Colleen M. Flood* THE EVIDENTIARY BURDEN FOR OVERTURNING GOVERNMENT’S CHOICE OF REGULATORY INSTRUMENT: THE CASE OF DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS†

This article explores Michael Trebilcock’s claim that the federal government’s present restrictions on direct-to-consumer advertising (DTCA) of prescription drugs should not withstand a Charter challenge and his argument that a less intrusive, more nuanced regulatory regime could be implemented. The author explores the government’s challenges in mounting a s. 1 defence, analysing the role and limitations of social-science evidence and recognizing that both inherent methodological difficulties and the manner in which health services researchers frame their approach to policy questions are such that there may never be sufficiently robust evidence of competing policy alternatives for the government to use in a s. 1 challenge. The article then goes on to review the appropriate evidentiary hurdles the government should be required to satisfy to justify this kind of policy in the face of a constitutional challenge and raises the question of the courts’ competence to assess the policy ramifications of choosing to take a more stringent approach to review. The policy approaches to DTCA in other countries are explored to demonstrate that although alternative regulatory regimes exist in theory, the reality is that they are not enforced, and as such are not real alternatives to the current regime. The author explores what evidence is available regarding the advantages and disadvantages of DTCA and concludes that the latter outweigh the former, that the prospect of more nuanced regulations are theoretical only, and that Canada should maintain its present regulatory restrictions.

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1 Introduction

Planning how to reflect on Michael Trebilcock’s career has been tremendously difficult – he has influenced my thinking profoundly and has long

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now been a mentor and friend. How could I possibly do him justice? The answer is that I can’t, in one essay, and this entire volume must be read to illuminate the breadth of his enormous contributions to date and to hint at what is yet to come. My contribution is to reflect on a recent foray of Michael’s into the field of health law and policy. He ventured into this domain as an expert witness for CanWest MediaWorks in its constitutional challenge to Canada’s regulation of direct-to-consumer advertising (DTCA) of prescription drugs. In what follows I venture to explore our disagreement over the legitimacy of the present prohibitions on DTCA in order to muse about the role and limitations of social science evidence and the appropriate evidentiary hurdles a government should be required to satisfy to justify this kind of policy in the face of a constitutional challenge.

In December 2005, CanWest initiated a lawsuit against the federal government alleging that the prohibition of DTCA is an unjustified infringement of freedom of expression as guaranteed under s. 2(b) of the Canadian Charter of Rights and Freedoms. CanWest’s commercial interest in this challenge is based on the fact that the prohibition places the media company at a competitive disadvantage to comparable American firms because, unlike those firms, it cannot sell advertising space to pharmaceutical companies – an extremely lucrative endeavour. It is predicted that if the ban on DTCA were lifted in Canada, the pharmaceutical industry would spend approximately CAD$500 million in the first year. However, it is also estimated that lifting the ban would lead to at least CAD$1.1 billion in extra drug sales in that first year.

In his affidavit for the Ontario Superior Court, Michael drew upon his expertise in the choice of governing instruments and the design of regulatory policies for minimizing market failure, arguing that the current limits are a disproportionate response to the risks posed by DTCA. The CanWest Charter challenge was scheduled to be heard in Ontario’s Superior Court from 15–19 June 2009. However, the plaintiff was granted an indefinite adjournment, primarily because the company was said to be ‘teetering on the verge of bankruptcy’ and therefore unable

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to proceed with the litigation at that time. Although the CanWest litigation appears to have reached a (potentially temporary) standstill, the case nonetheless raises complex and difficult issues of ongoing relevance surrounding the use of social science evidence in Charter challenges, as well as in policy formation more broadly.

In what follows, I focus on the concerns arising from the use of social science evidence in litigation relating to policy choices in the health care system and in public health. In some cases, the courts have interpreted s. 1 of the Charter as requiring clear evidence from government in support of its policy choices, and clear evidence that less restrictive policies would not achieve the same objectives. In other cases, courts have deemed the relevant question to be whether government had a reasonable basis for its policy choices. My point is that on complex matters such as the regulation of DTCA, there will always be uncertainty as to whether government has hit upon the optimal solution. My concern is that if the courts take a stringent approach to s. 1 and require government to prove that the current regulatory scheme is optimal, government is surely destined to fail where the available social science evidence is weak because of inherent methodological difficulties that make it impossible to prove empirically the relative benefits of different policy approaches. Related to this is the issue of how health services researchers frame their approach to policy questions, which, as I discuss, is to assume that the status quo will prevail in the absence of evidence that an alternative has greater benefits, as opposed to assuming that the status quo must change unless there is clear evidence of the negative effects of alternative policies. This way of framing research questions means that there may never be sufficiently robust evidence of competing policy alternatives that a government could use in a s. 1 challenge where courts take a more stringent approach to the level of evidence required. In the DTCA case, this is particularly problematic because nearly all countries in the developed world have taken a similar approach to Canada’s in significantly restricting DTCA; how, then, can one empirically demonstrate the relative benefits of policy approaches that exist in theory but not in reality?

In this relatively short essay I also raise the question of the courts’ competence to assess the policy ramifications of choosing to take a more stringent approach to review. For example, in this specific case, are the courts sufficiently attuned to the public choice problems that might arise from

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5 Public choice theory is directed to the study of political science based upon economic principles. It accepts that politicians, in acting in their own self-interest, may not act in the public good. Their own self-interest may include the desire to be re-elected, to receive promotion and favour, etc. Some argue that those who explore governmental
removing the existing prohibitions and creating a more nuanced regulatory framework for DTCA? It does not seem that any jurisdiction has successfully negotiated the politics involved in regulating multinational drug companies and resolved the myriad public choice problems to arrive at a DTCA regime that – as Michael Trebilcock notes – will ‘maximize the potential benefits of DTCA while reducing the potential harm.’

II Direct to consumer advertising in Canada

Direct-to-consumer advertising of drugs refers to any unsolicited promotional endeavour to present information about pharmaceuticals to the public via popular media, including television and radio advertisements, newspaper and magazine ads, billboards, direct mailings, and advertising on the Internet. DTCA has been largely prohibited in Canada since 1949. The federal Food and Drugs Act broadly prohibits the advertising of prescription-only drugs to the public; the legislation also states that no person shall advertise any food, drug, cosmetic, or device to the general public as a treatment, preventative, or cure for any of the diseases, disorders, or abnormal physical states referred to in Schedule A – which includes a number of serious illnesses such as cancer, congestive heart failure, diabetes, and depression. Finally, the act prohibits deceptive or misleading advertising. Advertising is defined very broadly to include any representation by any means for the purpose of promotion – and thus is not limited to paid communication or to specific media.

 behaviour using public choice theory have a strongly pessimistic view of human nature (see, e.g., Daniel A. Farber & Philip P. Frickey, Law and Public Choice: A Critical Introduction (Chicago: University of Chicago Press, 1991). Others would say that public choice theory simply does not romanticize the role of government. Buchanan, credited with Tulloch as being one of the founders of public choice theory, says, ‘Public choice theory has been the avenue through which a romantic and illusory set of notions about the workings of governments and the behavior of persons who govern has been replaced by a set of notions that embody more scepticism about what governments can do and what governors will do, notions that are surely more consistent with the political reality that we may all observe around us.’ (James M. Buchanan, ‘Politics Without Romance: A Sketch of Positive Public Choice Theory and Its Normative Implications,’ in James M. Buchanan and Robert D. Tollison, eds., The Theory of Public Choice – II (Ann Arbor: The University of Michigan Press, 1984) at 11.).

