Direct-to-Consumer Advertising in the Digital Age: The Impact of the Internet and Social Media in the Promotion of Prescription Drugs in Canada

by

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A thesis submitted in conformity with the requirements for the degree of Master of Laws

Graduate Department of the Faculty of Law

University of Toronto

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Abstract

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While a significant amount of research has been produced in Canada on direct-to-consumer advertising (DTCA) of prescription drugs in general, very little work has been undertaken specifically with regard to the role of social media and emerging Internet technologies. While Health Canada has reaffirmed that existing DTCA regulations apply to new Internet and social media technologies, there are several unique features of these technologies that make the application of existing regulations an uncertain process. Further, given the difficulties Health Canada has faced in directly regulating DTCA in traditional media, there is significant skepticism around whether government regulators have the resources or political will to effectively monitor new digital media. Consequently, independent third party oversight and industry self-regulation may play an important role in regulating digital channels. Finally, regulators should not simply be limited to regulating online DTCA; social media is equally available to government for use in health promotion.
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1 Introduction

Direct-to-consumer advertising (DTCA) of prescription drugs is prohibited in Canada, as in most developed countries; the only two countries that allow such advertising are the United States and New Zealand. However, in recent years there has been a significant shift in the interpretation of the laws banning DTCA, which has led to a growing volume of made-in-Canada advertising. Consequently, DTCA is becoming an increasingly controversial issue in Canada. Proponents of DTCA claim that the ban denies Canadians the right to access health information and that DTCA has the potential to improve health and save lives by encouraging consumers to recognize symptoms and seek medical care at an earlier stage.\(^1\) However, critics contend that DTCA may harm the public by promoting unnecessary and inappropriate use of prescription drugs and that it “fails to provide viewers with a balanced, complete and accurate appraisal of the range of available treatments and their contribution to therapy.”\(^2\)

While a significant amount of research and literature has been produced in Canada on the issue of direct-to-consumer advertising of prescription drugs in general, very little work has been undertaken specifically with regard to the role of social media marketing and emerging Internet technologies. While more and more research on the topic of pharmaceutical social media marketing is beginning to emerge, much of the knowledge base has, in fact, been developed by social media marketing firms and consultants with the aim of encouraging pharmaceutical companies to enter the social media arena. As such, there has been little research undertaken with respect to the actual policy implications of pharmaceutical social media marketing, and where it does exist, it tends to be US-centric. Therefore, this thesis also aims to examine the issue specifically in the Canadian context, and consider how the existing laws and regulatory framework in Canada translate into the social media sphere. To provide background for the discussion of the regulation of the Internet and social media, Chapter 2: Current Regulatory Framework in Canada begins with an overview of the general regulatory framework of DTCA in Canada as it applies to all forms of communication, followed by a discussion of how the unique aspects of social media may influence the distinction between advertising and other activities.

In recent years, social media sites such as Facebook, Twitter and YouTube have transformed the way that the world communicates. Companies from all sectors of the economy are scrambling to capitalize on the marketing and promotional opportunities offered by this new medium. However, the


\(^2\) ibid at 6.
pharmaceutical industry has been slow to jump on the bandwagon, largely due to a lack of guidance from regulators on acceptable use of social media technologies to promote pharmaceutical products. As communications media have evolved, pharmaceutical companies have tended to wait for regulators to release guidelines on acceptable marketing practices before making significant investments in a new medium. Chapter 3: Pharmaceutical Marketing in the Digital Age aims to provide a snapshot of current and emerging trends in pharmaceutical DTCA in the Internet and social media context. First, this chapter describes the technological trends and fiscal pressures that are pushing the pharmaceutical industry towards digital channels, followed by a discussion of current Canadian examples of DTCA as they appear in social media.

More than ever before, consumers are turning to the Internet as their primary source of health information. In addition, as social media technologies have made the Internet increasingly interactive, consumers themselves are now taking an active role in the creation and propagation of health information through user-generated content and sharing capabilities. Consequently, as more and more consumers turn to the Internet as a source of health information, there is an attendant need to ensure that this medium is effectively regulated.

