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# Direct-to-Consumer Advertising of Pharmaceuticals on Television: A Charter Challenge

*Elvina C. Chow\**

## I. INTRODUCTION

Traditionally, the advertising of prescription drugs through television has been directed to medical professionals. Doctors and pharmacists act as the intermediary between pharmaceutical companies and the ultimate consumers, the public. Recently, pharmaceutical and media companies have challenged provisions in the *Food and Drug Act (FDA)*,<sup>1</sup> which prohibit direct-to-consumer advertising (DTCA) of drugs on television, as a violation of their freedom of expression.<sup>2</sup> Media and pharmaceutical companies contend that their commercial interest is at a competitive disadvantage to comparable American businesses since, unlike the latter, Canadian companies cannot sell advertising space to pharmaceutical companies or advertise their brand to increase awareness of their drug directly to consumers.

The federal government, on the other hand, argues that the objective of the restrictions on DTCA stems from the government's need to protect public health and to prevent Canadians from being misled by erroneous information. Additionally, the legislature is hesitant to lift the current restrictions on drug advertising on television due to the current situation in the U.S., where pharmaceutical advertising has exorbitantly driven up healthcare costs.<sup>3</sup> However, their objectives are aggravated by their lower level of control over cross-border drug advertisements, which stream on American cable networks into Canadian homes. If the ban on DTCA is lifted in Canada, it is predicted that the pharmaceutical industry would spend approximately \$500 million on pharmaceutical advertisements in the first year. However, it is also estimated to lead to at least \$1.1 billion in extra drug sales in that

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<sup>1</sup> RSC 1985, c. F-27.

<sup>2</sup> *Canwest MediaWorks Inc. v. Canada (Minister of Health)*, 2008 FCA 207, 382 N.R. 365.

<sup>3</sup> Barbara Mintzes, Steve Morgan & James M. Wright, "Twelve Years' Experience with Direct-to-Consumer Advertising of Prescription Drugs in Canada: A Cautionary Tale", online: (2009) 4:5 PLoS ONE e5699 <<http://clinicaltrials.ploshubs.org/article/info:doi/10.1371/journal.pone.0005699>>.

first year.<sup>4</sup>

The Supreme Court of Canada has consistently wrestled with the conflict between legislation designed to protect consumers' health and the constitutional guarantee of the fundamental freedom of expression.<sup>5</sup> This paper investigates the justification for the current regulatory framework for pharmaceutical advertising on television. Aware that the provisions in the *FDA* are able to withstand *Charter of Rights and Freedoms*<sup>6</sup> (*Charter*) scrutiny, several possible policy initiations are nevertheless proposed.

The paper is divided into five separate sections. Having first introduced DTCA of pharmaceuticals on television in Section I, I will now turn to a more comprehensive examination of DTCA in Canada in Section II. Next, I will fully examine the nature of expression characterized in drug advertising in Section III, before delving into the main argument of the paper, a Section One challenge *Charter* challenge in Section IV. Finally, I conclude that the current prohibitions against DTCA of drugs on television are justified and will provide a few recommendations in Section V.

## II. DTCA IN CANADA

The *FDA* currently enables the federal government to regulate prescription drug advertising on television with the purpose of protecting public health and safety.<sup>7</sup> Restrictions on drug advertisements on television fall under section 3(1) of the *FDA* which 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."<sup>8</sup> More specifically, Schedule A contains 46 diseases, disorders or abnormal physical states, for which all diseases listed in Schedule A require a medical practitioner's intervention to gain access to prescription drugs treating those illnesses.<sup>9</sup>

The restrictions were further broadened to cover all prescription drugs listed in an additional appendix known as Schedule F.<sup>10</sup> The rationale is that people who are seriously ill from diseases set out in Schedule A, and who require prescription drugs set out in Schedule F, may be vulnerable to the unscrupulous marketing of prescription medicines.<sup>11</sup> Therefore, the federal government has relied on doctors and pharmacists to provide consumers with reliable unbiased information.

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

<sup>5</sup> *Supra* note 3.

<sup>6</sup> *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c. 11.

<sup>7</sup> *Supra* note 4 at 1.

<sup>8</sup> *Supra* note 1, s. 3(1).

<sup>9</sup> *Ibid.*, Sch. A.

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

<sup>11</sup> *Supra* note 4 at 1.

The *FDA* defines advertising as “any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.”<sup>12</sup> Canada’s current regulatory scheme permits two types of pharmaceutical advertisements: help-seeking and reminder advertisements. Help-seeking advertisements do not mention a specific brand, but discuss a condition and suggest viewers or readers to ask their doctors for more information. Reminder advertisements contain only the brand name and cannot include health claims or hints about the product’s use, such as a listing of the drug’s medical treatments and risks.<sup>13</sup>

In terms of regulation, Health Canada is the national regulatory authority for DTCA. However, the ultimate responsibility for the enforcement of the *FDA*, including violations of drug advertising on television, has been entrusted to three separate agencies:

1. The Code of Marketing Practices Committee of Rx&D, the public association representing 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.<sup>14</sup>

The Rx&D standardizes drug advertising on television by requiring its members to follow its *Code of Ethical Practices*.<sup>15</sup> The ASC reviews and pre-clears prescription drug and non-prescription drug advertising on television.<sup>16</sup> The PAAB, in conjunction with the ASC, act as law enforcement for violations against the *FDA*. If the agencies find an advertisement that is inconsistent with the legislation, the company is asked to withdraw the advertisement and/or replace it with another that complies with the law.

Contraventions of pharmaceutical television advertisements are handled directly by Health Canada. Generally, the complainant receives a letter within 30 days acknowledging the complaint and notifying that the matter is currently being investigated. However, a timeline is not provided, and the complainant is not consulted during the investigation. It is unusual for a complainant to receive a letter regarding the decision in less than six months after filing a complaint.<sup>17</sup>

Additionally, Health Canada’s Health Product and Food Branch Inspectorate may employ “a wide array of enforcement mechanisms including fines, injunctions, prosecution and imprisonment, forfeiture, public warning or advisory, and letters to trade and regulated parties.”<sup>18</sup>

<sup>12</sup> *Supra* note 1, s. 2.