7 Gregory A. Abel et al., ‘Direct-to-Consumer Advertising in Oncology’ (2006) 11 Oncologist 217 at 218 [Abel et al., ‘Direct-to-Consumer’]. The Internet is a growing source of DTCA; this may be problematic for nations in which DTCA is banned, as citizens are nonetheless exposed to online DTCA originating from other countries.
9 Ibid., Schedule F
10 Ibid. at s. 3(1).
11 Ibid. at s. 9(1).
Canada’s regulatory scheme, although frequently portrayed as a complete ban, does permit two types of pharmaceutical advertisements: ‘help seeking’ and ‘reminder’ ads. The first category does not permit mention of a specific brand of drug but, rather, allows advertising that describes a condition and suggests that viewers or readers who are experiencing certain symptoms ask their doctor about an unspecified treatment. For example, an advertisement might describe seasonal allergy symptoms – such as runny nose, sneezing, and itchy, watery eyes – and suggest that people experiencing these symptoms talk to their doctor.12 ‘Reminder’ ads – the second category – can mention the brand name but cannot contain health claims or indications of the product’s use. A Health Canada policy issued in 2000 on branded and unbranded ads clarified that ‘reminder ads’ are also permitted.13

Health Canada is the national regulatory authority for DTCA;14 however, actual review of ads for compliance with regulatory requirements is conducted by private or other agencies.15 Three organizations are of particular significance:

(1) RX&D – the national association representing Canada’s research-based pharmaceutical companies;
(2) Advertising Standards Canada (ASC) – an advertising industry association; and
(3) the Pharmaceutical Advertising Advisory Board (PAAB) – an independent review agency comprising multiple stakeholders.

RX&D de facto regulates advertising by requiring its members to adhere to its Code of Ethical Practices.16 ASC initially had the responsibility of reviewing non-prescription drug advertisements for compliance with regulations, which has expanded to include the review of prescription-drug DTCA.17 The PAAB similarly provides advisory opinions on whether

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pharmaceutical advertisements directed to health professionals and consumers comply with regulations.\textsuperscript{18}

Health Canada may employ a wide number of enforcement mechanisms for violations of the Food and Drug Act, including fines, injunctions, prosecution and imprisonment, forfeiture, public warning or advisory, and letters to trade and regulated parties.\textsuperscript{19} However, actual enforcement of the regulations appears to be almost non-existent – indicating that either self-regulation by the industry is largely working or enforcement is simply lax. No penalties have been imposed on any drug company for illegal advertising activities since 1978.\textsuperscript{20} Unlike the US Food and Drug Administration (FDA), Health Canada has no personnel dedicated to the enforcement of drug advertising regulations.\textsuperscript{21}

While DTCA is subject to strict regulatory limits in Canada and in most OECD countries, it is permitted in the United States and New Zealand. In the sections that follow, I explore the policy approaches to DTCA in these jurisdictions, as well as the recent proposal to liberalize DTCA in the European Union, in order to illustrate existing alternative policy options – and, thus, what evidence there is in existence suggesting that Canada that could take a less intrusive approach to regulating DTCA – and to reflect on whether there is a model for a regulatory regime that better balances the harms and benefits of DTCA, as advocated by Michael Trebilcock.

\section*{III DTCA in other jurisdictions}

\subsection*{A UNITED STATES}
American drug companies began to advertise their products in print in the 1980s and expanded to television and radio ads in 1997 with the loosening of FDA restrictions on content.\textsuperscript{22} The US media are now flooded with advertisements for drugs designed to treat a wide range of health issues. DTCA encouraging patients to consult their doctor about a particular drug represents 37 per cent of the total pharmaceutical advertising budget.\textsuperscript{23}

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\bibitem{18} Pharmaceutical Advertising Advisory Board, PAAB Homepage, online: PAAB <http://www.paab.ca/en/home/>.
\bibitem{19} Health Canada & Food Branch Inspectorate, Compliance and Enforcement Policy, version 2, POL-0001 (Ottawa: Health Canada, 2005).
\bibitem{21} Mintzes, Public Health Implications, supra note 13 at 10.
\bibitem{23} David C. Vladeck, ‘The Difficult Case of Direct-to-Consumer Drug Advertising’ (2007) 41 Loy.L.A.L.Rev. 259 at 269 n.58 [Vladeck, ‘Difficult’]. In addition to these marketing tactics, pharmaceutical companies sometimes also engage in more covert marketing
A 2008 study published by researchers at York University found that the US pharmaceutical industry spends almost twice as much on advertising as it spends on research and development; the authors calculated that US$57.5 billion was spent on promotional activities in 2004 alone.24

The FDA regulates the manufacture, sale, and distribution of medical devices — including pharmaceuticals — under the authority of the federal Food, Drug and Cosmetic Act (FD&C Act).25 The FD&C Act’s regulations provide that the ads cannot be false or misleading and cannot omit material facts; furthermore, they must present a fair balance between benefit and risk information. For print DTCA, the regulations specify that the risks addressed in the drug’s approved labelling must also be disclosed; for broadcast DTCA, regulations require ads to disclose the most significant risks (the most serious and most common) that appear in the drug labelling and to make adequate provision for dissemination of the drug’s FDA-approved labelling in connection with the advertisement.26 In theory, this seems a reasonable approach that appropriately balances the benefits and harms, in line with the type of regulation Michael Trebilcock would prefer for Canada. Yet the dominant perception of drug information is as the ‘snake oil salesman of the information age.’27 Part of the problem in the United States appears to be an inability on the part of the FDA to review the growing number of advertisements and a lack of willingness to enforce the regulations vigorously.


26 Daniel Schultz, ‘FDA Oversight of Direct-to-Consumer Advertising of Medical Devices’ (statement before the Senate Special Committee on Aging, 17 September 2008), online: Food and Drug Administration <http://www.fda.gov/NewsEvents/Testimony/ucm096272.htm>. Although it is unclear which provisions apply to Internet advertising, which has not yet been classified as either broadcast or print, the FDA states that it will enforce its regulations against online ads. Timothy S. Hall, ‘The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet’ (2003) 7 DePaul J. Health Care L. 1 at 7–8.

