories of information; that is, the products’ names and their specific therapeutic claims. This last type is called “product claim” and is permitted in the United States.

However, the current capacity of Health Canada to effectively restrict “real advertising” remains uncertain. Various actors have expressed serious doubts about the ability of Health Canada to deal with the “offenders”.¹⁰ As an illustration, it took Health Canada six months to inform Wyeth-Ayerst Canada of its contravention of the Food and Drug Regulations. Wyeth-Ayerst astutely aired branded television advertisements (ads) for a birth control pill and, a few weeks later, aired unbranded ads with the same actors. Although this tactic could appear *prima facie* to be in accord with Health Canada’s policy statement, a notice of violation was sent to the drug company.¹¹ In another case involving Glaxo Wellcome (now GlaxoSmith-Kline), it took seven weeks after its first ad was aired for Health Canada to intervene.¹² One explanation to the lack of efficiency might be that, since “official” advertisement is not permitted, Health Canada remains relatively ineffectively equipped to deal with DTCA issues. This is particularly obvious when considered in light of the means available to the U.S. Food and Drug Administration (FDA).¹³

Is the Pharmaceutical Industry the Only Party Involved?

The pros and cons of DTCA have been extensively discussed by various actors. Most notably, opponents to DTCA argue that it can mislead patients, stimulate inappropriate and unnecessary prescriptions of drugs, and promote new drugs for which certain adverse effects remain unknown. On the other hand, its proponents claim that DTCA can educate and empower patients, improve compliance with treatment, and encourage earlier diagnosis of medical conditions.

Beyond this binary debate, for which convincing arguments and supporting data can be found on both sides, one astonishing fact remains: responsibilities of key actors, such as physicians and the government institutions, are often neglected. The focus is almost exclusively on the pharmaceutical industry.

No surprisingly, people are quite quick to blame the pharmaceutical industry. The David-versus-Goliath parallel may be quite tempting for some and it remains relatively easy to

put the responsibility of many problems on this industrial giant. Even though the pharmaceutical industry is far from exempt from some claims, its mandate has the advantage of being clear: create profit and wealth for shareholders. Are the mandates of the other actors quite so clear?

There are some examples that illustrate such a discourse. For instance, the information that advertising stimulates inappropriate and unnecessary pre-

scriptions of drugs is often cited to advocate against drug advertising to consumers. Indeed, many studies have demonstrated that there is a significant link between prescribed drugs and advertisements.¹⁴ This influence exists whether the advertising is directed at health professionals or at consumers.¹⁵ However, are the pharmaceutical companies the only ones to blame for such results? Should medical professionals not be more aware of such an influence on their practice? Since physicians are already influenced by the advertising directed at them (including other promotional activities such as free samples, financed conferences, information sessions, colloquia, etc.), to what extent should Direct-to-Consumer advertising be restricted, due to its potential influence on physicians?

As another example, the argument that the pharmaceutical industry mainly promotes new drugs for which eventual effects are difficult to predict is often cited. The industry has an obvious “business” interest in promoting new drugs that are still under patent protection, thus benefiting from lucrative market exclusivity. Basically, the pharmaceutical companies want to promote their products, maximize profits while they are alone in the market and create brand loyalty for the time when the product ceases to benefit from patent

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protection. However, isn't one of Health Canada's chief roles to approve products after making sure they are safe? Can the population presume that a Health Canada approval means that adequate evaluation has been done with respect to drugs that are available to the public? If new drugs represent a danger, shouldn't the evaluation procedure, as well as adverse event follow-up processes, be reinforced? Shouldn't physicians also be more cautious when prescribing new drugs?

But in the DTCA debate, the questions mentioned above are rarely answered or even discussed. The role of physicians and the government is an important part of the debate related to DTCA and needs to be addressed. Otherwise, the debate focuses almost exclusively on the good or the evil that can result from DTCA. This approach is *prima facie* biased and excludes from relevant consideration a practice that, in fact, already exists in Canada. Accordingly, in the next section, I will focus on how the further involvement of physicians and the government could make DTCA a safer practice.

Possible Options for a Canadian Solution to DTCA

Any appropriate DTCA solution should inevitably have the protection of patients/consumers as its priority. The choice of strict regulation and policy appears inevitable, as the issue of DTCA raises many concerns; only the assurance of strong regulation would be acceptable to Canadians. Since I have underlined that the responsibility of the government and physicians has often been underestimated in the previous section, I propose solutions that give a greater role to these actors.

