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**The Evidentiary Burden for Overturning Government's Choice of Regulatory Instrument: The Case of Direct-to-Consumer Advertising of Prescription Drugs**

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**I. Introduction**

Quality versus quantity, as the adage goes, frequently entails a trade-off between the diversity of topics a scholar explores and how deeply or wisely he or she explores them. Michael Trebilcock is a rare intellectual who defies this expectation. As canvassed in this volume, the breadth of issues he explores in his work is extraordinary, including and without limitation consumer law, contract law, electricity regulation, international trade, law and development, immigration law and health law and policy. He

approaches each with completeness, analytic rigour, imagination, often a little bit of humour, and just the right balance of humility and confidence. He can render extremely complex matters intelligible, capture the heart of a problem, and come up with pragmatic solutions. These skills, exemplified in his writing and his speaking, serve him well in scholarship, policy development, as a teacher and graduate supervisor, and in his role as expert witness.<sup>1</sup>

Thinking about how to reflect on Michael's career has been tremendously difficult – he has influenced my thinking profoundly and has long now been a mentor and friend. How could I possibly do him justice? The answer is I can't in one paper, 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 a modest reflection 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 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 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 section 2(b) of the Canadian *Charter of Rights and Freedoms (Charter)*. 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. If the ban on DTCA is lifted in

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<sup>1</sup> A survey of Canada's top corporate litigators by *Lexpert* identifies Michael as one of Canada's leading expert witnesses. Online: Charles River Associates, <<http://www.crai.com/NorthAmerica/ProfessionalStaff/listingdetails.aspx?id=3500>>. For instance, he has given evidence on the economic implications of bargaining issues in the telecommunications industry, *TELUS Communications Inc. et al.*, 2004 CanLII 65643 (C.I.R.B.), comparative accident compensation regimes, *Hartling v. Nova Scotia (Attorney General)*, 2009 NSSC 38, and competition law, *Commissioner of Competition v. Sears Canada Inc.*, 2005 CACT 2. Additionally, the Supreme Court of Canada has referred to Michael's work in a number of decisions. For example, they cited his writing on immigration law in *Chieu v. Canada (Minister of Citizenship and Immigration)*, 2002 SCC 3, competition law in *R. v. Nova Scotia Pharmaceutical Society*, [1992] 2 S.C.R. 606, the law of damages in *Whiten v. Pilot Insurance Co.*, 2002 SCC 18, and corporate law in *London Drugs v. Kuehne & Nagel International Ltd.*, [1992] 3 S.C.R. 299.

Canada, it is predicted that the pharmaceutical industry would spend approximately \$500 million CDN in the first year. However, it is also estimated to lead to at least \$1.1 billion CDN in extra drug sales in that first year.<sup>2</sup>

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.<sup>3</sup> The *CanWest Charter* challenge was scheduled to be heard in Ontario's Superior Court from June 15 to 19, 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 to proceed with the litigation at that time.<sup>4</sup> CanWest is currently working to restructure approximately \$4 billion of debt, and is selling off assets and renegotiating debt agreements.<sup>5</sup> (Michael, I am sure, would note their financial difficulties underscore their point regarding the competitive disadvantage faced as a result of the DTCA restrictions!) 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 explore the regulatory climate for DTCA in Canada and abroad, the policy concerns it raises, and the potential outcome of a future DTCA *Charter* challenge. In particular I focus on the concerns arising from the use of social science evidence in this type of litigation. On complex matters such as the regulation of DTCA, there will always be uncertainty as to whether government has struck upon the optimal solution. If the burden is upon government to prove – in the face of testimony from expert witnesses employed by the opposing side – that the current regulatory scheme is optimal, my

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<sup>2</sup> "CanWest's Charter Challenge on Prescription Drug Advertising: A Citizens' Guide" at 4, online: Women and Health Protection, <[http://www.whp-apsf.ca/pdf/charter\\_challenge\\_en.pdf](http://www.whp-apsf.ca/pdf/charter_challenge_en.pdf)>.

<sup>3</sup> *CanWest MediaWorks Inc. v. Attorney General of Canada*, Ottawa 05-CV-303001PD2 (Ont. Sup. Ct. Just.)(Affidavit of Michael J. Trebilcock),.

<sup>4</sup> Ann Silversides, "Charter challenge of ban on direct-to-consumer advertising to be heard by Ontario court in mid-June" (2009) 181 CMAJ 1 at 1.

<sup>5</sup> The Canadian Press, "Charter challenge to drug advertising rules by CanWest delayed until the fall," (12 June 2009), online: Canada East <<http://www.canadaeast.com/rss/article/697735>>..

concern is that government is surely destined to fail where the available social science evidence is weak because of inherent methodological difficulties that make it impossible to reach other than tentative answers to any question. The question looming in the background is: what evidentiary basis should courts require of legislators in cases involving complex policy choices and competing, but relatively weak, social science evidence? Further, in this specific case are the courts sufficiently attuned to the public choice problems<sup>6</sup> that might arise from removing the existing prohibitions and creating a more nuanced regulatory framework? It does not seem that any jurisdiction has successfully negotiated the politics involved in regulating multi-national drug companies and resolved the myriad of public choice problems to arrive at a DTCA regime which— as Michael notes— should “maximize the potential benefits of DTCA while reducing the potential harm.”<sup>7</sup>

## **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. This includes television and radio advertisements, newspaper and magazine ads, billboards, direct mailings and advertising on the internet.<sup>8</sup> DTCA has been largely prohibited in Canada since 1949. The federal *Food and Drugs Act*<sup>9</sup> broadly prohibits the advertising of prescription-only drugs to the public.<sup>10</sup> The legislation also states that no person shall advertise any food, drug, cosmetic or device to the general public as a treatment,

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<sup>6</sup> 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 behaviour using public choice theory have a strongly pessimistic view of human nature (see for example Daniel A. Farber & Philip P. Frickey, *Law and Public Choice: A Critical Introduction* (Chicago: University of Chicago Press, 1991). Others perhaps would say that public choice theory simply does not romanticize the role of government. Buchanan and Tullock, credited with being the founders of public choice theory say “[Public Choice] is nothing more than common sense, as opposed to romance. To some extent, people then and now think about politics romantically. Our systematic way of looking at politics is nothing more than common sense” (Buchanan, James M., and Gordon Tullock. *The Calculus of Consent: Logical Foundations of a Constitutional Democracy*. Ann Arbor: University of Michigan Press, 1962. )

<sup>7</sup> *Supra* note 3.

<sup>8</sup> Gregory A. Abel *et al.* “Direct-to-Consumer Advertising in Oncology” (2006) 11 *The Oncologist* 217 at 218. The internet is a growing source for DTCA. This may be problematic for nations in which DTCA is banned, as citizens are nonetheless exposed to online DTCA originating from other countries.

<sup>9</sup> R.S.C., 1985, c. F-27.

<sup>10</sup> *Ibid.*, Schedule F.