Following the US Government Accountability Office’s November 2006 report calling for improvement in the FDA’s oversight of DTCA,28 s. 503B was added to the FD&C Act in February 2008. This new section gives the FDA secretary the authority to require drug companies to submit any television advertisement for a drug for review ‘not later than 45 days before dissemination of the television advertisement.’29 In conducting this review, the secretary may make recommendations on changes to information included in the drug label but has the authority to require change only in two special circumstances: if the advertisement is lacking a specific disclosure, and thereby poses a ‘serious risk,’ or if the drug has been FDA approved for less than two years and the advertisement does not disclose the date of approval.30 In terms of DTCA review, the FDA has expressed concern about its ability to assess the ads in a timely fashion.31 Because of its limited authority to require change and its limited ability to conduct its reviews, the FDA seems – to put it bluntly—a toothless regulatory tiger.

Prima facie the United States provides a model for nuanced regulation of DTCA, along the lines Trebilcock would advocate, that balances harms and benefits32 – but that regulation is not enforced. The US context provides little hope that the politics involved with regulating multinational corporations can be easily surmounted: the FDA has little real power to regulate the content and nature of advertisements, and multinational drug companies seem largely successful in preventing further regulatory intrusion and in protecting taxation subsidies, at least to date. To underscore the point, alternative regulatory regimes may exist in theory, but if the reality is that they are not enforced, should they be considered by courts as real alternatives to a current regulatory regime selected by the government?

B NEW ZEALAND

DTCA is permitted in one other developed country apart from the United States – Michael Trebilcock’s birthplace, New Zealand. The DTCA regulatory scheme in New Zealand is even more liberal than the US model,
relying primarily upon industry self-regulation. However, as I discuss further below, the context of New Zealand’s system, particularly the rigorous review of prescription drugs within the universal public health plan, dilutes the impact of a liberal DTCA regime.33

Drug advertisements in New Zealand are regulated by the Medicines Act 1981.34 Standards governing content are generally more permissive than those in the United States; for example, the legislation does not require the inclusion of risk information in the audio portion of television DTCA, and this information therefore usually appears briefly as text at the end of the advertisement. Advertisements are pre-screened by the Therapeutic Advertising Pre-vetting System (TAPS). However, the Ministry of Health does not conduct regular monitoring of either the TAPS or advertisement compliance with legislation. Although individuals may complain if they feel an advertisement violates the regulations, the ministry has never used its authority to prosecute for a breach.35

The other entity responsible for regulating pharmaceutical advertisements is the Advertising Standards Authority (ASA), which developed its Code for Therapeutic Advertising in 1999.36 Individuals may complain to the ASA if they feel the code has been breached. The ASA Complaints Board (ASCB) – made up of four public representatives and four members of the advertising industry – adjudicates the claims and renders decisions that are only voluntarily binding. These decisions typically request that the offending ads be modified or withdrawn. Furthermore, the ASCB does not receive government funding but, rather, receives resources from pharmaceutical company levies in a ‘user pays’ system.37 Given this funding source, and the fact that members of the advertising industry make up 50 per cent of the board, its independence and impartiality are questionable.

33 Trebilcock suggests that the issue of public or private insurance should be divorced from the DTCA issue (in that public insurers do not have to pay for all drugs if they do not wish to do so); however, the issue of public and/or private insurance and the mechanisms for paying and negotiating the purchase of drugs for the public plan are likely to have a significant effect on the extent and effect of DTCA. Moreover, the difficulty of developing health care systems and their own internal trajectories make it unrealistic to suggest merely that one could always reform the health care system if necessary.
36 Toop et al., ibid. at 29.
37 Ibid.
Although New Zealand has possibly the most liberal DTCA regulatory regime in the Western world, this system nonetheless operates in a unique policy climate. In particular, New Zealand, unlike Canada, has a universal public payment scheme for prescription drugs, and rigorous cost-effectiveness evaluations are conducted by an arm’s-length agency, the Pharmaceutical Management Agency (PHARMAC). Thus, prescription drugs may be approved for distribution in New Zealand, but there is, in effect, a very small (private) market unless PHARMAC approves the drug for inclusion in the public formulary. In Canada, by contrast, there is a significant private market for prescription drugs.

PHARMAC is responsible for managing the Pharmaceutical Schedule – the list of government-subsidized medicines – and negotiating the price of prescription drugs with drug companies. 38 This agency is unique among public formularies in the developed world, as it works within a capped budget, and thus requires explicit trade-offs between drugs and their associated prices, benefits, and risks. PHARMAC does not regulate prices directly but stimulates price competition through processes such as tendering for sole-source supply (requesting quotes) and reference pricing (applying the same subsidy to all drugs with the same or similar effects). 39 All new products added to the formulary are subject to contracts stipulating that if predicted use thresholds are passed, the company must compensate the public plan (thus diminishing the incentive to advertise, as increased uptake beyond the threshold will not increase profits). An environment in which drug companies have only a relatively modest ability to penetrate a market dominated by a public payer likely significantly dilutes the effect of DTCA on drug use (and, thus, the consequent benefits and harms to patients) and price increases.

Politically, allowing DTCA in New Zealand may also be something of a gesture to industry’s concerns over PHARMAC’s strong influence over both price and use of prescription drugs, producing a net benefit from a policy perspective. In other words, throwing the industry a bone in terms of DTCA may allow New Zealand to achieve other critical objectives: keeping the total cost of prescription drug spending within a capped budget and negotiating reduced prices.

C EUROPEAN UNION
Although the European Union largely forbids DTCA, possible deregulation is an ongoing part of the EU health care policy agenda. In July 2001, the European Commission announced a proposal to amend the law to allow a five-year trial period for prescription drug advertising for three chronic conditions – HIV/AIDS, diabetes, and asthma. This proposal provoked considerable debate in Europe. Experts predicted an unsustainable spiral of health care spending, with potentially devastating public health consequences, resulting from the strain placed on state-funded health systems. In October 2002, an overwhelming majority of members of the European Parliament voted against the reform proposal. For the past two years, however, DTCA has been back at the forefront of EU policy debates, and throughout 2008 the European Commission held public consultations on a proposal that would allow drug companies to provide ‘information’ about prescription drugs to patients through the media.

D CONCLUSION
Michael Trebilcock advocates a more nuanced approach to regulating DTCA than that presently allowed in Canada – one that would better capture what he views as the benefits of DTCA while minimizing the harms. His argument feeds into the s. 1 analysis (discussed further below) that there is a way of achieving the government’s objectives related to advertising of drugs that is less intrusive on the right to free speech. However, a review of countries that permit broad DTCA shows a failure of regulatory enforcement that must at least be explored; if the political context is such that regulation will not be enforced, then it cannot be claimed that a more nuanced regulatory scheme would improve consumer welfare overall. Furthermore, digging deeper into the systems that permit DTCA in these countries reveals that all is not quite what it may seem. For example, while New Zealand appears to take a liberal approach to DTCA, it does so in the context of a rigorous single-payer approach in a universal insurance scheme for prescription drugs (which Canada does not have) and a commitment to negotiating deep discounts on prices for new prescription drugs – a process that also does not exist in Canada and is unlikely to come into existence, given the importance of the pharmaceutical industry in Quebec. A quick comparative review also reveals that there are significant pressures

40 Toop et al., Health or Profit, supra note 35 at 19.
41 The vote was 494 against to forty-two in favour: ibid. at 40.
42 Critics of this proposal feel that it is merely DTCA under another name: ‘Direct to Consumer Advertising under a Different Name’ (2008) 371 Lancet 1972 at 1972.
to review restrictions on DTCA, for example in European countries.