<sup>13</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 7.

<sup>14</sup> *Ibid* at 9.

<sup>15</sup> *Ibid*.

<sup>16</sup> *Ibid*.

<sup>17</sup> *Ibid* at 11.

<sup>18</sup> *Ibid*.

Health Canada also considers a number of factors when determining enforcement, including “risks to health and safety, the company’s compliance history, pre-meditation, likelihood of recurrence, expected effectiveness, effects on public confidence in Health Canada, and the department’s priorities and available resources.”<sup>19</sup> Unlike the United States Food and Drug Administration, Health Canada has no personnel dedicated to the enforcement of drug advertising regulations.<sup>20</sup> This perhaps explains why penalties have not been imposed on any pharmaceutical companies for illegal advertising activities since 1978.<sup>21</sup>

While DTCA is subject to strict regulatory limits in Canada and in most countries, the United States and New Zealand are the only two nations with legal DTCA of pharmaceuticals on television. Their experiences serve as a useful comparator to the situation in Canada, and will be used for analysis in the following section of this paper.

### (a) The Effect of Cross-Border Drug Advertising on Television

For the purposes of this paper, I will mainly examine the effect of cross-border American prescription drug advertisements rather than New Zealand’s effect due to its geographic proximity and likelihood of spill-over in Canada.

American pharmaceutical commercials are able to name the brand of the drug and the drug’s targeted use as well as give specific details of the risks involved when taking the medication. American drug advertisements on television may also direct consumers to other sources of information such as websites or toll-free numbers. This is in contrast to Canada’s regulatory framework where drug advertisements are only allowed to mention the name or the condition it treats, but are prohibited from providing both.<sup>22</sup>

Canadians, through cable television, receive many of these prohibited advertisements from American television stations. The cross-border effect has led to roughly 53% of Canadians to believe that prescription drug advertising is legal, even though it is restricted by the *FDA*.<sup>23</sup> This had led many Canadians to believe that DTCA is permitted in Canada and others to criticize that the restrictions on DTCA is ineffective. Moreover, the spill-over of American drug advertisements dilutes the federal government’s objective to protect Canadians. The American Food and Drug Administration does not require the pre-clearance of drug advertisements before they are released, thus leaving most American advertisements on television unregulated.<sup>24</sup> Arguably, the Canadian regulatory framework becomes ineffective when American television advertisements are readily available on Canadian television.

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<sup>19</sup> *Ibid.*

<sup>20</sup> *Ibid.*

<sup>21</sup> Standing Committee on Health, *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs* (Ottawa: House of Commons, 2004) at 9.

<sup>22</sup> *Supra* note 13 at 8.

<sup>23</sup> “Ipsos-Reid Survey Shows Strong Public Support for Direct-to-Consumer Advertising of Prescription Medications”, *Canada NewsWire, News Release* (31 January 2002).

<sup>24</sup> *Ibid.*

### III. FREEDOM OF EXPRESSION

Critics of the current regulatory DTCA framework have challenged the restrictions as a limitation on freedom of expression. Though it is possible that other *Charter* challenges can be made, a detailed discussion of all possible *Charter* challenges is beyond the scope of this paper. This section will describe the courts' perspectives on commercial expression before delving into a constitutional analysis on a potential violation of freedom of expression.

The guarantee of freedom of expression is set out in section 2(b) in the *Charter* as follows: "freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication."<sup>25</sup> To start, it is necessary to define the term "expression" as it applies to pharmaceutical advertisements on television. The expression characterized in advertisements is generally known as commercial expression. Pure commercial expression's primary purpose is to increase profits.<sup>26</sup> A claim against the federal prohibitions against DTCA of medications on television may be challenged under commercial expression.<sup>27</sup>

The Supreme Court of Canada first addressed the issue of commercial expression under section 2(b) in the leading case, *Ford v. Québec (Attorney General)*.<sup>28</sup> The case involved challenges against the sole use of French in commercial advertising. The Court discarded "the view that commercial expression serves no individual or societal value in a free and democratic society [. . .] undeserving of any constitutional protection."<sup>29</sup> Thus, the judgment cemented the idea that freedom of expression was not confined to political expression but also extended to expression made for commercial purposes.

According to Professor Hogg, an expert in constitutional law, commercial expression is guaranteed for two reasons. Firstly, commercial expression literally derives from the definition of the word "expression" and as such, makes a contribution to the "marketplace of ideas."<sup>30</sup> Secondly, many intrinsic political, economic and social ideas are inherent in commercial speech. Thus, commercial expression including drug advertisements on television is constitutionally protected.

The Supreme Court of Canada, since the late 1980s, has consistently ruled that commercial expression is an activity protected under section 2(b) of the *Charter*. The main rationale for protecting commercial expression has been the reliance of a free-market economy consisting of informed consumers, and thus, the protection of the consumer.<sup>31</sup> The Court has also granted considerable protection to expression through section 2(b) of the *Charter*. This includes the protection of the right to

<sup>25</sup> *Supra* note 6, s. 2(b).

<sup>26</sup> Robert J. Sharpe, "Commercial Expression and the Charter" (1987) 37 UTLJ 229 at 230.

<sup>27</sup> *Supra* note 2.

<sup>28</sup> [1988] 2 S.C.R. 712, 54 D.L.R. (4th) 577.

<sup>29</sup> *Supra* note 28 at para. 59.

<sup>30</sup> Peter W. Hogg, *Constitutional Law of Canada: Student Edition 2007* (Toronto: Carswell, 2007) at 418.