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.<sup>11</sup> 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 specific media.<sup>12</sup>

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 ad might describe seasonal allergy symptoms – such as runny nose, sneezing, and itchy, watery eyes – and suggest that people experiencing these symptoms should talk to their doctor.<sup>13</sup> “Reminder” ads – the second category – can mention the brand name but can not contain health claims or indication of the product’s use.<sup>14</sup> A Health Canada policy issued in 1996 on branded and unbranded ads clarified that “reminder ads” are also permitted.<sup>15</sup>

Health Canada is the national regulatory authority for DTCA, providing policies to regulate DTCA, guidelines for the interpretation of those regulations and oversight for regulated activities.<sup>16</sup> Actual review and pre-clearance of ads for compliance with regulatory requirements is conducted by

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<sup>11</sup> Canada’s Food and Drugs Act and Regulations. <[www.hc-sc.gc.ca/food-aliment/friia-raaii/food\\_drugsaliments\\_droguess/act-loi/e\\_index.html](http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugsaliments_droguess/act-loi/e_index.html)>.

<sup>12</sup> *Ibid.*, s. 9(1): “No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive, or is likely to create an erroneous impression regarding its composition, merit or safety.” Advertising is “any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.”

<sup>13</sup> “Correct Help-Seeking Ad,” online: Food and Drug Administration<<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm082288.htm>>.

<sup>14</sup> Colin Meek, “Direct-to-Consumer Advertising of Prescription Medicines: A Review of International Policy and Evidence” (2001) Royal Pharmaceutical Society of Great Britain.

<sup>15</sup> Barbara Mintzes, *What are the Public Health Implications? Direct-to-Consumer Advertising of Prescription Drugs in Canada* (Toronto: Health Council of Canada, 2006) at 8.

<sup>16</sup> “Regulatory Requirements for Advertising,” online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index-eng.php>>.

independent agencies.<sup>17</sup> 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) Pharmaceutical Advertising Advisory Board (PAAB) – an independent review agency comprised of multiple stakeholders.<sup>18</sup>

Rx&D regulates advertising by requiring its members to adhere to its *Code of Ethical Practices*.<sup>19</sup> ASC initially had the responsibility of reviewing and pre-clearing non-prescription drug advertisements, which has expanded to include the review of prescription drug DTCA.<sup>20</sup> The PAAB operates a pre-screening service for pharmaceutical advertisements directed to health professionals and a review service for DTCA.<sup>21</sup> If ASC or the PAAB find an ad is inconsistent with regulations, the company is asked to withdraw the ad and/or replace it with another that complies with the law.<sup>22</sup>

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.<sup>23</sup> However, actual enforcement of the regulations appears to be almost non-existent – indicating that either self-regulation by the industry is largely working, or else enforcement is simply lax. No penalties have been imposed on any drug companies for illegal advertising activities since 1978.<sup>24</sup> Health Canada considers a number of factors

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<sup>17</sup> “Advertising Preclearance,” online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/index-eng.php>>.

<sup>18</sup> Colin Meek, “Direct-to-Consumer Advertising of Prescription Medicines: A Review of International Policy and Evidence” (2001) Royal Pharmaceutical Society of Great Britain.

<sup>19</sup> *Code of Ethical Practices*, online: Rx&D <[http://www.canadapharma.org/Pharm\\_comm/Code/Code%20of%20Ethical%20Practices%20-%20January%202009.pdf](http://www.canadapharma.org/Pharm_comm/Code/Code%20of%20Ethical%20Practices%20-%20January%202009.pdf)>

<sup>20</sup> “Consumer Drug Advertising Clearance”, online: ASC <<http://www.adstandards.com/en/AdvertisingPreclearance/consumerDrugs.aspx>>.

<sup>21</sup> PAAB Homepage, online: PAAB <<http://www.paab.ca/en/home/>>.

<sup>22</sup> “How Complaints About Advertising are Handled”, online: ASC <<http://www.adstandards.com/en/ConsumerComplaints/howComplaintsAreHandled.aspx>> and Bill Hearn & Todd Prendergast, “Canada” in *The International Comparative Legal Guide to Pharmaceutical Advertising 2005* (London: Global Legal Group, 2005) at 67, online: McMillan Binch Mendelsohn LLP <[http://www.mcmillan.ca/Upload/Publication/BHearn\\_TPrendergast\\_Pharmaceutical%20Advertising%202005.pdf](http://www.mcmillan.ca/Upload/Publication/BHearn_TPrendergast_Pharmaceutical%20Advertising%202005.pdf)>

<sup>23</sup> Health Canada and Food Branch Inspectorate, *Compliance and Enforcement Policy*, version 2,POL-0001(Ottawa: Health Canada, 2005).

<sup>24</sup> Standing Committee on Health. *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs* (Ottawa: House of Commons, 2004), online: Parliament of Canada

when determining enforcement, including risks to health and safety, the company's compliance history, premeditation, likelihood of recurrence, expected effectiveness, effects on public confidence in Health Canada, and the department's priorities and available resources. Unlike the United States Food and Drug Administration (FDA), however, Health Canada has no personnel dedicated to the enforcement of drug advertising regulations.<sup>25</sup>

While DTCA is subject to strict regulatory limits in Canada and most OECD countries, it is permitted in the US and New Zealand. In the sections that follow, I explore the policy approach to DTCA in these jurisdictions, as well as the recent proposal to liberalize DTCA in the European Union, in order to illustrate alternate policy options and reflect on whether there is a model for a regulatory regime that better balances the harms and benefits of DTCA.

### **III. DTCA in other jurisdictions**

#### *DTCA in the United States: A regulatory scheme example*

American drug companies began to significantly advertise their products to the public in the early 1980s.<sup>26</sup> Since then, DTCA has increased exponentially, with the US media now flooded with advertisements for drugs designed to treat a wide range of health issues. Pharmaceutical companies often begin advertising as soon as their products are approved by the FDA. Spending on promotion has risen to over \$27 billion USD per year annually including \$11.4 billion USD on advertising. DTCA encouraging patients to consult their doctor about a particular drug comprises 37% of this budget.<sup>27</sup> A 2008 study

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<[www.parl.gc.ca/InfocomDoc/Documents/37/3/parlbus/commbus/house/reports/healrp01/healrp01-e.pdf](http://www.parl.gc.ca/InfocomDoc/Documents/37/3/parlbus/commbus/house/reports/healrp01/healrp01-e.pdf)>

<sup>25</sup> Mintzes, *supra* note 12 at 10.

<sup>26</sup> Mintzes, *supra* note 12 at 13.