Tension arises from the desire of pharmaceutical companies to improve their profits through increasing use of their products and the ability of publicly funded health care systems to absorb these additional costs, particularly where there are concerns about the marginal nature of benefits associated with such extra expenditures.

IV Overview of a Charter challenge

In this section I provide a brief overview of Charter challenges so as to facilitate the discussion of evidentiary burden that follows. First, the claimant must prove that government breached one of her Charter rights. In freedom of expression claims, courts employ a two-step test. First, the Court asks whether the plaintiff’s activity falls within the sphere of conduct protected by the guarantee. In the CanWest challenge, the Court would ask whether DTCA could be classified as an attempt to convey meaning. In the second stage of the test, the Court inquires whether the purpose or effect of the government action – in this case, the regulation of DTCA – was to restrict freedom of expression. Once the plaintiff has established a violation of her Charter rights, the onus shifts to the government to justify its action, pursuant to s. 1. In assessing whether the government has discharged this burden, courts employ the test set out in R. v. Oakes. Under this test, courts ask whether the government’s legislative objective is pressing and substantial, whether there is a rational connection between this objective and the legislation, whether the means chosen to achieve this objective minimally impair the right in question, and, finally, whether there is proportionality between the limits on the right and the objective in question. The Oakes test was initially conceived as a ‘stringent standard of justification’ – one in which ‘rights are the norm and are of presumptive importance,’ and cannot be limited unless ‘the exceptional criteria which justify their being limited’ are met. However, in some cases courts have exhibited

45 Under s. 1 of the Charter, the protected rights and freedoms may be subject to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.
a very high degree of deference to governmental decisions, requiring little justification for a rights violation.48

The Supreme Court of Canada addressed similar issues to the DTCA claim – freedom of expression in advertising versus the government’s interest in protecting the public’s health – in three previous cases. The first of these was Rocket v. Royal College of Dental Surgeons of Ontario,49 in which the appellants successfully claimed that extensive restrictions on dentists’ advertisements violated their freedom of expression and that these violations were not saved by s. 1. The other two cases related to restrictions on tobacco advertising. In the first of these, RJR-MacDonald v. Canada (A.G.), Canada’s major tobacco companies successfully challenged the 1989 federal Tobacco Products Control Act (TPCA), which prohibited all forms of tobacco advertising, restricted other forms of promotional activities, and required health warnings on tobacco product packaging.50 Following this case, the federal government enacted new legislation, the Tobacco Act, which was the subject of another Charter challenge in 2007 in Canada (A.G.) v. JTI-MacDonald Corp.51 This legislation, which was largely upheld by the Court, banned lifestyle advertising and promotion, advertising appealing to young persons, and false or misleading advertising but permitted information and brand preference advertising. Because of the similar issues they raise, these cases provide some indication of how courts may respond to a DTCA Charter challenge.

The greatest challenge for government in mounting a s. 1 defence will be in defending the DTCA provisions as minimally impairing freedom of expression; this will require the government to provide evidence about the relative effectiveness of possible alternative regulatory regimes. In RJR-MacDonald, the majority of the Court held that the rights infringement was not justified, as the legislation was not minimally impairing. Although the decision acknowledged the importance of deference, the majority was critical of the government’s failure to introduce evidence relating to whether less intrusive regulations would fail to achieve its public health objectives.52 Accordingly, when the amended tobacco legislation reached the courts some twelve years later, the government had,

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51 2007 SCC 30 [JTI-MacDonald].
unsurprisingly, greatly improved the evidentiary basis for its decision and noted the existence of similar or equivalent legislation existing in almost every other developed country. In a DTCA case, government would similarly have to amass evidence defending its policy choice, which might be difficult given the methodological difficulties relating to research of alternative policy regimes (i.e., less intrusive means) that largely exist only in theory (or, if in existence, involve regulation that is not consistently enforced).

With respect to the evidence base available, the government’s current DTCA policy has been the subject of recent scrutiny from both Health Canada and the House of Commons Standing Committee on Health. Their reports emphasize that DTCA will increase costs but will not result in accurate, unbiased information being passed to patients or the public. But evidence of this nature is unlikely, on its own, to be persuasive. The government must also adduce evidence speaking to less impairing alternatives. And this is where there are some significant barriers because of the different ways in which researchers and courts approach potential policy options. In general, health services and policy researchers will frame their research questions from the position that one should not move from the status quo (in this case, the ban on DTCA) unless there is evidence that an alternative regime would have better outcomes; in contrast, the Court in a s. 1 analysis will set aside the status quo (namely, the offending legislation) unless there is evidence that this is the least intrusive means of achieving the policy goal. Compiling this type of evidence is difficult, short of changing the law in certain areas and comparing those test populations to the rest of Canada. A study of this type would be rife with problems – for example, the feasibility of controlling what advertisements certain segments of the population are exposed to.

Given the difficulties of conducting research trials, the government will likely have to resort more generally to the experience of other jurisdictions in justifying its restrictions on DTCA. There is a catch-22 here: the mere fact that most countries limit DTCA may not be sufficient to establish minimal impairment, but the absence of other countries allowing DTCA makes it difficult to build a strong evidence base with respect to the relative merits and problems of alternative policy approaches.

53 For example, the JTI-MacDonald trial decision, [2003] R.J.Q. 181 at para. 171–6, noted that following RJR-MacDonald, the minister of health had a team of fifty people assembled to develop a comprehensive anti-smoking strategy which resulted in the submission of 3000 comments and eighty-five papers, the preparation of a report representing the minister’s range of options, and the submission of four options to cabinet.

54 See notes 19 and 20 supra.
It also bears considering that if the courts, in applying s. 1, require a stringent test of clear evidence substantiating governmental policy choices, then Canadian governments may be hindered in their ability to develop innovative policy or to respond to emerging risks to safety for which there is limited evidence at the time of the policy response. While other countries will be able to implement policies on the basis of this preliminary evidence or to respond to emerging issues (e.g., in 1987, the accumulating evidence of the impact of advertising on tobacco addiction), Canadian governments may be relegated to waiting for evidence on policy alternatives to emerge from these jurisdictions, in order to more fully establish that Canada has opted for the least intrusive means to achieve a particular policy objective.

In the tobacco cases, the Court showed some deference to government at the proportionality stage of the *Oakes* analysis. I pause here to touch on the similarities, if any, between the market for prescription drugs and the market for tobacco and, further, how prescription drugs vary significantly in two important respects from markets for other kinds of goods and services. First, like tobacco use but unlike the use or consumption of many other products, the consumption of pharmaceuticals carries inherent risks. However, the harms arising from DTCA of prescription drugs are not as clear-cut as those arising from tobacco advertising. DTCA will spur greater consumption of pharmaceuticals, which can result, for example, in their use in untested populations – the elderly, those with co-morbidities, pregnant women, and children. But unlike cigarettes, not every prescription drug has the same level of risk associated with it – and, of course, many have significant benefits. Therefore, as Trebilcock points out, in some circumstances advertising that spurs more consumption may be beneficial. But setting aside the requirements of a Charter analysis and simply returning to the question of what is good policy, demonstrating that in a (small) number of cases DTCA could be beneficial is not sufficient. To develop sound public policy, one would instead have to inquire whether the overall benefits of DTCA outweigh the costs – using the best evidence available to calculate the benefits and costs.