<sup>31</sup> Keith Dubick, "Commercial Expression: A "Second-Class" Freedom?" (1996) 60 Sask L Rev 91.

receive and impart information,<sup>32</sup> which arguably includes a consumer's right of access to health information from drug advertisements on television. This guarantee could thus be invoked to challenge federal restrictions on DTCA on drug advertisements on television given that the prohibitions limit the right of pharmaceutical manufacturers to directly inform the public, which restricts the public's access to information about their drugs. Therefore, federal restrictions on DTCA of drugs on television are vulnerable to a *Charter* challenge based on the freedom of expression guarantee in section 2(b).

### (a) Violation of Freedom of Expression

For a freedom of expression claim, the Supreme Court of Canada outlined a two-step test from the landmark case on expression, *Irwin Toy Ltd. v. Quebec (Attorney General)*.<sup>33</sup> To start, the court must question whether the plaintiff's activity falls within the protective scope of section 2(b). Any activity which conveys or attempts to convey meaning or expressive content falls within the protective scope of 2(b) unless it is violent.<sup>34</sup> By violent, the Supreme Court of Canada means physically aggressive-type of violence. Hence, threatening, silencing or intimidating speech, because it is not actually physically violent, is still within the scope of section 2(b).<sup>35</sup>

For commercial expression of DTCA of pharmaceuticals on television, the courts would ask whether drug advertisements on television communicating directly to consumers could be classified as an activity which conveys or attempts to convey meaning. As found in *Ford v. Québec (Attorney General)*, commercial expression clearly falls within the protective realm of section 2(b).<sup>36</sup> Based on the court's broad interpretation of the freedom of expression guarantee,<sup>37</sup> DTCA of medications on television would probably be found as a form of expression with substantive informational content and within the scope of section 2(b).

The courts, in the second step of the *Irwin Toy* test, then ask whether the purpose or effect of the challenged law is to restrict attempts to convey meaning. In this case, the challenged law is the regulatory framework of DTCA in Canada. The effect of the restrictions in the *FDA* prohibits pharmaceutical companies from producing advertisements that convey meaning directly to consumers. Additionally, Canadian media companies are prohibited from airing brand-name television advertisements that communicate directly to the public without a medical professional as an intermediary. The federal government, therefore, controls efforts to convey a meaning such as drug advertisements by directly restricting the content. Thus, the legislation entrenches upon the section 2(b) guarantee and a violation of freedom of

<sup>32</sup> Rhonda R. Shirreff, "For Them to Know and You to Find Out: Challenging Restrictions on Direct-to-Consumer Advertising of Contraceptive Drugs and Devices" (2000) 58 UT Fac L Rev 121 at 138.

<sup>33</sup> [1989] 1 S.C.R. 927, 58 D.L.R. (4th) 577 [*Irwin Toy*].

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

<sup>35</sup> *R v. Keegstra*, [1990] 3 S.C.R. 697, [1991] 2 W.W.R. 1.

<sup>36</sup> *Supra* note 28.

<sup>37</sup> *Supra* note 33.

speech is established.

#### IV. APPLYING THE OAKES TEST

Once a *Charter* violation has been established, the federal government bears the onus to justify its restrictions pursuant to section one of the *Charter*. The courts employ the test set out in *R. v. Oakes*<sup>38</sup> to establish a whether a limitation is justified under section one.

For the *Oakes* test, the government must first demonstrate that the objective of the legislation is “pressing and substantial” to warrant the restriction, in this case, on freedom of expression. Afterwards, the courts will assess the means used to override the constitutional right and whether the means used satisfy three proportionality criteria. Primarily, there must be a rational connection between the reason for the *Charter* override and the objective of the legislation. Second, the means must minimally impair the right in question. And finally, the effects of the limiting measure must be proportional to their objective. In general, a rule of thumb is that the more deleterious the effects, the more important the objective must be.

##### (a) Is The Legislative Objective Pressing And Substantial?

The federal government may suggest three separate objectives as pressing and substantial to warrant overriding freedom of expression of DTCA of pharmaceuticals on television: in the interest of safety and public health, protecting Canadians from misleading information, and reducing healthcare costs.

##### (i) Safety and Public Health

The broad objective of protecting the public’s health through restricting DTCA of medications on television was first identified with the *FDA* in the case *Ciba-Geigy Canada Ltd. v. Apotex Inc.*<sup>39</sup> As Gonthier J. explains:

Prescription drugs contain medicinal substances which, while beneficial in small doses, can be harmful or even fatal to health in larger quantities. It is then quite natural for society to limit access to such products as a means of protecting the individual. The advisability of use is determined by a professional, the physician or in some cases the dentist, and distribution is the responsibility of a specialized “merchant”, the pharmacist.<sup>40</sup>

For this reason, the federal government is justified in intervening between consumers and pharmaceuticals, especially in the context of the media. The media’s widespread influence can greatly affect patient’s demand for dangerous prescription drugs.

In *R. v. Thomas Lipton Inc.*,<sup>41</sup> Lipton contravened section 3 of the *FDA* by directly advertising its margarine in magazines as a preventative treatment for heart disease, which is a disease listed in Schedule A. Given that margarine is readily available without the need of a doctor’s consent, the danger was that consumers

<sup>38</sup> [1986] 1 S.C.R. 103, 26 D.L.R. (4th) 200 [*Oakes*].

<sup>39</sup> [1992] 3 S.C.R. 120, 95 D.L.R. (4th) 385.

<sup>40</sup> *Ibid* at para. 103.

<sup>41</sup> [1989] 26 C.P.R. (3d) 385, 51 C.C.C. (3d) 104 (Ont. Prov. Ct.).



would buy vast amounts of margarine to medicate themselves rather than speaking to a healthcare professional about their condition. The Ontario Superior Court accepted this as a genuine danger, given the magnitude and seriousness of heart disease. Likewise, the courts may also accept a similar argument that pharmaceutical advertising to consumers directly on television may be a potential hazard to safety and public health as consumers may self-diagnose themselves rather than seek medical attention.