<sup>27</sup> David C. Vladeck, "The Difficult Case of Direct-to-Consumer Drug Advertising" (2007) 41 *Loyola Los Angeles Law Review* 259 at 260. In addition to these marketing tactics, pharmaceutical companies sometimes also engage in more covert marketing ploys. Recently unveiled court documents in the US showed that ghostwriters paid by a pharmaceutical company played a major role in producing 26 scientific papers backing the use of hormone replacement therapy in women. This suggests that the level of hidden industry influence on medical literature is greater than previously known. Natasha Singer, "Medical Papers by Ghostwriters Pushed Therapy," *New York Times* (5, August 5, 2009).

published by York University researchers found that the US pharmaceutical industry spends almost twice as much on advertising as on research and development.<sup>28</sup>

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)*.<sup>29</sup> The *FD&C Act*'s regulations provide that the ads cannot be false or misleading and cannot omit material facts; furthermore, the ads must present a fair balance between benefit and risk information. For print DTCA, the regulations specify that a brief summary of all 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 or make adequate provision for dissemination of the drug's FDA-approved labelling in connection with the ad.<sup>30</sup> This appears to be more similar to the kind of regulation that Michael would prefer over Canada's as it speaks to balancing the harms and risks. Why then is the dominant perception of drug information that of "snake oil salesman of the information age?"<sup>31</sup> Part of the problem in the US appears to be the lack of the ability and willingness to vigorously enforce these regulations on the part of the FDA.

Following the US Government Accountability Office's November 2006 report calling for improvement in the FDA's oversight of DTCA,<sup>32</sup> section 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 ad for a drug for review "not later than 45 days before dissemination of the television

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<sup>28</sup> Marc-Andre Gagnon & Joel Lexchin, "The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States" (2008) 5(1) *PloS Med*, online: *PloS Medicine*, <<http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001>>.

<sup>29</sup> *Food, Drug and Cosmetic Act*, 21 U.S.C.

<sup>30</sup> Daniel Schultz, "FDA Oversight of Direct-to-Consumer Advertising of Medical Devices," online: Food and Drug Administration <<http://www.fda.gov/NewsEvents/Testimony/ucm096272.htm>>. Note that Internet ads have not been designated as falling within the 'broadcast' category but nevertheless the FDA nevertheless 'actively enforces' its regulations on the internet - Timothy S. Hall, *The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet* (2003) 7 DEPAUL J. HEALTH CARE L. 1-41 at 8.

<sup>31</sup> Nicole A. Rothstein, "Comment: Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the US and Canada" (2001) 53 *Fed. Comm. LJ* 343 at 347.

<sup>32</sup> United States Government Accountability Office, "Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising," Report to Congressional Requesters, November 2006 <<http://www.gao.gov/new.items/d0754.pdf>>.

advertisement.”<sup>33</sup> In conducting this review, the Secretary may make recommendations on changes to information included in the drug label if they are necessary to protect consumer well-being, or in order to be consistent with the prescribing information for the drug. However, these are only recommendations; the Secretary does not have the authority to *require* change, except 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 ad does not disclose the date of approval.<sup>34</sup> In terms of DTCA review, the FDA has expressed concern regarding its ability to assess the ads in a timely fashion.<sup>35</sup> 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.

During the debates that gave rise to the adoption of section 503B, the US Congress also entertained a policy proposal that would have banned outright all DTCA in broadcast media. Proponents of this plan argued that it was unproblematic because it is doctors not patients who make prescribing decisions, and because there would still be other available channels of drug promotion. As one might expect, critics of the proposal claimed that a ban on DTCA in broadcast media would be a restraint on the dissemination of information, thus depriving consumers of important knowledge relating to their own medical care. They categorized such a ban as a paternalistic violation of the First Amendment.<sup>36</sup> Given that the courts have traditionally imposed very high standards for regulations that encroach on freedom of expression – especially when less intrusive options are available – it seems unlikely that such a ban on DTCA could succeed in the US.<sup>37</sup>

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<sup>33</sup> “Preview of Television Advertisements”, online: Food and Drug Administration, <<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm108087.htm>>.

<sup>34</sup> <*Ibid.*>.

<sup>35</sup> David C. Vladeck, “The Difficult Case of Direct-to-Consumer Drug Advertising” (2007) 41 *Loyola Los Angeles Review* at 259-295.

<sup>36</sup> Vladeck, *supra* note 23 at 288.

<sup>37</sup> For example, in *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 at 501 (1996) Justice Stevens explains that “the First Amendment directs us to be especially sceptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”

Another policy proposal currently being considered in the US is removing the tax deductions currently available to pharmaceutical companies for prescription drug advertising. This plan would raise an estimated \$37 billion USD, which would be used to help fund President Obama's universal health care plan.<sup>38</sup> It might also reduce the quantity of US DTCA, as the increased costs would deter potential advertisers.

*Prima facie* the US provides a model for nuanced regulation of DTCA along the lines Michael would advocate that balances harms and benefits,<sup>39</sup> but it 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 multi-national drug companies seem largely successful in preventing further regulatory intrusion and in protecting taxation subsidies, at least to date.

#### *DTCA in New Zealand*

DTCA is permitted in one other developed country apart from the US – Michael's birth-place of New Zealand. DTCA is a more recent phenomenon in that jurisdiction, beginning in the mid-1990s. New Zealand's DTCA regulatory scheme 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 public health care system and the rigorous system of review for prescription drugs inside the public plan arguably dilute the impact of DTCA. This can be contrasted to the health care systems of the US and Canada, where there is a significant role for private spending on pharmaceuticals, through out-of-pocket payments and private health insurance.<sup>40</sup>

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<sup>38</sup> Ryan J. Donmoyer, "House Considering \$37 Billion Drug Tax, Rangel Says," online: Bloomberg.com <<http://www.bloomberg.com/apps/news?pid=20601103&sid=aeEJZicjYE60>>.

<sup>39</sup> *Supra* note 3.

<sup>40</sup> Michael 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); however, the issue of public and/or private insurance and the mechanisms for paying and negotiating the purchase of drugs for the public plan likely would have a significant effect on the extent and effect of DTCA.

Advertisements in New Zealand are regulated by the *Medicines Act 1981*.<sup>41</sup> Standards governing content are generally more permissive than those in the US. For example, the legislation does not require the inclusion of risk information in the audio portion of television DTCA; therefore, this information usually appears briefly as text at the end of the ad. Advertisements are also pre-screened by the Therapeutic Advertising Pre-Vetting System (TAPS). However, the Ministry of Health does not conduct regular monitoring of either the TAPS system or ad compliance with legislation. Although individuals may complain if they feel an ad violates the regulations, the Ministry has never used its authority to prosecute for a breach.<sup>42</sup>

The other entity responsible for regulating pharmaceutical advertisements is the Advertising Standards Authority (ASA), which developed its *Code for Therapeutic Advertising* in 1999.<sup>43</sup> 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 which are only voluntarily binding. These decisions typically request that the offending ads be modified or withdrawn. While the Board does have the capability to impose more stringent sanctions, these have rarely (if ever) been used. Furthermore, the ASCB does not receive government funding, but receives resources from pharmaceutical company levies in a “user pays” system.<sup>44</sup> Given this funding source, and the fact that members of the advertising industry comprise 50% of the Board, its independence and impartiality is questionable.

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, there is a universal public payment scheme for prescription drugs, and rigorous cost-effectiveness evaluations are conducted

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<sup>41</sup> *Medicines Act 1981* (N.Z.), 1981/118.