The comparative vulnerability of the public in the smoking cases versus those exposed to DTCA may also make it difficult to establish proportionality, particularly in the case of prescription drug advertising. In the case of tobacco products, government may have a stronger argument for a more rigorous and widespread ban, given that a member of the public may be persuaded by those advertisements to take up smoking. In contrast, a patient who views an advertisement for a particular pharmaceutical still requires a doctor’s prescription to obtain the drug. However, this view of physicians as protective and fully informed agents runs contrary to evidence that physicians are heavily influenced in their prescribing habits by the demands of patients and that rates of prescribing vary
with levels of investment in marketing campaigns (see the discussion in Part VI below). Clearly, of course, if DTCA had no influence over the actual amount or number of drugs consumed, then companies would not spend significant sums on DTCA. A physician may know that a drug is of marginal or questionable benefit to a patient but still prescribe it for both social and cultural reasons (patient expectations, the desire to do something in response to an expressed need, etc.) and economic reasons.

Related to this latter point is the second distinction between the market for prescription drugs and the market for other products, namely moral hazard arising from the presence of public or private health insurance. Physicians often do not have a financial incentive to consider the costs of what they prescribe, thanks to the presence of insurance, and thus do not factor into their prescribing the relative costs and benefits of different drugs. Physicians have few incentives to do anything but cede to a patient’s demand for a particular drug – particularly in a fee-for-service payment system – provided there is not a significant clinical risk to the patient. Unless the physician’s expertise is meaningfully called upon, the patient remains vulnerable, and this argues in favour of deference to the government’s DTCA policy. In other words, if a physician categorically knows that a drug is not safe for a patient, then he or she will not prescribe it, but beyond that there is a large spectrum of effectiveness, ranging from not effective at all to curative. Neither physician nor patient has an incentive to be concerned about the costs associated with choices falling closer on the spectrum to marginal effectiveness. Trebilcock argues that this moral hazard problem is mitigated in Canada by the fact that out-of-pocket payments account for 20 per cent of total Canadian expenditures on prescription drugs. However, this is an average across all Canadians, and one cannot conclude that every Canadian faces a significant co-payment that will force him or her to weigh competing options efficiently. Some individuals (about 10 per cent) have no drug insurance, and thus pay large out-of-pocket


56 Trebilcock, ‘Testing the Limits,’ supra note 3 at 185.

57 A Health Canada report concludes that 90 per cent of Canadians have some coverage for routine expenditures. Fraser Institute data similarly indicate that 89 per cent of Canadians are protected against exposure to severe drug expenses, 9 per cent are partially protected, and 2 per cent are not protected at all. Valerie Paris & Elizabeth Docteur, Pharmaceutical Pricing and Reimbursement Policies in Canada (Paris: OECD, 2006) at 33.
amounts or go without prescription drugs; others have full coverage and pay very little.\textsuperscript{58} Furthermore, these co-payments do not necessarily correspond to the relative cost of the drugs, and so they are not an incentive to decrease the use of more expensive drugs (\textit{e.g.}, they are often flat co-payment fees).\textsuperscript{59}

\section*{V Social science evidence and the section 1 analysis}

Although it is clear that the onus is on the government to meet all elements of the \textit{Oakes} test, what is less apparent is the level of evidence required to discharge this burden. How should one deal with evidence that is weak not through any fault on the government’s part but because of impediments in research design and methodologies and confounding factors? As will be discussed in more detail in Part VI below, DTCA is one of those situations. The social science evidence regarding the health benefits and cost-effectiveness of DTCA is far from conclusive: it is clear that health care spending will likely increase in a liberal DTCA regime, but what is not clear is the impact (positive and negative) upon morbidity and mortality as a result of increased prescription drug use. A further unknown is how this cost–benefit analysis would be affected by different variations in a regulatory regime. In \textit{Oakes}, the Court suggested a high evidentiary burden\textsuperscript{60} that has proved problematic in cases relying on social science evidence because of the nature of the research and methodological problems – it is rare indeed that there are black-and-white answers to complex social problems. As Sujit Choudhry has noted, public policy is often ‘based on approximations and extrapolations from this available evidence, as well as inferences from comparative data, and, on occasion, educated guesses.’\textsuperscript{61}

\begin{footnotesize}
\textsuperscript{58} In 2000, about 29 per cent of private plans did not require any co-payment: ibid. at 32.

\textsuperscript{59} Some jurisdictions have implemented policies to correlate the cost of drugs with the patient’s out-of-pocket payment. For example, British Columbia employs reference-based pricing whereby only the lowest-cost medically equivalent drug will be covered. Heather Kent, ‘BC’s Reference-Based Pricing Stirs Controversy’ (2000) 162 Can.Med.Assoc.J. 1190.

\textsuperscript{60} \textit{Oakes}, supra note 46 at 138.

\textsuperscript{61} Sujit Choudhry, ‘Worse than \textit{Lochner}?’ in Colleen Flood, Lorne Sossin, & Kent Roach, eds., \textit{Access to Care, Access to Justice: The Legal Debate over Private Health Insurance in Canada} (Toronto: University of Toronto Press, 2005) 75 at 81. Also in this volume, Christopher Manfredi highlights several significant differences between policy making and the judicial system that complicate the blending of the two in the s. 1 analysis; he notes that while ‘the adversarial system is generally bipolar, depends on historical facts about events that transpired between disputing parties, and seeks to implement retrospective remedies,’ ‘policy formation is multi-polar, relies on social facts about ongoing phenomena, and seeks to regulate social relations prospectively.’ Christopher P. Manfredi, ‘\textit{Déjà vu} All Over Again: Chaoulli and the Limits of Judicial
In cases involving complex social science data, the s. 1 test can create a conflict between the demand for definitive proof to justify government’s policy choices and the reality of policy making in the face of incomplete knowledge and factual uncertainty, particularly where government is trying to prevent harms from occurring. In *RJR-MacDonald*, LaForest J. noted that requiring evidential certainty ‘could have the effect of paralysing the operation of government . . . it would not be possible to make difficult but sometimes necessary legislative choices.’ Furthermore, depending on how closely they scrutinize this evidence, courts run the risk of substituting their own policy choices for those of the legislature, rather than merely engaging in the interpretation of Charter rights. Moreover, without knowing the intricacies of the political context in which reform is occurring, courts may be too romantic with respect to the political feasibility of a more nuanced regulatory structure than currently exists.