While Health Canada has reaffirmed that existing DTCA regulations apply to new Internet and social media technologies, there are a number of unique features of these new technologies that make the application of existing regulations an uncertain process. As such, during discussions with Health Canada in April 2009, the Pharmaceutical Advertising Advisory Board (PAAB) outlined the issue of social media marketing as an emerging method of communication and raised the idea of Health Canada creating guidelines for the pharmaceutical industry’s use of social media. However, although Health Canada recognized that such emerging technologies would introduce a new dynamic to compliance and enforcement activities and acknowledged the need to be active in this area, they have not yet made any move to clarify the issue. Chapter 4: The New Dynamics of Social Media explores how the unique aspects of social media make the application of existing regulations an uncertain process. In particular, social media introduces new dynamics such as user-generated content, consumer propagation and targeted marketing, which are often not properly addressed in the existing regulatory framework. This section aims to highlight some of the specific areas where greater regulatory guidance is required from Health Canada in order to clarify the application of the existing rules to digital media.

Chapter 5: Regulatory Approaches discusses some of the difficulties of regulating DTCA, both in general, and in the context of the Internet and social media. This chapter describes three different regulatory approaches – direct government regulation, independent third party oversight, and industry self-
regulation – and some of the advantages and disadvantages of each as they currently exist in Canada. Unfortunately, Health Canada’s has a poor track record when it comes to actually enforcing the existing DTCA regulations. Given the difficulties Health Canada has faced in directly regulating DTCA in traditional media, there is significant skepticism around whether government regulators have the resources or political will to effectively monitor new digital media. As such, it is argued in this chapter that independent third party oversight and industry self-regulation may play an important role in filling the gap in the regulation of digital channels. Nonetheless, the ability of these bodies to effectively regulate the Internet and social media context will likely depend on greater regulatory guidance from Health Canada to clarify the rules of the game.

Finally, in responding to of the pharmaceutical industry’s burgeoning interest in the social media boom, regulators should not simply be limited to restricting or regulating the online advertising of drug products. After all, social media is equally available to health care professionals, advocacy groups, government and consumers as a tool to spread their own health information. Chapter 6: Beyond Regulation explores alternatives to regulation that may be effective in improving the health information that consumers access online. Namely, in this section it is argued that comprehensive health information sites sponsored by the government or a third party could provide a more neutral and reliable resource than pharmaceutical industry sponsored sites. Indeed, the pharmaceutical industry is likely already aware that social media is a double-edged sword: although it can be used to promote their own products, social media can also be a powerful tool for health professionals and patients to come together to report adverse drug event and share concern and scepticism around a particular drug product.

1.1 Rationale for the Regulation of DTCA

While the pharmaceutical industry has an important role to play in the discovery, manufacture, and distribution of drugs, there is an undeniable conflict of interest in allowing them to play too strong of a role in providing “health information” through advertisement. The objective of investor-owned, for-profit corporations, in any sector of the economy, is to maximize profit. Consequently, as with any form of advertisement, pharmaceutical companies may find it profitable to use persuasion and exaggeration in their consumer-directed marketing activities, which makes it unlikely that the health information contained in prescription drug advertising can be considered as strictly informative. The problem is that these “messages are intended to promote the use of newer, more expensive drugs (even if older,
cheaper ones work as well) and to increase brand recognition (but not the awareness of side effects, or of non-pharmacologic options for treatment and prevention).”

One important objective of public health policy is to ensure that consumers have access to fair and balanced health information. In this vein, “the rationale for the regulation of DTCA is not to limit consumer access to health information, but rather to provide consumers with independently developed, balanced, comparative information on the full range of available medical treatments.”

Before launching into a discussion of the regulation of DTCA in the Internet and social media, it is important to first understand the policy rationale that underlies the restrictions on DTCA in Canada. As such, the following sections provide an overview of the main justifications for limiting DTCA in both traditional and digital media.

1.1.1 The Power and Peril of DTCA

Although all advertisements in Canada are subject to regulations that prohibit false and misleading messages, DTCA for prescription drugs is subject to additional restrictions due to the unique safety concerns connected to these products. First of all, prescription drugs are different from other consumer goods in that they frequently require the expert knowledge of a trained physician in order to be used properly. Although prescription drugs are administered with the goal of benefiting the health of the patient, they also have the potential to cause undesirable and even severe side effects. Therefore, doctors must take into account a wide range of individualized factors when making the decision to prescribe a particular drug to a patient.