<sup>42</sup> Les Toop et al., *Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?* (Christchurch: New Zealand Department of General Practice, 2003) at 28, online: University of Otago <<http://www.uoc.otago.ac.nz/zz/report.pdf>>.

<sup>43</sup> *Ibid*, at 29. .

<sup>44</sup> Les Toop et al., “Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?” (February 2003) Report to the Minister of Health, at 29 <<http://www.uoc.otago.ac.nz/zz/report.pdf>>.

by an arm's length agency, the Pharmaceutical Management Agency (Pharmac). Pharmac is responsible for managing the Pharmaceutical Schedule – the list of government-subsidized medicines – and negotiating the price of prescription drugs with drug companies.<sup>45</sup> This agency is unique amongst public formularies in the developed world as it works within a capped budget so explicit trade-offs are made between drugs and their associated prices, benefits and risks. Pharmac does not regulate prices directly by requiring companies to supply drugs at a particular price, but stimulates price competition through processes like tendering for supply (requesting quotes) and reference pricing (applying the same subsidy to all drugs with the same or similar effects).<sup>46</sup> All new products to the formulary are part of contracts which stipulate that if thresholds are passed in terms of predicted utilization that funded is clawed back by Pharmac. Consequently, in such an environment DTCA is likely only to have impact for prescription drugs excluded from the public plan, e.g. Viagra. An environment where 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 utilization (and thus the consequent effect on 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 formulary-setting activities, thus producing a net benefit from a policy perspective. In other words, chucking the industry a bone in terms of DTCA may allow New Zealand to achieve other critical objectives of keeping the total cost of prescription drug spending within a capped budget and negotiating reduced prices.

### *DTCA in the European Union*

Although the European Union (EU) largely forbids DTCA, it 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. The policy would have changed two regulations similar to those in force in Canada.

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<sup>45</sup> Pharmac, "How Should High Cost Medicines be Funded?" (2006) at 3, online: Pharmac <[www.pharmac.govt.nz/2006/12/15/HCMConsult.pdf](http://www.pharmac.govt.nz/2006/12/15/HCMConsult.pdf)>.

<sup>46</sup> Pharmac, "Making funding decisions," online: Pharmac <[http://www.pharmac.govt.nz/2008/12/16/05\\_PHARM\\_Infosheets\\_DECISION-%20MAKING.pdf](http://www.pharmac.govt.nz/2008/12/16/05_PHARM_Infosheets_DECISION-%20MAKING.pdf)>.

Firstly, the government would amend a clause banning advertising of prescription-only drugs. Additionally, they would have to delete the aforementioned conditions from a list of specific diseases for which manufacturers are prohibited from advertising treatments to the public.<sup>47</sup> 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.<sup>48</sup> In October 2002 an overwhelming majority of the Members of the European Parliament voted against the reform proposal.<sup>49</sup>

#### **IV. Overview of a *Charter* challenge**

Although a detailed discussion of *Charter* challenges is beyond the scope of this paper, in this section I briefly describe this process as context for the discussion regarding evidentiary burden that follows. Firstly, the claimant must prove that government breached one of her *Charter* rights.<sup>50</sup> In a freedom of expression claims, courts employ a two-step test. Firstly, the court asks whether the plaintiff's activity falls within the sphere of conduct protected by the guarantee.<sup>51</sup> 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 those limits pursuant to section 1.<sup>52</sup> In assessing whether the government has discharged this burden, courts employ the test set out by the

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<sup>47</sup> Toop, *supra* note 37 at 39. This list is analogous to Schedule A in Canada's *Food and Drugs Act*.

<sup>48</sup> Toop, *supra* note 37 at 19.

<sup>49</sup> 494 against to 42 in favour. Colin Meek, *Direct-to-Consumer Advertising (DTCA) of Prescription Medicines: Fourth Quarterly Update* (London: Royal Pharmaceutical Society of Great Britain, 2003) at 2, online: RPSGB <[www.rpsgb.org/pdfs/dtcarev0212.pdf](http://www.rpsgb.org/pdfs/dtcarev0212.pdf)>, .

<sup>50</sup> The Constitutional Law Group, *Canadian Constitutional Law*, 3rd ed. (Toronto: Emond Montgomery Publications Ltd, 2003) at 737.

<sup>51</sup> *Irwin Toy Ltd. v. Quebec (Attorney General)*, [1989] 1 S.C.R. 927.

<sup>52</sup> Under section 1 of the *Charter*, the protected rights and freedoms may be subject to such reasonable limits prescribed by law which can be demonstrably justified in a free and democratic society -- *Canadian Charter of Rights and Freedoms*, Section 1, Part 1 of *The Constitution Act, 1982*, Assented to March 29, 1982. From Department of Justice Canada: <<http://laws.justice.gc.ca/en/charter/1.html>>.

Supreme Court of Canada in *R. v. Oakes*.<sup>53</sup> 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. The *Oakes* test was initially conceived of 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.<sup>54</sup> However, in some cases the courts have exhibited a very high degree of deference to governmental decisions, requiring little justification for a rights violation.<sup>55</sup>

The Supreme Court 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*,<sup>56</sup> in which the appellants successfully claimed that extensive restrictions on dentists' advertisements violated their freedom of expression and 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 (Attorney General)*, 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.<sup>57</sup> Following this case, the federal government enacted new legislation, the *Tobacco Act*, which was the subject of another *Charter* challenge in *Canada (Attorney General) v. JTI-MacDonald Corp.*<sup>58</sup> This legislation, which was largely upheld by the Court, banned lifestyle advertising and promotion, advertising appealing to young persons, and false

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<sup>53</sup> [1986] 1 S.C.R. 103 [*Oakes*].

<sup>54</sup> Sujit Choudhry, "So What Is the Real Legacy of *Oakes*? Two Decades of Proportionality Analysis under the Canadian *Charter*'s Section 1" (2006) 34 S.C.L.R. (2d) 501 at 506.

<sup>55</sup> Colin Feasby, "Constitutional Questions About Canada's New Political Finance Regime" (2007) 45 Osgoode Hall L. J. 513 at 541 criticized the "overly deferential approach favoured by the Supreme Court of Canada in two recent democratic process cases." The two cases in question are *R. v. Bryan*, [2007] 1 S.C.R. 527 and *Harper v. Canada*, [2004] 1 S.C.R. 827

<sup>56</sup> [1990] 2 S.C.R. 232 [*Rocket*].

<sup>57</sup> *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1995] 3 S.C.R. 199 [*RJR MacDonald*].

<sup>58</sup> 2007 SCC 30 [*JTI MacDonald*].

or misleading advertising, but permitted information and brand preference advertising. Due to the similar issues they raise, these cases provide some indication of how courts may respond to a DTCA *Charter* challenge.