Accordingly, in some cases involving complex social policies, the Supreme Court has shown flexibility in the standard of evidence required. In these cases, the Court has deemed the relevant question to be whether the government has a ‘reasonable basis’ for its policy choices. While this standard does not require definitive, scientific proof, an absence of evidence is also unacceptable – the government must have a factual basis for its decisions. The Court has called this approach the ‘reasonable apprehension of harm’ test. However, there has been disagreement over the boundary of the ‘reasonable apprehension of harm,’ particularly with respect to what inferences courts may draw to bridge the evidentiary gap. The decisions of the majority and the minority of the Supreme Court of Canada in *Chaoulli v. Quebec (A.G.)* illustrate these competing positions.

The minority in *Chaoulli*, who would have upheld the prohibition on private insurance, showed deference to Quebec’s position that ‘significant growth in the private health care system (which the appellants advocate) would inevitably damage the public system,’ concluding that ‘governments are entitled to act on a reasonable apprehension of risk of such damage.’ In reaching its decision, the minority was sensitive to both of the concerns mentioned above – the difficulty of providing...
proof in light of incomplete knowledge and factual uncertainty, and the appropriate role of the judiciary. With respect to the former, the minority said, ‘The first major evidentiary difficulty for the appellants is the lack of accurate data. The major studies concluded that the real picture concerning waiting lists in Canada is subject to contradictory evidence and conflicting claims.’\textsuperscript{68} Quoting the majority in \textit{R. v. Malmo-Levine}, the \textit{Chaoulli} minority also considered its role in reviewing governmental decisions: ‘Members of Parliament are elected to make these sorts of decisions, and have access to a broader range of information, more points of view, and more flexible investigative processes than courts do.’\textsuperscript{69} In contrast, in the face of this conflicting evidence, McLachlin C.J., writing for the majority, ‘clearly indicated which side of the debate [she] found more persuasive.’\textsuperscript{70} Instead of asking whether government had established a reasonable basis for its policy decision, the majority determined which side of the debate it found more persuasive and substituted its view for that of the legislature.

Because the ‘reasonable apprehension of harm’ test features prominently in the freedom of expression jurisprudence,\textsuperscript{71} a court hearing a DTCA challenge may invoke it to support the government’s justification of the ban. However, given the varying approaches of the courts to social science evidence, such as that of the majority in \textit{Chaoulli}, it is difficult to predict exactly how high it would set the evidentiary bar for governments attempting to justify existing DTCA regulations.

\textbf{VI The advantages and disadvantages of DTCA}

DTCA is a complex issue, around which policy must unfortunately be crafted using inconclusive and incomplete evidence. A Charter claim attacking the DTCA provisions would present a court with the very challenges described in the previous sections, namely questions about the appropriate standard of proof required of government and the appropriate role of the judiciary in policy making. In what follows I discuss the types of evidence courts would be likely to hear in a DTCA claim and the limitations of that evidence.

\textbf{A ADVANTAGES OF DTCA}

Two commonly cited advantages of DTCA are that by providing information, it fosters autonomy and empowers patients to seek involvement in their treatment decisions. In the past, patients have had little direct

\textsuperscript{68} Ibid. at para. 217.
\textsuperscript{69} Ibid. at para. 176.
\textsuperscript{70} Manfredi, ‘Déjà vu,’ supra note 61 at 145.
\textsuperscript{71} Choudhry, ‘Worse than \textit{Lochner},’ supra note 61 at 84.
access to health information. But today, with technological advances such as the Internet, patients have significantly greater access to health information, albeit of varying quality.\footnote{Colin Meek, \textit{Direct-to-Consumer Advertising of Prescription Medicines: A Review of International Policy and Evidence} (London: Royal Pharmaceutical Society of Great Britain, 2001) at 5 [Meek, \textit{Direct-to-Consumer}].} This change is consistent with the general trend in health care toward more assertive, less deferential, and more demanding patients, arising from a combination of growing affluence, exposure to health information in the media, and higher educational standards.\footnote{Reshma Jagsi, ‘Conflicts of Interest and the Physician–Patient Relationship in the Era of Direct-to-Patient Advertising’ (2007) 25 J.Clin.Oncol. 902 at 904 [Jagsi, ‘Conflicts of Interest’].} This movement is part of a broader trend in the law toward individual autonomy, as exemplified by the law of informed consent to medical treatment.

Advertising provides information to the public about available pharmaceuticals, thereby ostensibly empowering them to take part in treatment choices.\footnote{WHP, ‘Citizens’ Guide,’ supra note 2 at 4.} Therefore, proponents – including pharmaceutical companies and those representing advertisers and publishers – assert that DTCA provides a public service by fulfilling an educational role,\footnote{Jagsi, ‘Conflicts of Interest,’ supra note 73 at 903.} that the new class of ‘patient-consumer’ has a ‘right to know,’ and that a ban on DTCA deprives the public of important new medical information.\footnote{Meek, \textit{Direct-to-Consumer}, supra note 72 at 7.}

However, the extent to which DTCA will truly empower and educate depends on the quality, impartiality, and accuracy of the information drug companies are willing or required to provide.\footnote{The exception to this is the argument that there is a value in being notified of the existence of new drugs, for which the quality of the information is less important.} An unsurprising hypothesis is that the primary function of advertising is to boost pharmaceutical sales, as opposed to providing information.\footnote{WHP, ‘Citizens’ Guide,’ supra note 2 at 3.} Indeed, providing comparative information about the true relative costs and benefits of a drug (e.g., that there are no substantive differences in outcome between one drug and another much cheaper version) may be antithetical to the goal of boosting sales. Systematic reviews of advertising content and the regulatory history in the United States and New Zealand consistently show poor information quality. A content analysis of advertisements in ten leading US magazines found that nearly 90 per cent ‘described the benefits of a medication in vague, qualitative terms’ and failed to provide evidence to support their claims.\footnote{Mintzes, \textit{Public Health Implications}, supra note 13 at 25. This is just one example of the plethora of studies criticizing the informational value of advertising.}
treatment choice, such as the likelihood of success, other available options, and cost, is often lacking.\textsuperscript{80} For example, researchers in California analysing the educational content of 320 US magazine ads found that 90 per cent failed to mention the likelihood of treatment success, 80 per cent made no mention of other helpful activities (such as diet or exercise), 70 per cent did not mention causes or risk factors for the treated condition or other treatments, and 60 per cent omitted information about how the drug works.\textsuperscript{81} The same authors found that the public significantly overestimated the regulatory protections in place: 43 per cent of respondents believed that only drugs that were completely safe could be advertised to the public.\textsuperscript{82} Trebilcock argues that such failings could be corrected in Canada through a more rigorous and better-enforced regulatory regime. This is undoubtedly true in theory; however, given that no such regime exists anywhere in the world, one wonders if perhaps the political context and/or regulatory challenges bar the practical application of a more nuanced regime in reality.