Health Canada

Mandatory pre-clearance of drug advertising may represent a good way for Health Canada to control standards for DTCA.¹⁶ In order to decide on what information ads should contain, Canada could explore the U.S. experience. For instance, the Food and Drug Administration (FDA) has mentioned in different guidelines that a "fair balance" of information be provided to consumers.¹⁷ This notion refers to a balance of information about effectiveness versus information about risks. Canada may also apply the standard imposed by the Supreme Court of Canada concerning information that should be given to a patient before consenting to certain types of care.¹⁸ This standard requires that physi-

cians provide information relating to "material, special or unusual risks". In broad strokes, such a standard imposes the disclosure of risks that are common and significant, as well as those that are rare but serious (for example, paralysis or death).¹⁹ Even though this standard would require adaptation to the reality of television advertising,²⁰ it could also provide a good indication of what information should be given to consumers via television ads.

Another advantage of mandatory pre-clearance would be the possibility for Health Canada to require a mention of approval in ads that successfully make it through the process. Obviously, there would have to be mention of the limits of what such approval entails, so that patients clearly understand the role of Health Canada. With such a mention, people would be able to distinguish the Canadian ads from their American counterparts. This would also indicate which drugs are available in Canada.

To relieve Health Canada of the economic burden that a pre-clearance service may represent, this service could be financed by the pharmaceutical companies. To that end, a fee for submitting an ad for pre-clearance could be imposed. In Québec, such an approach already exists for pharmaceutical companies wishing to submit a research protocol for approval by Research Ethics Committees.²¹

Physicians

The fact that many studies have indicated that advertisement has an impact on prescribing behaviour²² makes it clear that part of the solution is to intervene with physicians directly. With the explosion of drugs and drug therapy options, it has arguably become more and more difficult for physicians to adequately keep pace with all the available information. For many physicians, a significant part of their continuing education in pharmacology is provided by various activities organized by the pharmaceutical industry.²³ Exposure to informative and unbiased assessments of drug therapies can thus be limited. Since physicians have the ultimate power of prescribing a drug or not, finding ways to maintain and improve their prescribing behaviour is essential.

DTCA will put more pressure on physicians to keep up with drug information. Based on an FDA survey, advertising encourages patients to obtain more health information from physicians and pharmacists.²⁴ This additional source of pressure is a good thing as long as physicians are adequately prepared to face it. The argument too often put forth that



medical professionals are too busy to adequately discuss health issues with their patients is not acceptable for ethical and deontological reasons. The primary concern of physicians must at all times remain the well-being of their patients and their professional liability can be engaged for not doing so. Thus, physicians need to be prepared, and if their education on drugs is lacking, part of the solution lies in improving their knowledge.

As a means to improve physicians' education about drugs, Canadian policymakers should work towards increasing the flow of non-commercial research. In addition, medical schools should strengthen the pharmaceutical component of medical education and strategies should be developed and implemented to further encourage continuing education from non-partisan sources. Another interesting means of tackling this issue would be to consider ways of promoting greater cooperation among physicians and clinical pharmacists. This idea was proposed at the National Health Policy Forum in April 1998.²⁵ Data indicates that enhancing communication between physicians and pharmacists improves prescribing practices.²⁶ This strategy would have the noticeable benefit of further involving the pharmacist, a health practitioner whose role is often neglected in health care and who possesses a considerable amount of knowledge in drugs. The possibility of sharing more "neutral" information on drugs would consequently be greatly enhanced.

Undue influence in prescribing patterns needs to be further addressed by the medical community. This issue is currently overlooked in Canada and physicians' codes of conduct concerning what conduct is expected from physicians towards the pharmaceutical industry vary among Canadian provinces. Guidelines must be created and, with that regard, the Canadian Medical Association (CMA)²⁷ plays an important role, as it provides standards for the practice of the medical profession at a pan-Canadian level. In 2001, the CMA updated its general guidelines regarding the interaction between physicians and the pharmaceutical industry. Nevertheless, these guidelines do not directly tackle the issue of undue influence in prescribing behaviours.²⁸ The Canadian Medical Protective Association (CMPA) would also likely

be an important actor to involve due to its influence on the practice of medicine in Canada and its role in prevention with respect to practices that could have legal implications. Providing guidelines would have the important benefit of highlighting the existence of the issue of the pharmaceutical industry's influence over prescribing behaviour and of improving awareness amongst those for whom the guidelines are intended.

The solutions discussed in this section are some of the options that could be chosen for implementation with respect to DTCA in Canada. Many other options are also available, but I chose to focus on the ones above, as they address the roles of oft-neglected actors in the DTCA issue.