The DTCA restrictions would undoubtedly be deemed a breach of the right to freedom of expression, given that the courts have repeatedly viewed advertising as a legitimate form of expression. However, the type of expression at issue may affect a court's s. 1 analysis. As the Supreme Court acknowledged in *Rocket*, although commercial expression is protected, the courts can be sensitive to context, as "not all expression is equally worthy of protection. Nor are all infringements of free expression equally serious."<sup>59</sup>

Also working in favour of the government's position in a DTCA challenge is the Court's acknowledgement of the importance of deference in these types of cases. Of particular relevance to this case are the comments of the Court in *JTI MacDonald* regarding complex policy choices: "Effective answers to complex social problems, such as tobacco consumption, may not be simple or evident. There may be room for debate about what will work and what will not, and the outcome may not be scientifically measurable. Parliament's decision as to what means to adopt should be accorded considerable deference in such cases."<sup>60</sup> In a DTCA claim, the government may raise the argument that the impugned provisions were enacted to protect vulnerable patients (including members of the public who may in the future become patients), which may persuade a court to accord the government further deference. In this regard, the Supreme Court of Canada commented in *Rocket* that:

As non-specialists, [the public] would lack the ability to evaluate competing claims as to the quality of different dentists...The consuming public would thus be far more vulnerable to unregulated advertising from dental professions than it would be to unregulated advertising from manufacturers or suppliers of many other, more standardized, goods or services. The fact that the provincial legislature here acted to protect a vulnerable group argues in favour of viewing its attempted compromise with some deference.<sup>61</sup>

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<sup>59</sup> *Supra* note 55 at 246.

<sup>60</sup> *Supra* note 57 at para. 41.

<sup>61</sup> *Supra* note 55.

Note the interpretation of the term “vulnerable”: the Court in *Rocket* considered consumers of DTCA *vulnerable* merely because of their lack of expertise to evaluate claims – the consumers did not have to be desperate or have a serious medical problem.

However, contra this is the fact that a patient’s desire for a particular drug is mediated through a physician. This may persuade the court that there is not as great a need to protect vulnerable patients from advertising. Further, the government may have difficulty defending the DTCA provisions as minimally impairing freedom of expression. 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 that less intrusive regulations would fail to achieve its public health objectives.<sup>62</sup> Accordingly, when the amended tobacco legislation reached the courts, the government had greatly improved the evidentiary basis for its decision.<sup>63</sup> In a DTCA case, government would similarly have to amass evidence defending its policy choice, which may be difficult given the competing advantages and disadvantages of allowing this type of advertising and the weak scientific base of evidence both for and against DTCA.

The government’s current DTCA policy has expert support; it is the result of recent scrutiny from both Health Canada and the House of Commons Standing Committee on Health. For instance, in 2003, the Committee on Health spent two months conducting hearings on the health-related aspects of prescription drugs, ultimately concluding that Canada should continue to limit DTCA.<sup>64</sup> Their report emphasized that DTCA will increase costs but will not result in accurate, unbiased information being passed to patients or the public. Of interest is that the Committee advocated for an even more restrictive

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<sup>62</sup> Christopher P. Manfredi, “Expressive Freedom and Tobacco Advertising: A Canadian Perspective” (2002) 92 *American Journal of Public Health* 3 360 at 361.

<sup>63</sup> For example, the *JTI MacDonald* trial decision [2003] R.J.Q. 181 at para. 171-176 noted that following *RJR MacDonald*, the Minister had a team of 50 people assembled to develop a comprehensive anti-smoking strategy which resulted in the submission of 3,000 comments, 85 papers, the preparation of a report representing the Minister’s range of options, and the submission of four options to cabinet

<sup>64</sup> House of Commons Standing Committee on Health, *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs* (2008), online: Parliament of Canada <<http://cmte.parl.gc.ca/Content/HOC/committee/373/heal/reports/rp1282198/healrp01/08-rap-e.htm>>.

regime and did not consider it necessary to continue to allow “reminder ads” for the purposes of price comparison shopping (as most Canadians are enrolled in public or private insurance plans that set prices.) With regard to Health Canada’s work, one of the aspects of DTCA policy most susceptible to criticism under the minimal impairment test was the list of conditions under Schedule A for which no DTCA was permitted. Mintzes called this list a “hodgepodge” noting that it included conditions like baldness.<sup>65</sup> In an effort to justify the additional restrictions on advertising products treating these conditions, the Schedule has undergone a number of revisions to restrict the list to serious diseases.<sup>66</sup>

In earlier similar cases, the government had difficulty establishing minimal impairment due to the breadth of the ban at issue. In *Rocket*, the Court pointed out that an advertisement that listed a dentist’s hours of operation or the languages that the dentist speaks would be useful to the public, without harming or undermining trust in the profession or being misleading. Similarly, in *RJR MacDonald*, the Court was critical of the fact the ban encompassed purely informational advertising and brand preference information. The ban on DTCA may similarly be viewed as too broad to pass the minimal impairment requirement. For example, merely mentioning the medical condition a drug is intended to treat, without making any representations about its efficacy, could be construed as merely providing information.<sup>67</sup>

Government may also face difficulty at the proportionality stage of the *Oakes* analysis. In *JTI MacDonald*, the Court noted: “The prohibited speech is of low value. Information about tobacco products and the characteristics of brands may have some value to the consumer who is already addicted to tobacco. But it is not too great. On the other hand, the beneficial effects of the ban for young persons and for society at large may be significant.”<sup>68</sup> The harms arising from DTCA are not as clear cut. DTCA will spur greater consumption of pharmaceuticals, which can result, for example, in their use in untested

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<sup>65</sup> Mintzes, *supra* note 12 at 7.<sup>65</sup> <[http://www.healthcouncilcanada.ca/docs/papers/2006/hcc\\_dtc-advertising\\_200601\\_e\\_v6.pdf](http://www.healthcouncilcanada.ca/docs/papers/2006/hcc_dtc-advertising_200601_e_v6.pdf)>.

<sup>66</sup> Health Canada, “Questions and Answers: Schedule A and Section 3 Regulatory Amendments and Associated Guidance”, online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/scha\\_qa\\_qr-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/scha_qa_qr-eng.php)>. Furthermore, Health Canada has worked to improve the specificity of conditions on this list. For example, the general term “liver disease” was replaced with a more specific, very serious disease, “hepatitis.”

<sup>67</sup> The amended tobacco legislation defined information advertising as “advertising that provides factual information to the consumer about a product and its characteristics or the availability or price of a product or brand of product.” *Tobacco Act*, S.C. 1997, c. 13, s. 22(4).

<sup>68</sup>JTI McDonald, para 94.

populations like the elderly, those with co-morbidities, pregnant woman and children (I discuss the risks further below). 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 Michael points out, in some circumstances spurring more consumption may be beneficial. But demonstrating that in a (small) number of cases DTCA could be beneficial cannot be the basis of sound policy and instead one would have to inquire whether the 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 advertisements. In the smoking cases, government arguably has a stronger argument for a more rigorous and widespread ban, given the fact 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 that drug.