DTCA can distort the relationship between patients and physicians because the physician becomes the gatekeeper for the advertised commodity rather than for prioritizing health care based on the concerns of patients. Ideally, a decision by a physician to prescribe a particular drug should be based on a dialogue between doctor and patient that touches on different treatment options and the attendant risks and benefits of each option. However, the economics of prescribing suggest that doctors may be more susceptible to patient requests for specific drugs than they would like to admit. First of all, in Canada, patients are free to choose their own doctor. Therefore, “if advertising induces sufficient brand-loyalty in the patient and a physician does not grant requests for the brand, the patient may choose to seek the prescription from another doctor.” Secondly, the majority of physicians in Canada are paid on a fee-for-service basis that creates an incentive to constrain the time spent consulting and

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6 Morgan Affidavit, supra note 3 at para. 27.
counseling with patients. Therefore, “in the face of a patient that appears brand loyal, it would therefore be economically rational (though not necessarily clinically appropriate or cost effective) for physicians to select [the brand name drug].”

Many critics argue that DTCA creates a preference among consumers for recently launched drugs over older, established treatments. Regardless of the actual therapeutic value of the advertised drug, manufacturers of newer, patented products have a disproportionate opportunity to finance expensive advertising campaigns, “leading the market supply of information to concentrate on newer products to the exclusion of older ones.” Moreover, newer drugs tend to be heavily marketed early in the product life cycle when the product may not be adequately assessed for safety. A well-publicized example of this problem is the case of the infamous drug Vioxx, which was withdrawn from the market in 2004 after a clinical trial revealed that long-term use of this pain medication was associated with a nearly doubled risk of heart attack or stroke. Although Vioxx had never been proven to be more effective than older, cheaper alternatives, an aggressive DTCA campaign for Vioxx led to the drug being prescribed to a very large number of people soon after its launch, and ultimately, to a correspondingly higher number of adverse drug events. Consequently, the Vioxx crisis stands as a stark reminder that the use of new drugs should be approached with caution and “unless new products present major advantages over existing ones, they should not routinely replace standard treatments until extensive experience with the products has been gained and independent assessments are available.”

The promotion of newer, more expensive brand name prescription drugs through DTCA can have significant cost implications for both individual patients and government health budgets. Spending on pharmaceuticals is one of the fastest growing components of health care expenditures in Canada and the second-largest category of health expenditures after only hospitals. Drug expenditures were projected to grow by 4.0% from 2010 to reach $32.0 billion in 2011, amounting to 16.0% of total health

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7 Ibid.
8 Ibid at para. 35.
9 As a rule, clinical trials investigate only the short-term effects of the drugs and tend to be conducted only on small patient groups. Further, the majority of these studies do not compare the new drug to existing products in the same therapeutic class, but rather are placebo-controlled trials. Consequently, the only conclusions that can be drawn are that the new drug is superior to receiving no treatment (placebo), but not necessarily superior to existing treatment options. See CanWest MediaWorks Inc. v. Canada (A.G.) (Affadavit of Joel Lexchin on behalf of the A.G. at para. 39) [Lexchin Affidavit].
10 Merck spent more than US$500 million dollars advertising Vioxx during its five years on the market, which generated sales of more than US$2.5 billion. In fact, in 2000 Merck spent more money advertising Vioxx than PepsiCo spent advertising Pepsi. Market research has shown that around one quarter of Vioxx sales were generated from DTCA advertising in print and television. See CanWest’s Charter Challenge on prescription drug advertising: A Citizen’s Guide (June 2006), online: Women and Health Protection <http://www.whp-apsf.ca/pdf/charter_challenge_en.pdf> [Citizen’s Guide] and Mintzes, 2006, supra note 1.
11 After its initial launch in 1999, some 20 million people took the drug. In the U.S. alone, it is estimated that between 88,000 and 139,000 people suffered a heart attack or stroke as a result of taking Vioxx, 30-40% of which likely resulted in death. See Maragaret Clune & Rena Steinor, “The Hidden Lesson of the Vioxx Fiasco: Reviving a Hollow FDA” (October 2005), online: Centre for Progressive Reform <http://www.progressivereform.org/articles/Vioxx_514.pdf>.
care spending.\textsuperscript{13} With the modern proliferation of pharmaceuticals, there is a vast range in prices for different drugs that treat the same condition. However, there is a modern tendency for physicians and patients to select brand-name products despite the fact that they are, in the vast majority of cases, the more expensive options. Since drug costs are often largely or entirely funded by public or private insurance, many patients have no financial incentive to carefully consider prices when purchasing a drug. Similarly, there are virtually no incentives for a prescribing physician to consider the price of drugs since they do not bear any of the cost for the drugs they prescribe. Further, research has shown that “relatively few prescribers have adequate knowledge of the relative cost of commonly prescribed drugs.”\textsuperscript{14}