In this article, I have discussed the status of DTCA under Canadian law and policies. Whereas DTCA is restricted in principle, it is nevertheless a reality for Canadians as a result of certain loopholes in the law and given widespread access to U.S. media. Thus, there is great need for Canadians to address DTCA as a practical issue. In the debate related to consumer advertising, one can see that the pharmaceutical industry is often an easy target for blame, leading to an underestimation of the responsibility that other important actors, such as physicians and the government, should have. Consequently, I propose solutions concerning DTCA that could promote greater involvement of these actors; that is, mandatory pre-clearance for consumer advertising and improvement of physician drug education, including the possible influence that the pharmaceutical industry could have on a physician's practice.

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1. On the desire of patients to get more information and be more involved in health care, see for example Rhonda R. Shirreff, "For Them to Know and You to Find Out: Challenging Restrictions on Direct-to-Consumer Advertising of Contraceptive Drugs and Devices" (2000) 58 U.T. Fac. L. Rev. 121 [*Shirreff*]; R.A



- Van Der Zwart, “Advantages of Direct-to-Consumer Advertising of Prescription Drugs Out-weigh Disadvantages” *The Decision Group*, online: The Decision Group <www.thedecisiongroup.nl>; Jennifer L. Gold, “Paternalistic or Protective? Freedom of Expression and Direct-to Consumer Drug Advertising Policy in Canada” (2003) 11 Health L. Rev. 30 [Gold].
2. Most recently, Health Canada has conducted consultations with, among others, the industry, academia and consumers about advertising of health products. DTCA was among the topics discussed. No agreement on whether Canada should go forward with such advertisement practices was reached during these consultations. The report on these consultations is available online at: <www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/lr_advertising_report_e.html>.
 3. 53% of Canadians think that prescription drug advertising is legal, see “Ipsos-Reid Survey Shows Strong Public Support for Direct-to-Consumer Advertising of Prescription Medications” *Canada NewsWire* (31 January 2002), online: Canada NewsWire <<http://www1.newswire.ca>>. This is probably due to the fact that Canadians have such easy access to American media.
 4. Some authors have argued that DTCA would not resist a constitutional challenge on the grounds that it represents a violation of the guaranteed right to freedom of expression under section 2 (b) of the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c.11. See for example Elizabeth L. McNaughton & Christopher. M. Goodridge, “The Canadian Approach to Freedom of Expression and the Regulation of Food and Drug Advertising” (2003) 58 Food Drug L. J. 521; Gold, *supra* note 1; Shirreff, *supra* note 1.
 5. R.S.C. 1985, c. F-27, s. 3 (1).
 6. *Ibid*, s. 2.
 7. Health Canada, *The Distinction Between Advertising and Other Activities*, (Policy) (Health Products and Food Branch, 1996), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/actv_promo_vs_info_e.pdf>.
 8. See David M. Gardner *et al.* “Direct-to-Consumer prescribing drug advertising in Canada: Permission by default?” (2003) 169 (5) Can. Med. Assoc. J 425; Gold, *supra* note 1.
 9. *Food and Drug Regulations*, C.R.C., c.870, s. c. 01.044. Advertising for Viagra is an example of a “reminder” advertisement.
 10. See for example Ann Silversides, “Direct-to-consumer prescription drugs ads getting bolder” (2001) 165(4) CMAJ 462 [Silversides]; Barbara Mintzes *et al.*, *An assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines (DTCA) – Executive Summary*, Center for Health Services and Policy Research (1 February 2002); Barbara Mintzes & Rosanna Baraldi, “Direct-to-Consumer Prescription Drug Advertising: When Public Health Is No Longer A Priority”, online: <www.whp-apsf.ca/en/documents/dtca_priority.html> [Mintzes].
 11. See Silversides, *ibid* for the details about this case.
 12. See the details in *ibid*. After such practices had occurred, Health Canada specifically mentioned in another policy statement that prohibition of advertising applies when consumers can easily link two announcements and the message contained in these announcements. Health Canada, *Advertising Campaigns of Branded and Unbranded Messages*, (Policy Statement) (November 2000).
 13. See U.S., *Statement before the Senate Special Committee on Aging*, (Washington D.C.: 2003) (Janet Woodcock – Director for the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration), available online: <www.fda.gov> [Woodcock]. Examples of warning letters are available on the website.
 14. See *infra* note 22. It should be mentioned that the influence on physicians might be more acute in the U.S., where the managed care market and physicians may be more influenced by their clientele.
 15. See for example National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising, 2000* (research report) (Washington: NIHCM Foundation, 2001), available online: NIHCM Foundation <www.nihcm.org>.
 16. This option has been proposed by certain actors. See for example Silversides, *supra* note 10.
 17. See documents available on the FDA’s website, <www.fda.gov>. For example, see Center for Devices and Radiological Health and FDA, *Draft Guidance for Industry and FDA, Consumer-Directed Broadcast Advertising of Restricted Devices*, (Draft Guidance), 2004, available online: FDA <www.fda.gov>.
 18. *Reibl v. Hughes*, [1980] 2 R.C.S 880; *Hopp v. Lepp*, [1980] 2 R.C.S. Also, see the court’s interpretation of “material” and “unusual or special” risks in *White v.*