This view of physicians as protective agents has to be mitigated by evidence that physicians are influenced in their prescribing habit by the demands of patients; physicians often do not have a financial incentive to be attuned to the costs of what they prescribe (moral hazard arising from first dollar public and private insurance) and more-over themselves may under-appreciate the risks of prescribing to subsets of patients not included in research trials. 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 *de facto* meaningfully called upon, the patient remains vulnerable – which argues in favour of deference to the government's DTCA policy.

## **V. Social science evidence and the s. 1 analysis**

Although it is clear that the onus is on the government to meet all of the elements of the *Oakes* test, what is less apparent is the level of evidence required to discharge this burden. How should one deal with a weak evidentiary base, not because of a lack of energy on the part of government in collecting and analyzing evidence, but because of impediments in research design and methodologies and confounding factors? As will be discussed in more detail in section VII, 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 increase in a DTCA regime but what is not clear is the impact (positive and negative) upon morbidity and mortality as a result of increased utilization. A further unknown is how this cost-benefit analysis would be impacted by different variations in a regulatory regime. In *Oakes*, the Court suggested a high evidentiary burden: “Where evidence is required in order to prove the constituent elements of a s. 1 inquiry, and this will generally be the case, it should be cogent and persuasive and make clear to the Court the consequences of imposing or not imposing the limit.”<sup>69</sup> This burden has proven problematic in cases relying on social science evidence, due to the nature of this research and methodological problems – it is rare indeed that there are black and white answers to complex social problems ascertained and investigated using current research methodologies. 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.”<sup>70</sup><sup>71</sup>

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 policymaking in the face of incomplete knowledge and factual uncertainty<sup>72</sup> particularly where government is trying to prevent harms occurring. In *RJR MacDonald*, LaForest J. noted that requiring evidential certainty “could have

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<sup>69</sup> *Suprasupra* note 47 at 138.

<sup>70</sup> Sujit Choudhry, *Access to Care, Access to Justice*, page 81.

<sup>71</sup> Manfredi highlights several significant differences between policymaking and the judicial system, which 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.”— Manfredi *supra* note 66 at 150.

<sup>72</sup> Choudhry, *supra* note 48 at 503. Sujit Choudhry, “So What Is the Real Legacy of *Oakes*? Two Decades of Proportionality Analysis under the Canadian *Charter*’s Section 1” (2006) 34 S.C.L.R. (2d) at 503, 524.

the effect of paralysing the operation of government...it would not be possible to make difficult but sometimes necessary legislative choices.”<sup>73</sup> Furthermore, the analysis of this type of data raises questions about the appropriate role of the judiciary. Depending on how closely it scrutinizes 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 regarding the political feasibility of a more nuanced regulatory structure than that which 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.<sup>74</sup> 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.<sup>75</sup> 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. One well-known example of this is *RJR MacDonald*, where the Court split on the issue of the link between tobacco advertising and consumption, as there was a lack of evidence connecting the two.<sup>76</sup> The debate between the majority and the minority was whether the court could infer that by convincing smokers not to quit, brand preference and informational advertisements resulted in a sustained level of consumption.<sup>77</sup> Some twelve years later the court is now persuaded that there is sufficient evidence to now make this connection.

While in certain cases involving inconclusive social science evidence, courts have shown more deference to governmental policy choices – employing the reasonable apprehension of harm test – in

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<sup>73</sup> *Supra* note 52 at para. 67.

<sup>74</sup> Choudhry, *supra* note 48 at 511.

<sup>75</sup> Choudhry, *supra* note 48 at 525.

<sup>76</sup> Sujit Choudhry, *supra* note 48 at 527. “So What Is the Real Legacy of *Oakes*? Two Decades of Proportionality Analysis under the Canadian *Charter*’s Section 1” (2006) 34 S.C.L.R. (2d) at 525.

<sup>77</sup> Choudhry, *supra* note 64 at Access page 85.

other cases, courts have held the government to a stricter standard of proof. The decisions of the majority and the minority of the Supreme Court of Canada in *Chaoulli v. Quebec (Attorney General)*<sup>78</sup> illustrate these competing positions. This case challenged the legislative prohibition on private health insurance. In determining whether government had justified its policy choices, the Court had to grapple with conflicting social science evidence regarding wait lists and the impact privatization would have on the public system.

The minority in *Chaoulli*, who would have upheld the prohibition on private insurance, showed greater deference to government: Quebec “takes the view that significant growth in the private health care system (which the appellants advocate) would inevitably damage the public system...governments are entitled to act on a reasonable apprehension of risk of such damage.”<sup>79</sup> In reaching its decision, the minority was sensitive to both of the concerns I mentioned above – the difficulty of providing proof in light of incomplete knowledge and factual uncertainty, and the appropriate role of the judiciary. With regard 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.”<sup>80</sup> Quoting the majority in *R. v. Marmo-Levine*, the *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.”<sup>81</sup> 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.”<sup>82</sup> 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.

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<sup>78</sup> 2005 SCC 35.

<sup>79</sup> *Ibid.* at para. 176.

<sup>80</sup> *Ibid.* at para. 217.

<sup>81</sup> *Ibid.* at para. 176.

<sup>82</sup> Manfredi, *supra* note 64 at 145.

Because the “reasonable apprehension of harm” test features prominently in the freedom of expression jurisprudence,<sup>83</sup> a court hearing a DTCA challenge may invoke this test 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 *Chaoulli*, it is difficult to predict exactly how high it would expect a government to jump in terms of persuasiveness of the evidence presented justifying existing DTCA regulations.

## VI. The Advantages and Disadvantages of DTCA

DTCA is a complex policy issue, where policy must unfortunately be crafted using inconclusive and incomplete evidence. A *Charter* claim attacking the DTCA provisions would present courts with the very challenges described in the previous sections, namely questions over 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 discuss its limitations.

### *Advantages of DTCA*

Two related commonly-cited advantage of DTCA are patient empowerment and autonomy through the provision of information, and involvement of the patient in treatment decisions. In the past, while medical professionals had access to information about health care and drugs, the availability of such information for patients was quite limited. Today, with technological advances such as the internet, patients have greater access to health information, albeit of varying quality.<sup>84</sup> 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

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<sup>83</sup> Choudhry, *supra* note 64 at 84. .

<sup>84</sup> Colin Meek, *Direct-to-Consumer Advertising of Prescription Medicines: A Review of International Policy and Evidence* (London: Royal Pharmaceutical Society of Great Britain, 2001) at 5.

educational standards.<sup>85</sup> This movement is part of a broader trend in the law towards 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 the public to take part in treatment choices.<sup>86</sup> Therefore, proponents—including pharmaceutical companies and those representing advertisers and publishers—assert that DTCA provides a public service by fulfilling an educational role,<sup>87</sup> to the extent that pharmaceutical companies and those representing advertisers and publishers argue 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.<sup>88</sup>

However, the extent to which DTCA will empowering and educational actually empower the public depends on the quality of the information drug companies are willing to or are required to provide. Patients are empowered only to the extent that they receive complete, accurate, impartial and reliable information about their various treatment options. Critics of DTCA maintain that the advertising is not designed to provide information, but rather to boost pharmaceutical sales.<sup>89</sup> Evidence from systematic reviews of ad content information and the regulatory history in the US and New Zealand consistently show poor information quality. Furthermore, information integral to informed treatment choice, such as the likelihood of success, other available options, and cost, was often lacking.<sup>90</sup> For example, researchers in California analyzing the educational content of 320 US magazine ads found that 90% failed to mention the likelihood of treatment success, 80% made no mention of other helpful activities (such as diet or exercise), 70% did not mention causes or risk factors for the treated condition or other treatments, and 60% omitted information about how the drug works. Similarly, a content analysis of ads in 10 leading

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<sup>85</sup> Reshma Jagsi, “Conflicts of Interest and the Physician-Patient Relationship in the Era of Direct-to-Patient Advertising” (2007) 25 *Journal of Clinical Oncology* 902 at 904.