However, there is a notable difference between the facts in *R. v. Thomas Lipton Inc.* and the restrictions prohibiting DTCA of drugs on television. Margarine is readily available in supermarkets without needing a signed prescription from a medical professional. Conversely, prescription medications require a doctor's intervention before a pharmacist may distribute the drug. The danger of allowing DTCA of medications on television may not be as real of a threat as in *R. v. Thomas Lipton Inc.* given that doctors and pharmacists still act as an intermediary between prescription drugs and consumers.

Additionally, in the Supreme Court of Canada case, *RJR-MacDonald Inc. v. Canada (Attorney General)*,<sup>42</sup> McLachlin J. mandated that the purpose of the legislation must be "accurately and precisely defined" so that its importance may be properly evaluated. Overstating the legislation's objective, such as the case at hand of protecting public health in general, may result in the *FDA* being declared unconstitutional for its broad breadth.

### **(ii) Misleading Information**

A stronger argument for the government would be that the DTCA restrictions are justified as a means to protect the public from misleading information. A similar argument was proposed by the Crown in *RJR-MacDonald Inc. v. Canada (Attorney General)*.<sup>43</sup> The Crown argued that tobacco companies were primarily motivated by profit and thus commercial manipulation of the public to entice consumers to try their products was a likely consequence. This objective was upheld by the Supreme Court of Canada.

The federal government could make a similar argument that pharmaceutical and media companies are motivated by profit and could easily influence the information in their drug advertisements on television to lead the public to believe it is targeted to a certain disease. For example, a Canadian television advertisement for Diane-35 was found to have raised safety concerns about the promotion of its unapproved use as a contraceptive and lack of information about its increased risks of blood clots.<sup>44</sup> Diane-35 was only approved as a treatment for severe acne users and not as a contraceptive in Canada. Yet, Berlex Canada Inc., the manufacturer, ran reminder advertisements suggesting otherwise as a promotional marketing strategy for the drug. Nevertheless, though commercial manipulation driven by profits is a genuine fear, in *RJR-MacDonald Inc. v. Canada (Attorney General)*, McLachlin, Sopinka and Major JJ. decided that "motivation to profit is irrelevant to the determination of whether the government has established that the law is reasonable or

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<sup>42</sup> [1995] 3 S.C.R. 199, 127 D.L.R. (4th) 1.

<sup>43</sup> *Ibid.*

<sup>44</sup> *Supra* note 3.

that it is justified as an infringement on freedom of expression.”<sup>45</sup>

**(iii) Rising Healthcare Costs**

The strongest argument the federal government can make in support for DTCA restrictions on drug advertisements on television is that the prohibition minimizes healthcare costs. The government’s concern is that lifting the ban will inevitably drive more consumers to request brand-name drugs seen on television from their physicians more often than their non-advertised generic counterparts. This has been the experience in the United States and is the main impetus to the government’s stance on the *FDA* restrictions.<sup>46</sup>

Additionally, new studies have been showing the same American trend of increased prescriptions of DTCA drugs occurring in Canada. In one Canadian study, patient requests for DTCA prescription drugs influenced physicians’ prescribing volume and choice. The results showed that doctors were pressured to fulfill the patient’s demand for the DTCA drug and thus increased prescribing volume of that drug.<sup>47</sup> This confirms results from a 2002 survey of over 1500 doctors in which 67% reported feeling pressured to prescribe DTCA drugs.<sup>48</sup> Given that the federal government subsidizes the healthcare system, healthcare costs will inevitably rise when more patients are asking for costlier medications rather than taking the less-expensive but equally effective generic versions of the same drug. The issue of whether cost-cutting objectives are pressing and substantial, such as the one at hand, will be further discussed in the following section.

**(b) Proportionality Analysis**

Assuming that the federal government passes the first stage of the *Oakes* test, the second stage of the *Oakes* test is called the proportionality step which is divided into three separate parts.

**(i) Is there a Rational Connection between the Legislative Objective and the Legislation?**

Assuming the objectives are found to be sufficiently pressing and substantial, the onus is on the federal government to show whether the government’s restrictions on drug advertising on television are rationally connected to the recognized

<sup>45</sup> *Supra* note 42 at para. 171.

<sup>46</sup> Barbara Mintzes et al, “Influence of direct to consumer pharmaceutical advertising and patients’ request on prescribing decisions: two site cross sectional survey” (2002) 324 *Brit Med J* 278.

<sup>47</sup> Barbara Mintzes et al, *An assessment of the health system impact of direct-to-consumer advertising of prescription medicines (DTCA). Volume IV: pills, persuasion and public health policies. Report of an expert survey on direct-to-consumer advertising of prescription drugs in Canada, the United States and New Zealand* (Vancouver: University of British Columbia Health Policy Research Unit, 2001).

<sup>48</sup> Carmela DeLuca, *Direct to consumer advertising of prescription medicines: assessing the impact of consumer directed drug advertisement and the legality of current prohibitions* (Toronto: University of Toronto Health Law and Policy Group, 2005).

objective.

Working in the government's favour is the courts' position to give deference to the legislature when analyzing policy objectives. As stated in *JTI-MacDonald Corp. v. Canada (Procureure générale)* regarding complex policy choices: "effective answers to complex social problems [. . .] 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>49</sup> Given that the objectives behind the restrictions on DTCA of pharmaceuticals on television are policy-driven, the courts will likely defer to the government.

#### (A) Safety and Public Health

The first objective the federal government may propose is that the prohibition on advertising prescription drugs to consumers directly on television is warranted because of public safety and public health concerns. The rationale behind this objective is that prescription drugs are more toxic than over-the-counter drugs and thus consumers must go to an informed medical professional for more information. The federal government is concerned that individuals experiencing illnesses which require medical attention will diagnose themselves and manage their conditions with drugs advertised on television without full information.