Another advantage of DTCA is the potential for improved awareness and use of prescription drugs in areas of under-use. Evidence suggests that DTCA is effective in increasing prescription drug use and that it encourages patients to seek medical advice and to request treatment and care. These effects have been said to be particularly notable among patients of low socio-economic status, who are often not reached through public health campaigns.\textsuperscript{83} In addition to encouraging patients to seek medical advice, DTCA may also cause patients to feel increased confidence and control when interacting with their physicians.\textsuperscript{84} A study in Prevention magazine concluded that DTCA encouraged 21.2 million Americans to discuss medical conditions with their physicians that they had not previously addressed.\textsuperscript{85} Critics of these arguments point to the fact that DTCA does little to make the public aware of new drugs, given that 40 per cent of annual DTCA spending is invested in only ten drugs.\textsuperscript{86} To

\textsuperscript{80} WHP, ‘Citizens’ Guide,’ supra note 2 at 4.
\textsuperscript{84} Ibid. at 14.
\textsuperscript{86} Mintzes, Public Health Implications, supra note 13 at 26.
really address the problem of under-use, a regulatory regime could permit advertising of drugs for which there is demonstrated evidence of under-use – but, of course, this does not mean that such a regime would necessarily survive constitutional scrutiny.

B DISADVANTAGES OF DTCA

The disadvantages of DTCA primarily relate to concerns regarding the use of medications, given the risks associated with prescription drug consumption, and to the concomitant impact on health care budgets, particularly if the increased drug use has little tangible benefit in terms of health outcomes. Prescription drugs can have significant safety concerns. In 2004, for example, Merck had to pull its drug Vioxx – once popular for the treatment of pain and inflammation – off the market after studies showed that it doubled patients’ risk of myocardial infarction and stroke after eighteen months of use. By 2004 the drug had been sold for five years and used by more than 20 million people. 87 Increased drug use leads to higher rates of polypharmacy (the use of multiple medicines per person), which can result in more adverse drug reactions; these negative reactions, in turn, lead to increased medical costs. 88

There are also significant concerns about the increased use of drugs among patient populations for which research trials have not been conducted. Pharmaceutical testing is generally carried out on segments of the population that are the least risky; therefore, pregnant women, children, the elderly, and individuals with co-morbidities are commonly excluded from the trial process. It is thus problematic, even though a drug has been approved for general distribution, when increased prescribing occurs among these untested groups. 89

Furthermore, there is concern related to the types of prescription drugs that tend to be advertised (and, therefore, increasingly used). Drugs with

88 Large-scale safety studies show a strong link between the number of drugs a person takes at the same time and the risk of adverse drugs reactions. WHP, ‘Citizens’ Guide,’ supra note 2 at 1.
89 The early identification of post-market problems associated with prescription drugs is a significant problem, so much so that Prime Minister Stephen Harper promised the development of a Drug Safety and Effectiveness Network (DSEN) in 2007. In 2008, the federal government pledged $32 million over five years for the initiative, plus $10 million per year thereafter. The DSEN is a part of Health Canada and is overseen by the Canadian Institutes of Health Research (CIHR). Its aim is to promote the safe and effective use of pharmaceuticals by filling in knowledge gaps in order to make effective evidence-based decisions about drugs; it does this by providing public funding for post-market independent research of drugs in real-world environments. CIHR, ‘About DSEN’ (2009), online: CIHR <http://www.cihr-irsc.gc.ca/e/39389.html>.
proven benefits, no competitors, or well-established cost-effectiveness are not likely to be promoted; there is no reason for companies to spend money marketing drugs that are already likely to be prescribed. Companies instead advertise their newest products in an attempt to gain market share and recoup development costs. Many of these new drugs are no more effective than drugs already on the market; they are often costlier, and little may be known about their rare or long-term risks. For example, AstraZeneca spent US$1 billion marketing Nexium, a drug used to treat gastric reflux, to the American public; generic omeprazole achieves results comparable to those of Nexium at a significantly reduced cost. It is these drugs in competitive markets, at the margins of evidence-based medicine, for which advertising is often undertaken. There is understandable concern that these questionable drugs are the ones likely to be increasingly prescribed if DTCA policy is liberalized.

Opponents of DTCA particularly emphasize its pernicious effects on total cost and cost-effectiveness. Spending on prescription drugs is the fastest-rising health care expense in the United States and Canada. Increased sales of the twenty most heavily advertised drugs in 2000 – representing almost all DTCA spending – were responsible for nearly $10 billion of the $20.8 billion increase in US retail pharmaceutical costs between 1999 and 2000. If DTCA information is inaccurate, or if overall it promotes more inappropriate drug consumption, then DTCA increases health care costs without (substantially) improving health outcomes. Increased spending may be justified if the results are improved health outcomes, but there is little or no evidence that this is the case.

In addition to the major concerns about the impact of overuse of medications, another more abstract concern relates to the ‘medicalization’ of normal life. In other words, DTCA contributes to the use of prescription drugs for conditions that were ‘previously considered part of the normal range of human experience.’ Advertisements may seek to convince patients that they have chronic disorders that require persistent drug treatment. Furthermore, DTCA often directs people toward pharmaceutical solutions for problems that are of social or lifestyle origin and

90 WHP, ‘Citizens’ Guide,’ supra note 2 at 5.
91 Abel et al., ‘Direct-to-Consumer,’ supra note 7 at 219.
94 Shirreff, ‘For Them to Know,’ supra note 85 at 121.
95 Dominick L. Frosch et al., ‘Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising’ (2007) 5 Ann.Fam.Med. 6 at 10 [Frosch et al., ‘Creating Demand’].
that could be treated by non-pharmaceutical means such as diet or exercise. For example, people may be prescribed medication for high blood pressure when the same benefit could be achieved through weight loss. Furthermore, these advertisements tend to suggest that lifestyle changes are not a reasonable alternative to medication; in other words, they lead consumers to believe that the drug is necessary to treat the condition.97 This unnecessary medicalization diverts attention and resources away from alternative therapies that may achieve more optimal results. Rather than enhancing autonomy or self-responsibility, as proponents of DTCA claim, these ads and corresponding drug products may actually create dependency on the medical system and on pharmaceutical solutions.98

Another abstract concern is the potentially negative effect on the doctor–patient relationship. A study by Andrew Robinson et al. showed that most physicians view DTCA negatively, particularly because of the promotion of biased medical information, increased visit length and inefficiency, and the increase of inappropriate prescriptions.99 Of course, the counter-argument is that physicians may not be keen on more empowered patients, as it requires more time and attention on their part to deal with a patient’s request for a particular drug. There is a large body of evidence indicating that DTCA prompts consumers to request prescriptions for advertised products from their physicians, and that many of those requests are fulfilled despite being judged clinically inappropriate.100 For example, Richard Kravitz et al. conducted a randomized control trial of antidepressant prescription habits in which patients either asked for a prescription for Paxil (the advertised drug), requested a prescription for antidepressants generally, or made no request. These patients had either clinical depression or ‘adjustment disorder’; the latter does not require medication. Patient requests had ‘a profound

97 Frosch et al., ‘Creating Demand,’ supra note 95 at 10. For example, ‘several ads for cholesterol-lowering drugs appeared to suggest that non-pharmacological approaches were almost futile.’