<sup>86</sup> CanWest’s Charter Challenge on Prescription Drug Advertising: A Citizens’ Guide, online: Women and Health Protection, June 2006 at 4 <[http://www.whp-apsf.ca/pdf/charter\\_challenge\\_en.pdf](http://www.whp-apsf.ca/pdf/charter_challenge_en.pdf)>.

<sup>87</sup> Reshma Jagsi, “Conflicts of Interest and the Physician-Patient Relationship in the Era of Direct-to-Patient Advertising” (2007) 25 *Journal of Clinical Oncology* at 903.

<sup>88</sup> Colin Meek, “Direct-to-Consumer Advertising of Prescription Medicines: A Review of International Policy and Evidence” (2001) *Royal Pharmaceutical Society of Great Britain* at 7.

<sup>89</sup> *Supra* note 2 at 3..

<sup>90</sup> *Supra* note 2 at 4..

US magazines found that nearly 90% “described the benefits of a medication in vague, qualitative terms,” failing to provide evidence to support their claims.<sup>91</sup> Of course, Michael would argue that such failings could be corrected through a more rigorous and 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 practice.

Another advantage of DTCA is the potential for improved awareness and use of prescription drugs in areas of underutilization. Evidence suggests that DTCA is effective in increasing increases drug utilization, 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 socioeconomic status, who are often not reached through public health campaigns.<sup>92</sup> In addition to encouraging patients to seek medical advice, DTCA may also cause patients to feel increased confidence and control while interacting with their physicians.<sup>93</sup> 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.<sup>94</sup> Critics of these arguments point to the fact that DTCA does little to make the public aware of new drugs, with 40% of annual DTCA spending invested into only ten drugs.<sup>95</sup>

#### *Disadvantages of DTCA*

The disadvantages of DTCA rest primarily in concerns about increased utilization given the risks associated with prescription drug consumption and with the concomitant impact on health care budgets, particularly if the increased drug utilization has little tangible benefit in terms of health outcomes.

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<sup>91</sup> Mintzes, *supra* note 12 at 25.

<sup>92</sup> Elizabeth Murray *et al.*, “Direct-to-Consumer Advertising: Public Perceptions of Its Effects on Health Behaviours, Health care, and the Doctor-Patient Relationship” (2004) 17 *Journal of the American Board of Family Practice* 6 at 13.

<sup>93</sup> *Ibid.* at 14.

<sup>94</sup> R.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.othman

<sup>95</sup> Mintzes, *supra* note 12 at 26.

Prescription drugs can have significant safety concerns. For example, in 2004, Merck had to pull its drug Vioxx off the market, once popular for the treatment of pain and inflammation, after studies showed it doubled patients' risk of myocardial infarction and stroke after 18 months of use. This occurred after the drug had been sold for five years and used by more than 20 million people.<sup>96</sup> Increased drug use may lead 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.<sup>97</sup> 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 least risky; therefore, pregnant women, children, the elderly and individuals with co-morbidities are commonly excluded from the trial process. It is thus problematic when increased prescribing occurs among these untested groups.<sup>98</sup>

Furthermore, there is concern around the *types* of prescription drugs that tend to be advertised (and therefore increasingly used). Drugs with proven benefits, no competitors, or well-established cost-effectiveness would not likely 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, and they are often costlier. Furthermore, little may be known about rare or long-term risks associated with these products.<sup>99</sup> For example, AstraZeneca spent \$1 billion US marketing Nexium, a drug used to treat gastric reflux, to the American public. Generic omeprazole

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<sup>96</sup> Jerry Avorn, "Dangerous Deception: Hiding the Evidence of Adverse Drug Effects" (2006) 355 *New England Journal of Medicine* 2169 at 2169.

<sup>97</sup> 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 drug reactions. *Suprasupra* note 2.

<sup>98</sup> 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 5 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. Silversides, *supra* note 4 at 3-4.

<sup>99</sup> 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 drug reactions. Women and Health Protection, *supra* note 6, at 1.

would have achieved results comparable to Nexium, at a significantly reduced cost.<sup>100</sup> Therefore, 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 that are likely to be increasingly prescribed if DTCA policy is liberalized.<sup>101</sup>

Opponents of DTCA particularly emphasize its pernicious effects on cost and cost-effectiveness. Spending on prescription drugs is the fastest-rising health care expense in the US and in Canada. Critics of DTCA argue that this rise in pharmaceutical costs may be an inefficient use of valuable health care resources.<sup>102</sup> 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.<sup>103</sup> If DTCA information is inaccurate, or leads to inappropriate drug consumption, then DTCA increases health care costs without (substantially) improving health outcomes.<sup>104</sup> The mission of drug companies (and indeed their corporate duty) is unsurprisingly to make a profit, and they expect to get a return for the tens of billions of dollars they invest in marketing strategies like DTCA. Evidence shows that they get these returns,<sup>105</sup> and that it is patients (and in public health care systems, taxpayers) who foot the bill in terms of higher drug prices.<sup>106</sup> None of this of course is a problem if the additional funds are worth it in terms of improved health outcomes, but there is little or no evidence that this is the case. But in a constitutional challenge this approach to policy is turned on its head and instead if there is some benefit, however small, government is forced to provide evidence eliminating alternative regulatory regimes and showing at minimum a reasonable basis for the one under challenge.

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<sup>100</sup> *Supra* note 2 at 5. <[http://www.whp-apsf.ca/pdf/charter\\_challenge\\_en.pdf](http://www.whp-apsf.ca/pdf/charter_challenge_en.pdf)>.

<sup>101</sup> Gregory A. Abel et al. “Direct-to-Consumer Advertising in Oncology” (2006) 11 *The Oncologist* 219.

<sup>102</sup> See Harlan M. Krumholz & Joseph S. Ross, “Relationships with the drug industry: More regulation, greater transparency” (2009) 338 *BMJ* b211; Meek, *supra* note 77; Marcia Angell, “Relationships with the drug industry: Keep at arm’s length” (2009) 338 *BMJ* b222.

<sup>103</sup> *Supra* note 2 at 5..

<sup>104</sup> Murray, *supra* note 85 at 17..