A corollary is that more heavily advertised drugs tend to be newer on the market, and given their relatively new age, less information is readily available to the public.<sup>50</sup> The danger is that approximately 20% of drugs that are recent in the marketplace are withdrawn from the marketplace altogether or have new black box warnings on its product pamphlet due to serious safety concerns found afterwards.<sup>51</sup> Additionally, evidence from a study conducted on reminder advertisements in Canada showed that many heavily-advertised drugs were subject to regulatory warnings of serious risks.<sup>52</sup> The danger is that if the restrictions are lifted it will prompt consumers to readily take brand-name drugs that are relatively more dangerous than generic alternatives. Thus, there is a serious public health concern that is rationally connected to consumers seeking medical advice from a medical professional rather than relying on advertisements seen on television.

With respect to public safety, the Supreme Court of Canada commented in *Rocket v. Royal College of Dental Surgeons (Ontario)* 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 ar-

<sup>49</sup> 2007 S.C.C. 30, [2007] 2 S.C.R. 610, 281 D.L.R. (4th) 589 at para. 41.

<sup>50</sup> Edward A.M. Gale, "Lessons from the glitazones: a story of drug development" (2001) 357 *The Lancet* 1870.

<sup>51</sup> Karen E. Lasser et al, "Timing of new black box warnings and withdrawals for prescription medications" (2002) 287 *JAMA* 2215.

<sup>52</sup> *Supra* note 3.

gues in favour of viewing its attempted compromise with some deference.<sup>53</sup>

Likewise, restricting consumers' direct access to information from drug advertisements on television may be rationally connected to protecting the public from potentially dangerous medications given the public's inability to evaluate competing claims from different drugs. As such, there is a rational connection between mandating that consumers seek more information from a medical professional and protecting public health.

A mitigating factor, nevertheless, is that regardless of whether potentially dangerous drugs are advertised directly to the public, consumers must still receive a doctor's consent for the pharmacist to prescribe the drug. The public must still bring up their request for the drug to their medical professional and the medical professional is under oath to provide accurate factual information to the patient about the medication. Therefore, if the government was concerned with protecting public safety, arguably a more effective though drastic solution would be prohibiting the dangerous drugs from the marketplace altogether.

Arguably, it is also unreasonable for the federal government to advise doctors to prescribe a drug cautiously because of its serious health risks, and then ignore the effects of persuasive advertisements on television that make the same medication look safe to use. Most pharmaceutical advertisements on television downplay safety information.<sup>54</sup> Coupled with evidence that physicians are more likely to prescribe advertised drugs requested by patients, this suggests that even with a medical professional acting as an intermediary, there is no guarantee that the viewer is protected. Thus, the connection between advertising drugs directly to the public and endangering public health is tenuous at best given that the dangerous medications in question are still available in the marketplace and doctors will readily prescribe them even with the current DTCA restrictions in place.

## (B) Misleading Information

The second objective that the federal government may propose is that the DTCA restrictions on pharmaceuticals on television are warranted because they prevent consumers from receiving misleading information. The government's position stems from conclusions made in the Committee on Health's report: "Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs." After months of research and hearings, the Committee on Health concluded that Canada should continue to limit DTCA of pharmaceuticals since lifting the restrictions will not result in accurate, unbiased information for consumers.<sup>55</sup>

However, this objective is unlikely to succeed. The courts have refused to use the standard of the "uninformed and naïve" person.<sup>56</sup> People are naturally critical, and thus do not need restrictive rules to protect them from advertising. Additionally, since the internet is highly prevalent in our culture today, the standard of the

<sup>53</sup> [1990] 2 S.C.R. 232, 71 D.L.R. (4th) 68 at para. 35.

<sup>54</sup> Joel Lexchin & Barbara Mintzes, "Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No" (2002) *Journal of Public Policy & Marketing* 194.

<sup>55</sup> *Supra* note 21 at 10.

<sup>56</sup> *Supra* note 42.

uninformed and naïve consumer should be used tentatively. It is possible that with access to the internet, almost anyone can obtain information on a certain drug trial or the risks and complications of a brand-name drug. Therefore, the federal government cannot use the most oblivious consumer as the benchmark onto which a constitutional analysis will be applied.

Furthermore, even in the event when a consumer is misled over a certain drug, the consumer must still visit a medical professional before receiving a prescription drug. Most prescription drugs cannot be administered without a doctor's note. Any potential brand-name drug user would have to first consult with a doctor who would likely explain potential risks and dangers and thus clear up any misunderstanding the consumer may have. Thus, by stating that restrictions on DTCA drug advertisements on television are needed to prevent consumers from being misled by pharmaceutical and media companies is perplexing.

Assuming that medical professionals are commercially independent from pharmaceutical profits, doctors and pharmacists would give unbiased information and advice about the drug to their patients. However, this view may be negated by the event when medical professionals are given benefits and even fees when promoting a certain brand-name drug. In this way, even if the government may protect consumers from newly advertised medications, it may still not completely protect the public since doctors may still prescribe these drugs for profit. Another minor point is that physicians may be swayed by a patient's demand for a particular drug in an effort to maintain or increase their client base.

Another mitigating factor is that American television drug advertisements are filtered into Canada and thus are not privy to *FDA* restrictions. Researchers found that cross-border advertising from the United States increased prescribing of a minimally effective drug with a poor safety profile<sup>57</sup> and subsequently the drug was withdrawn from the marketplace.<sup>58</sup> This, arguably, leads to an ineffective Canadian regulatory framework since the objective of the restrictions can be circumvented by companies who have an American presence. Thus, the rational connection of restricting DTCA to protect Canadians from being misled is tenuous at best.