98 Meek, Direct-to-Consumer, supra note 72 at 51; WHP, ‘Citizens’ Guide,’ supra note 2 at 4.


effect on physician prescribing,’ even more so than the condition they presented with. Adam Block, however, acknowledges that DTCA may lead to antidepressant treatment in non-depressed people but argues that the costs of treating these asymptomatic individuals may be greatly outweighed by the benefit to depressed individuals who receive treatment. In other words, he argues that the benefits of treating individuals who require treatment may sometimes outweigh the costs of unnecessary treatment.

VII Conclusion

Overall, it is apparent that arriving at the appropriate regulatory solution is not a straightforward issue; there are complications in terms of ensuring that, if permitted, advertising improves overall health and, in the context of a public system, that the overall improvement is cost effective. One thing that is clear, however, is the absence of evidence to demonstrate the inappropriateness of the more nuanced regulatory regime Michael Trebilcock argues for. Even in terms of the overall costs and benefits of DTCA, as Meredith Rosenthal of the Harvard School of Public Health explains, it is difficult to obtain direct evidence of DTCA’s effect on health, and published research is limited:

Thus far, the debate has been supported primarily by indirect evidence – that is, evidence not of the positive or negative effects of DTCA on public health and welfare, but of its effects on consumer awareness, attitudes, perceptions and self-reported behaviour, and physician attitudes and self-reported behaviour. To date, no published analysis has established whether DTCA stimulates new utilisation that is primarily appropriate or cost-effective or the opposite. Obviously, it is not the case that the health services research community has missed the point, but that the methodological challenges of conducting such a study are substantial.

In his affidavit in support of CanWest’s challenge, Michael Trebilcock mentions that other expert opinions ignore the question of whether regulatory options other than a complete ban (as exists in Canada) are


available to governments that could maximize the benefits of DTCA while minimizing its adverse effects. This should perhaps not be surprising, however: since these other regulatory options do not in fact exist, it is only in theory that they may prove to have better outcomes than existing regulatory approaches. If there is a more nuanced regulatory regime, as prima facie is the case in the United States, then it is under-enforced or the context is so different, as is the case in New Zealand, that the impact and effect of DTCA cannot be translated to Canada. Empirically demonstrating the benefits of one possible competing policy regime over another presents an enormous methodological challenge, and, faced with such a challenge, it seems likely that a government will fail. Regulatory regimes cannot be accurately compared unless they are implemented in the same policy context. This is difficult to achieve, short of conducting pilot projects in certain parts of Canada, because once one regulatory regime is implemented, the policy context is affected. And given the nature of advertising, it is difficult to isolate certain populations from exposure to DTCA.

Furthermore, Canadians are already subject to a certain amount of DTCA (some say a very large amount) through exposure to American media; thus, US DTCA may already have a significant impact on Canadian consumers. Indeed, some use this as an argument in support of liberalizing Canada’s DTCA regime. But this argument speaks more to the futility of attempting to regulate the sector than, as Michael Trebilcock would argue, in favour of a more sophisticated regulatory system that better balances the harms and benefits of DTCA.

A further problem with the evidence in the DTCA claim and similar challenges (tobacco, private insurance, etc.) lies in the different approaches that social science researchers and judges take to assessing governmental policy decisions. Social scientists generally do not understand that the burden is on the government to provide evidence justifying its policy choices in a s. 1 analysis, nor do they frame their research questions in this way. Instead, researchers frequently begin by asking whether there is evidence justifying a shift to a different policy; in other words, they look at evidence supporting a new policy, and if there is no such evidence they assume the status quo will prevail. This is not, however, how a court approaches a s. 1 analysis. Many social science and public health researchers also assume or believe that health and safety policies should be grounded in the precautionary principle. According to this principle, if there are reasonable grounds for presuming that a policy

104 Supra note 3.
would have a negative health or safety effect, it should not be implemented, even in the absence of definitive evidence.\footnote{CanWest MediaWorks v. Canada (A.G.), Ottawa 05-CV-303001PD2 (Ont. Sup. Ct. Just.) (affidavit of Joel Lexchin). This principle originated in Europe in the early 1970s and gained broad recognition at the 1992 UN Conference on Environment and Development. Since then the principle has spread rapidly to multilateral agreements, international laws, and domestic laws and policies on a host of environmental and health care topics. Linda Cameron, \textit{Environmental Risk Management in New Zealand: Is There Scope to Apply a More Generic Framework?} (Wellington: New Zealand Treasury, 2006) at 11, online: New Zealand Treasury <http://www.treasury.govt.nz/publications/research-policy/PPP/2006/06/06/05.htm>.} Researchers I have spoken with are astonished to learn that courts do not necessarily approach policy issues in the same way.

Michael Trebilcock and other supporters of CanWest’s position argue that the limitations on DTCA cannot be justified under s. 1 because they are a disproportionately strict response to the potential negative effects, and preclude the potential benefits, of allowing this type of advertising. Trebilcock, for example, advocates the implementation of less severe regulatory options, noting that ‘there is ample regulatory latitude for regulating the content and format of such advertisements . . . , perhaps requiring prior approval of all advertisements, more effective post-approval monitoring of advertisements to ensure compliance, and more effective sanctions for non-compliance.’\footnote{Trebilcock, ‘Testing the Limits,’ supra note 3 at 184.} However, it is questionable whether the significant costs likely associated with this more diligent monitoring warrant the modest gains in autonomy and education to which loosening the restrictions on DTCA is likely to lead. Nonetheless, the government may have difficulty in establishing why it did not select less stringent legislative standards under the minimal impairment stage of the \textit{Oakes} analysis, because the burden of proof is on the government. In my view, it is open to a court to find that a less intrusive regime \textit{theoretically} could achieve the government’s goal related to health and safety.

Although Michael Trebilcock will perhaps be on the winning side, particularly if a court follows the recent approach to health-policy evidence taken in \textit{Chaoulli}, I do not necessarily think his position should prevail. Given all the evidence (both empirical and theoretical) I have reviewed, the risks of DTCA outweigh the benefits, and Canada should keep the present regulatory restrictions: there are significant safety problems associated with the misuse and overuse of prescription drugs and with market failure (moral hazard) driving the consumption of drugs with little or no consideration of relative cost-effectiveness; furthermore, the scientific complexity and uncertainty surrounding the safety of pharmaceuticals, the common misconceptions about drug advertising (\textit{e.g.}, that
drugs can be advertised only if they are safe), and the vulnerability of patients for whom drugs may provide a last hope call into question one of the fundamental presumptions underlying the law and economics literature — the rational, well-informed consumer. Education and empowerment through DTCA will never meaningfully empower patients without robust regulation and subsequent enforcement against multinational interests with enormous resources.

Advocates for liberalization, including Michael Trebilcock, frequently assume that such re-regulation is possible. However, public choice theory and the actual experiences of countries with liberal DTCA regimes both suggest that, given the political interests of governments and the situational power of global pharmaceutical companies, the prospect of such nuances is theoretical only.