<sup>105</sup> Common sense also dictates that pharmaceutical companies would not continue to spend billions of dollars on DTCA if they were not receiving a return for their investment.

<sup>106</sup> Angell, *supra* note 93. Abel, *supra* note 7 at 220-221.

In addition to the major concerns about the impact of over-utilization of medications, another more abstract concern relates to “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.”<sup>107</sup> Advertisements may seek to convince patients that they have chronic disorders which require persistent drug treatment.<sup>108</sup> Furthermore, DTCA often directs people towards pharmaceutical solutions for problems that are of social or lifestyle origin, and could be treated with non-pharmaceutical means such as diet or exercise. For example, people may be prescribed high blood pressure medication when the same benefit could be achieved through weight loss. 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 pharmaceutical solutions.<sup>109</sup>

Another abstract concern is the potentially negative effect on the doctor-patient relationship. A study by Robinson *et al.* showed that most physicians viewed DTCA negatively, in particular due to as the promotion of biased medical information, increased visit length and inefficiency, and the increase of inappropriate prescriptions.<sup>110</sup> Other evidence found 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.<sup>111</sup> 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.

## VII. Conclusion and the Limitations of DTCA Evidence

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<sup>107</sup> Dominick L. Frosch *et al.*, “Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising” (2007) 5 *Annals of Family Medicine* 6 at 10.

<sup>108</sup> Angell, *supra* note 93.

<sup>109</sup> Meek, *supra* note 77 at 51 and *supra* note 2 at 4. .

<sup>110</sup> Andrew R. Robinson *et al.*, “Direct-to-Consumer Pharmaceutical Advertising: Physician and Public Opinion and Potential Effects on the Physician-Patient Relationship” (2004) 164 *Arch Intern Med* 427 at 428.

<sup>111</sup> Murray., *supra* note 84 at 513.,

Overall, it is apparent from this brief review of the advantages and disadvantages of DTCA that arriving at the appropriate regulatory solution is not a straightforward issue. One thing that is clear, however, is the gap in the evidence on DTCA. Rosenthal, from the Harvard School of Public Health, explains that 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 not of the positive or negative effects of DTCA on public health or welfare but of its effects on consumer awareness, attitudes, perceptions and self-reported behaviour. To date no published analysis has established whether DTCA stimulates new utilization 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.<sup>112</sup>

Mintzes also acknowledges the gaps in the available research: “there are no direct analyses of health effects, and few studies have used methods that allow them to assess effects on behaviour.”<sup>113</sup>

In *RJR-MacDonald*, the Supreme Court was critical of the government's lack of evidence on less impairing alternatives, such as informational or brand preference advertising for tobacco products. The DTCA evidence tends to explore the advantages and disadvantages of DTCA generally, rather than addressing them within the various regulatory options. For example, there are studies exploring whether advertising leads to increased rates of prescription. It would be difficult for government to establish minimal impairment on this evidence. As in *RJR-MacDonald*, it would be open for a court to question whether a less intrusive regulatory scheme allowing informational advertising – providing a drug name and the condition it is intended to treat without any representations as to efficacy or lifestyle implications – would also result in higher levels of prescriptions. In his affidavit in the CanWest challenge, Michael mentions that other expert opinions in the proceedings ignore the question of whether there are regulatory

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<sup>112</sup> Meredith B. Rosenthal et al., “Promotion of Prescription Drugs to Consumers” (2002) 346 *The New England Journal of Medicine* 7 at 498-505.

<sup>113</sup> *Supra* note 12 at At 27.

options other than a complete ban available to governments that could maximize the benefits of DTCA while minimizing its adverse effects.<sup>114</sup>

A difficulty with the current DTCA evidence is that experts have predicted what they believe will be the impact of DTCA in Canada based on the experience of other jurisdictions. However, there are significant differences in Canada's population, culture, health care system and political climate. As described above, for example, New Zealand's public pharmaceutical scheme impacts the effects of DTCA. As was evident in *Chaoulli*, courts may struggle with the application of social science evidence from other jurisdictions and its transferability to Canada.<sup>115</sup> Furthermore, Canadians are already subject to a certain amount of DTCA (some say a very high amount) through our exposure to American media.<sup>116</sup> Thus, US DTCA may already have a significant impact on Canadian consumers – though it is difficult to determine the extent of its influence. This uncertainty makes it even more difficult to predict the potential impact of changing the regulation of DTCA in Canada.

A further problem with the evidence in the DTCA claim and similar challenges (tobacco, private insurance, etc.) is that social scientists are not lawyers and thus generally do not understand that the burden lies upon the government to provide evidence justifying its policy choices. Instead, they frequently approach research questions 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 none they assume the status quo will stand. This is not how a court approaches a section 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 would have a negative health or safety effect, it should not be implemented, even in the absence

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<sup>114</sup> *Supra* note 3.

<sup>115</sup> See generally Colleen M. Flood, Mark Stabile & Sasha Kontic, "Finding Health Policy 'Arbitrary': The Evidence on Waiting, Dying and Two-Tier Systems" in Flood *et al.*, *supra* note 64.

<sup>116</sup> Michael R. Law, Sumit R. Majumdar & Stephen B. Soumerai, "Effect of illicit direct to consumer advertising on use of etanercept, mometasone, and tegaserod in Canada: controlled longitudinal study" (2008) 337 *BMJ* a1055.

of definitive evidence.<sup>117</sup> In my conversations with researchers they are astonished to find out that courts do not necessarily approach policy issues in the same way.

In conclusion, Michael 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. Michael, for example, advocates for the implementation of less severe regulatory options.<sup>118</sup>

It seems to me that he is likely to be on the winning side of this debate, given the Supreme Court's evidentiary requirements under s. 1. In particular, the government may have difficulty establishing why they did not select less stringent legislative standards under the minimal impairment stage of the *Oakes* analysis. In my view, the court is likely to find that a less intrusive regime *theoretically* could achieve the government's goal related to health and safety.

Although I believe that Michael will be on the winning side, I do not necessarily think his position should prevail. Given all the evidence I have reviewed, I believe we should keep the present regulatory restrictions. I am not convinced that Canada should abandon its present regulatory restrictions. Patient education and empowerment through DTCA will never meaningfully empower patients without robust regulation and subsequent enforcement thereof against multinational interests with enormous resources. Advocates for liberalization frequently assume that such re-regulation is possible. However, public choice theory and the actual experiences of countries with liberal DTCA regimes (US and New Zealand have not implemented and/or enforced nuanced regulatory schemes that empower patients with information) ) both suggest that, given the political interests of governments and the situational power of Canada's global Rx&D companies, that the prospect of such nuances are is theoretical only.

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<sup>117</sup> Affidavit of Joel Lexchin, *CanWest MediaWorks Inc. v. Attorney General of Canada*, Ottawa 05-CV-303001PD2 (Ont. Sup. Ct. Just.)(Affidavit of Joel Lexchin), This principle originated in Europe in the early 1970s, gaining broad recognition at the 1992 United Nations 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, *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>>.

<sup>118</sup> *Supra* note 3.