### (C) Rising Healthcare Costs

The strongest objective that the federal government may propose is that restrictions are warranted since advertising drugs directly to consumers will drive an increase in healthcare costs. The assumption is that consumers will ask for brand-name drugs rather than their less expensive generic counterparts, which will in turn promote more visits to the doctor thereby burdening federal resources.<sup>59</sup> Both

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<sup>57</sup> B.W. Evans et al, "Tegaserod for the treatment of irritable bowel syndrome and chronic constipation", (Review) online: (2009) 4 Cochrane Database System Reviews <<http://onlinelibrary.wiley.com/doi/10.1002/14651858.cd003960>>.

<sup>58</sup> US Department of Health and Human Services, "Zelnorm (tegaserod maleate) Information" (30 April 2009) online: U.S. Food and Drug Administration <<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103223.htm>>.

<sup>59</sup> Canadian Pharmacists Association, "Position Statement on Direct-to-Consumer Advertising (DTCA)" (2001) online:

Health Canada and the House of Commons Standing Committee on Health argue that because of the genuine concern of rising healthcare costs, the federal government should continue to limit DTCA.<sup>60</sup>

Conversely, proponents for lifting DTCA restrictions argue that it is possible that DTCA of drug advertisements on television may actually reduce healthcare spending in the long run. If advertisements are allowed to list the symptoms of certain conditions, an ensuing visit to the doctor could mean an early diagnosis of a disease. Arguably, treatment of that same illness at a later stage would be more expensive. However, there is no documented evidence for this. Nevertheless, there has been documented evidence that removing DTCA restrictions increases healthcare costs. A study comparing French-speaking and English-speaking Canadian residents showed that DTCA advertising leads to higher healthcare costs due to increased prescribing of a brand-name drug.<sup>61</sup> Therefore, the federal government has evidence proving a rational connection between reducing healthcare spending and restrictions on DTCA.

Notably, the Supreme Court of Canada suggests that a cost-saving objective may indeed be a justifiable means of limiting a *Charter* right such as freedom of expression. In *New Brunswick (Minister of Health & Community Services) v. G. (J.)*,<sup>62</sup> the Supreme Court justified a breach of a *Charter* right by articulating the importance of restricting government spending. Professor Peter Hogg, a leading constitutional law expert, proposes that when the cost is excessive, the restriction of a *Charter* right may be permitted.<sup>63</sup>

### (ii) *Is the Legislation Minimally Impairing to the Right in Question?*

At the next step of the proportionality analysis, the court considers whether the impugned legislation, the restrictions on DTCA prohibiting pharmaceutical advertising on television, minimally impairs freedom of expression. This requires an examination whether the federal government has considered alternatives and less impairing means to achieve the same objective.<sup>64</sup>

If the government can show evidence that a less restrictive regime has proven to be unsuccessful in achieving the objective, the justification will be established. For example, in the dissent of *RJR-MacDonald Inc. v. Canada (Attorney General)*, the four dissenting judges found evidence that the current advertising regime of tobacco products was the result of an intensive twenty-year period of experimentation with less intrusive measures.<sup>65</sup> Accordingly, the dissenting judges would have

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<[http://www.pharmacists.ca/content/about\\_cpha/Who\\_We\\_Are/Policy\\_Position/pdf/dtca.pdf](http://www.pharmacists.ca/content/about_cpha/Who_We_Are/Policy_Position/pdf/dtca.pdf)>.

<sup>60</sup> *Supra* note 21.

<sup>61</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 *Brit Med J* 550.

<sup>62</sup> [1999] 3 S.C.R. 46, 177 D.L.R. (4th) 124.

<sup>63</sup> Peter W. Hogg, *Constitutional Law of Canada, 2001 Student Edition* (Toronto: Carswell, 2001) at 755.

<sup>64</sup> *Supra* note 42 at 352.

<sup>65</sup> *Supra* note 42 at 307.

upheld the prohibitive legislation.

In the case at hand, restrictions on DTCA of drug advertisements in the media began in 1949,<sup>66</sup> and over the years, the regulatory framework of DTCA has been narrowed. Thus far, drug advertisements have been prohibited from advertising the name of the drug in conjunction with their treatment. Less restrictive measures have never been in place, but rather, more diseases and illnesses have been added to Schedule A making the current regime more restrictive than in the past. The federal government can argue that a less restrictive regime has been ineffective.

On several occasions, the courts have found that legislation restricting advertising failed the minimal impairment stage. For example, the Supreme Court of Canada held in *Ford v. Québec (Attorney General)* that the legislation violated section 2(b) and failed the test of minimal impairment.<sup>67</sup> Likewise, the Supreme Court of Canada decided in *Rocket v. Royal College of Dental Surgeons (Ontario)*<sup>68</sup> that the objective could be maintained with less restrictive advertising prohibitions. Furthermore, in *RJR-MacDonald Inc. v. Canada (Attorney General)*,<sup>69</sup> the majority of the Supreme Court held that the total ban on tobacco advertising failed because it did not minimally impair freedom of expression. To succeed, the government would need to demonstrate that a total ban would be the only means to achieve its objective. Since the government did not produce evidence suggesting otherwise, the legislation failed this stage of the analysis.

In a DTCA challenge, the federal government would have to show evidence defending its policy choice. It would have to demonstrate that other less impairing methods to freedom of expression cannot achieve the same objective. Other less intrusive methods such as unambiguous warnings on advertisements, mandatory pre-clearance of all prescription drugs, and mandatory waiting times between drug approval and campaign launch may be considered less impairing than the current regulatory framework. However, there is no social science evidence demonstrating that either of these methods would achieve the government's objective.