- Turner*, (1981), 120 D.L.R. (3d) 269, 31 O.R. (2d) 773, 15 C.C.L.T. 81 (H.C.), aff'd (1982) 47 O.R. (2D) 764, 12 D.L.R.. (4TH) 319. For a comprehensive discussion on such a standard in health care, see Bernard M. Dickens, "Informed Consent" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy* (Butterworths, 2002) at 129 [Dickens].
19. See *Dickens*, *ibid.* at 141.
 20. The U.S. experience is interesting in that respect. Considering that ads are usually advertised in a short period of time, mentioning all the relevant information became a difficult task. Some advertisers were able to avoid this difficulty by providing a "sheet summary" at the end of the ad containing all the risks that required mentioning. This summary was almost unreadable for consumers. The FDA later changed its requirement by imposing that a "fair balance" of information should be provided to consumers. Greater detail on how the FDA has interpreted such a standard is provided on the FDA's website, <<http://www.fda.gov>>. See more specifically *Woodcock*, *supra* note 13.
 21. Fees usually vary from \$1,000 to \$2,000 per protocol (for sponsored studies).
 22. See for example Michie Hunt, "*Direct-to-Consumer Advertising of Prescription Drugs*", (background paper for the National Health Policy Forum) (Washington: George Washington University, 1998), online: <http://www.nhpf.org/pdfs_bp/BP_DTC_4-98.pdf> [Hunt]; Center for Health Services and Policy Research, "When Drug Advertising Works Only Too Well", College of Health Disciplines, The University of British Columbia (November 2003), online: <<http://www.chspr.ubc.ca/chspr/pdf/chspr03-10S.pdf>>; *Woodcock*, *supra* note 13; Erica Johnson, "Time may be right for more drug ads: Health Canada", *CBC News* (27 February 2002), online: CBC <www.cbc.ca>; Canadian Health Coalition and Health Action International (HAI-Europe), "Direct-to-Consumer Prescription Drug Advertising Health Canada's Proposals for Legislative Change" (January 2004). For a moderate interpretation of this conclusion, see John R. Graham, "Advertising Prescription Drug Benefits American Patients", Fraser Institute (22 October 2003), available online Fraser Institute <www.fraserinstitute.ca>; National Institute for Health Care Management, *supra* note 15.
 23. J. Avorn, M. Chen & R. Hartley, "Scientific versus Commercial Sources of Influence on the Prescribing Behaviour of Physicians," (1992) 73 *American Journal of Medicine* 4; Health and Public Policy Committee, "Improving Medical Education", 146; *Mintzes*, *supra* note 10.
 24. See *Woodcock*, *supra* note 13. See also Carol Lewis, "The Impact of Direct-to-Consumer Advertising", *FDA Consumer magazine* (March-April 2003), online: FDA <www.fda.gov/fdac/features/2003/203_dtc.html>.
 25. National Health Policy Forum held at The George Washington University in April 1998. See *supra* note 22.
 26. In that study, 15-minute one-on-one consultations between physicians and pharmacists were organised. Pharmacists were going to the physicians' office. This strategy helps to provide neutral information about drugs and can be tailored to the physicians' needs. See *Hunt*, *supra* note 22.
 27. The association is the insurer that represents more than 95% of physicians across Canada. See the CMPA's website: <www.cmpa.org>.
 28. For instance, the CMA guidelines broadly mention that "The practising physician's primary obligation is to the patient. Relationships with industry are appropriate only insofar as they do not negatively affect the fiduciary nature of the patient-physician relationship" (general principle no 3). It is also indicated that "In any relationship between a physician who is not an employee of the pharmaceutical industry and the industry itself the physician should always maintain professional autonomy, independence and commitment to the scientific method." (general principle no 5). See Canadian Medical Association, *Physicians and the pharmaceutical industry*, (Policy) (update 2001), available online: CMA <www.cma.ca>.