In terms of burden of proof, a complete ban on a form of expression is more difficult to justify than a partial ban. Arguably, the case at hand is a partial ban since advertising to consumers is still allowed but is mediated by medical professionals. A complete ban on advertising to consumers would be a complete prohibition of drug advertising in any media outlet. Given that over the years, the federal government has constricted DTCA of pharmaceuticals on television, it is highly likely that the courts will view this as the federal government experimenting with less intrusive measures. The current regulatory framework is the result of years of testing measures that were found to be inadequate to meet the government's objective. Only the current regulatory framework, therefore, can meet the government's objective. Therefore, it is highly likely that the legislation will pass the minimal impairment test.

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<sup>66</sup> Judy Z. Segal, "'Compliance' to 'Concordance': A Critical View" (2007) 28 *Journal of Medical Humanities* 81 at 90, online: <http://www.springerlink.com/content/ht44782548171533/>.

<sup>67</sup> *Supra* note 28.

<sup>68</sup> [1990] 2 S.C.R. 232, 71 D.L.R. (4th) 68.

<sup>69</sup> *Supra* note 42.

**(iii) *Is there Proportionality between the Limits on Expression and the Objective?***

Once the legislation passes the minimal impairment test, the courts consider the “sufficiently important” objective of the legislation against its potentially deleterious effects. The objectives of prohibiting DTCA of pharmaceuticals on television are aimed at protecting public safety and public health, preventing the public from being misled, and preventing an increase in healthcare spending. These objectives ultimately outweigh the deleterious effects of restricting DTCA of pharmaceuticals on television.

Relevant caselaw on freedom of expression suggests that this stage of the *Oakes* test is dependent on the nature of the expression. In *Thomson Newspapers Co. v. Canada (Attorney General)*, at issue was the publication of election polls close to the date of the election.<sup>70</sup> The nature of expression in *Thomson Newspapers Co. v. Canada (Attorney General)* was political and was found to violate the core of the expression guarantee. Additionally, in *RJR-MacDonald Inc. v. Canada (Attorney General)*, the dissenting judges found that tobacco advertising was motivated by profits.<sup>71</sup> The government produced ample evidence linking the sale of cigarettes to the decline in health of cigarette smokers. The judges ultimately decided that the destructive effects of tobacco advertising and the subsequent objective of protecting public health prevailed over the intrusive effects of violating the tobacco companies’ right to freedom of expression.<sup>72</sup>

In terms of DTCA of pharmaceuticals on television, the courts will take into account the nature of the expression. As characterized earlier, the expression in DTCA of pharmaceuticals on television is commercial. Unlike the expression in *Thomson Newspapers Co. v. Canada (Attorney General)*, commercial expression is not entitled to the same constitutional protection as political expression.<sup>73</sup> Similar to tobacco advertising in *RJR-MacDonald Inc. v. Canada (Attorney General)*, pharmaceutical advertising on television is profit-oriented.<sup>74</sup> The motive behind the promotion of drugs is to increase brand awareness in the marketplace which will ultimately increase sales. Both tobacco advertising and pharmaceutical advertising are forms of commercial expression. In *JTI-MacDonald Corp. c. Canada (Procureure générale)*, the Supreme Court observed that “the prohibited speech [of advertising] 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.”<sup>75</sup> Thus, given the similarity of drug advertising to tobacco advertising, it is highly likely that the courts will find drug advertising to be of low-value and thus not afforded as much constitutional protection as political expression.

<sup>70</sup> [1998] 1 S.C.R. 877, 159 D.L.R. (4th) 385 at 890.

<sup>71</sup> *Supra* note 42.

<sup>72</sup> *Ibid.*

<sup>73</sup> *Supra* note 33.

<sup>74</sup> *Supra* note 42.

<sup>75</sup> *Supra* note 49 at para. 94.



Regardless of the nature of expression, the Supreme Court has maintained that all forms of expression, unless violent, are constitutionally protected: “whether political, religious, artistic or commercial, freedom of expression should not be suppressed except where urgent and compelling reasons exist and then only to the extent and for the time necessary for the protection of the community.”<sup>76</sup> Therefore, even though pharmaceutical advertising on television is likely to be found to be of low-value, the courts will not strike down restrictions on DTCA without properly weighing the deleterious effects against the objectives.

One deleterious effect of the restrictions is the inability of consumers to access healthcare information pertinent to their healthcare choices. Proponents for a broader regulatory framework argue that DTCA of pharmaceuticals on television will likely lead to increased patient empowerment and autonomy through greater access to information. Direct drug advertising on television imparts more information to the public about available medications on the marketplace, thereby educating consumers of their choices.

However, the extent to which DTCA provides a public service by educating the public is dependent on the quality of content in the drug advertisements. Also, the educational component of the advertisements is reliant upon the pharmaceutical companies’ desire to release accurate and impartial information. However, studies from both New Zealand and the United States, the only two countries that currently allow DTCA of pharmaceuticals on television, have consistently demonstrated poor quality of content.<sup>77</sup> Information about likelihood of success, other options and costs of treatment were often absent from drug commercials.<sup>78</sup> Arguably, even if the restrictions are lifted, consumers are still not guaranteed that they will be receiving needed information from pharmaceutical companies.

Another deleterious effect of the restrictions on drug advertisements on television is the possibility for confusion from American advertisements. Advertisements originating from the United States are not privy to Canadian regulations and thus remain largely unregulated. There is currently an overflow of prescription drug television commercials into Canada from the United States. Given this, it is probable that the Canadian public will be misinformed about the brand-name drug promoted in American advertisements. Health Canada may counteract this effect by allowing pharmaceuticals to make standardized informative drug commercials. In this way, Canadian DTCA would provide a uniform unbiased informative outlet to the public.

An additional deleterious effect of DTCA restrictions is improved awareness and usage of medications. Studies have shown that disease awareness or drug awareness, effects of DTCA pharmaceutical advertising, lead to increased discussions with a doctor for specific conditions and illnesses.<sup>79</sup> Notably, these effects are widespread among various socioeconomic groups. This is particular important especially among patients of low socioeconomic status, who are arguably often not

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<sup>76</sup> *Supra* note 33.

<sup>77</sup> *Supra* note 54.

<sup>78</sup> *Supra* note 4 at 4.

<sup>79</sup> Abihilasha Mehta & Scott C. Purvis, “Consumer Response to Prescription Drug Advertising” (2003) 43 *Journal of Advertising Research* 194 at 194.

reached through public health campaigns.<sup>80</sup> Proponents for DTCA in Canada argue that the federal government should lift the restrictions in order to better serve vulnerable groups who are more likely to watch cable television than participate in mass public health initiatives. However, critics argue that the socioeconomic groups that are “likely to benefit” are mostly of low-income or are classified as the working poor. Arguably, these groups will probably be unlikely to afford the more expensive cable television notwithstanding the time to watch cable television while managing multiple jobs.

Finally, another deleterious effect is that the knowledge obtained from pharmaceutical advertisements may lead to improved public health by increasing appropriate consultations with doctors for undiagnosed health conditions. As patients become more empowered with more information, they will be more willing to take part in managing their illnesses in consultation with their doctor prompting greater satisfaction in the healthcare system.<sup>81</sup> Greater knowledge of a certain drug also leads to better patient involvement in treatment plans.<sup>82</sup> However, research shows that DTCA does little to make the public aware of all drugs available to the marketplace given that 40% of annual DTCA spending is devoted to only ten drugs.<sup>83</sup> Provided that only a small subset of prescription drugs are advertised, DTCA of pharmaceuticals on television will only increase appropriate consultations for *only* those limited number of drugs.

### (c) Assessing Objectives with Deleterious Effects

The federal government’s perspective assumes that the public cannot distinguish between factual and false claims. As such, the federal government has placed restrictions on pharmaceutical advertising on television to prevent the public from being misled in the name of preventing commercial manipulation. Furthermore, there is ample evidence demonstrating that many of the medications advertised on television have serious health warnings or are taken off the market altogether.<sup>84</sup> Thus, another objective of the government is to protect Canadians from dangerous drugs — a policy-oriented public health goal. Both objectives take for granted the standard of the average Canadian as an uninformed consumer. Since this consumer is incapable of viewing of viewing prescription drug advertisements on television critically and analytically, the federal government must therefore protect this vulnerable group.

However, both government objectives are mitigated by today’s current technology. Historically, it was difficult to access healthcare information unless patients visit their doctors. However, with today’s technological advances such as the

<sup>80</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>81</sup> *Supra* note 4.

<sup>82</sup> Ethan Cumbler et al, “Lack of patient knowledge regarding hospital medications” (2010) 5 *Journal of Hospital Medications* 83.

<sup>83</sup> *Supra* note 12.

<sup>84</sup> *Supra* note 3.

internet, patients have greater access to health information.<sup>85</sup> Therefore, today's patients are more informed and less deferential to their healthcare providers.<sup>86</sup> This is illustrated in a growing movement towards individual autonomy, as epitomized in current informed consent laws to medical treatment. Given that both of these objectives are mitigated, it is likely then that the deleterious effects of restricting DTCA of pharmaceuticals on television outweigh both objectives.

The federal government's strongest case is championing the objective of reducing healthcare costs. Lifting the restrictions on DTCA of pharmaceuticals on television will ultimately drive an increase in healthcare spending. Pharmaceutical advertising on television is the largest growing market in television advertising. Despite the illegality of DTCA in Canada, over \$90 million was spent on branded advertisements between 1995 to 2006.<sup>87</sup> Results from a comparative study between DTCA and non-DTCA environments show that increased DTCA advertising leads to more requests for advertised medicines and more prescriptions for them.<sup>88</sup> The government's concern is that if DTCA restrictions on pharmaceutical advertisements on television are lifted, conversations between patients and doctors will likely end with a prescription for a brand-name drug rather than a generic less-known pharmaceutical equivalent. There is recent strong evidence linking healthcare costs with DTCA of pharmaceuticals on television.<sup>89</sup> Additionally, the Supreme Court has consistently deferred to the legislature when assessing cost-cutting objectives.<sup>90</sup> In all likelihood, the restrictions on DTCA of drugs on television will likely stand since the objective greatly outweighs the deleterious effects.

## V. CONCLUSION

Evidence shows that DTCA of pharmaceuticals on television can and does cause harm. Firstly, most drug advertisements on television are promoting medications with severe health warnings and, in most cases, are later taken off the market. Secondly, most DTCA drug advertisements do not contain quality unbiased information. Most importantly, there is a direct correlation between drug advertising on television and healthcare costs. The federal government's strongest argument would be justifying the current regulatory framework under *FDA* as a means to lower these expenditures. As such, the restrictions on DTCA of prescription drugs on television would most likely withstand a *Charter* challenge given that the Supreme Court has deferred to the legislature in the past when analyzing cost-cutting objectives. The restrictions on DTCA of pharmaceuticals on television likely remain valid.

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<sup>85</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.

<sup>86</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>87</sup> *Supra* note 3.

<sup>88</sup> *Ibid.*

<sup>89</sup> *Ibid.*

<sup>90</sup> *Supra* note 62.

Nevertheless, there is undoubtedly a need for better enforcement with Canada's current regulatory framework. A recommendation would be to include active monitoring and eliminate conflicts within the *FDA*. To start, the federal government should adopt the Committee on Health's recommendation to eliminate reminder advertising since "any direct-to-consumer advertising, including reminder ads, could contribute to increased or inappropriate drug consumption."<sup>91</sup> Additionally, the federal government should review Canada's approach to cross-border television broadcasting. Currently, American drug advertisements containing illegal and often misleading content are allowed to be aired in Canada. This activity is inconsistent with the government's objectives. Hopefully, in this way, current policies will provide more of the type of accurate unbiased information Canadians need about prescription drugs.

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<sup>91</sup> *Supra* note 21.