Another important yet hard-to-measure effect of DTCA is its influence on people’s perception of health and how it should be maintained or regained; studies have shown that DTCA promotes prescription drugs over healthy lifestyle.\textsuperscript{15} A major area of controversy surrounds the concern that DTCA leads to the “medicalization” of regular human experience by promoting a “perception of vulnerability and illness for which the advertised drug is the solution”\textsuperscript{16} and encouraging viewers to consider medical causes for their everyday experiences. Prescription drug advertising is often linked to the increased use of “lifestyle” medications among the healthy and treatment of increasingly mild forms of common chronic illness.\textsuperscript{17}

1.1.2 Online Health Information and the Rise of “Cyberchondria”

As more and more consumers turn to the Internet as their primary source of health information, consideration needs to be given to how the health information consumers access online affects their perception of health. One the one hand, patients becoming more involved in their medical care may help improve health outcomes, particularly for chronic illnesses; researching medical concerns on reputable websites can be a positive step for patients if it helps them become more educated about their health.\textsuperscript{18} Patients may even be able to accurately diagnose themselves, particularly for common illnesses such as appendicitis and strep throat.\textsuperscript{19} On the other hand, the overwhelming number of

\begin{itemize}
\item \textsuperscript{13} Canadian Institute for Health Information, \textit{National Health Expenditure Trends, 1975 to 2011}, online: CIHI \url{<https://secure.cihi.ca/free_products/nhex_trends_report_2011_en.pdf> at XV}.
\item \textsuperscript{14} Morgan Affidavit, supra note 3 at para. 16.
\item \textsuperscript{16} Ibid at 101.
\item \textsuperscript{17} A lifestyle drug is a medication designed to improve the patient’s quality of life by addressing relatively minor and non-life threatening conditions such as baldness, impotence, wrinkles, and obesity (antidepressants are also sometimes considered in this category). Pharmaceutical companies often reject the term “lifestyle drug” as pejorative, claiming that it implies that the condition treated by the drug is unimportant. See Citizen’s Guide, supra note 10.
\item \textsuperscript{18} Christine S. Moyer “Cyberchondria: the one diagnosis patients miss” \textit{American Medical News} (30 January 2012), online: amednews.com \url{<http://www.ama-assn.org/amednews/2012/01/30/hill10130.htm> [Moyer, 2012].}
\item \textsuperscript{19} Ibid.
\end{itemize}
health information sites, some of which are unreliable, may mislead patients into thinking they have a medical problem. Doctors are increasingly faced with patients who arrive with a self-diagnosis based on information they have found on the Internet. When faced with unexplained symptoms, many consumers jump to the worst case scenario conclusion based on the health information they find online. For example, a patient may be convinced that a headache is caused by meningitis, or that a sore throat is a symptom of AIDS.\(^\text{20}\) The medical community and international media have begun to refer to these web-stoked fears as “cyberchondria”\(^\text{21}\), which may cause heightened patient anxiety and unnecessary screening tests that can result in medical complications. Moreover, “[c]yberchondria also demands that physicians spend more time in office visits as they discuss why the individual thinks he or she has a particular disease, educate the patient on why that diagnosis is unlikely and then determine the true cause of the symptoms.”\(^\text{22}\)

Discovering fair and balanced information on the Internet may become more difficult as the pharmaceutical industry itself becomes a dominant source of online “health information”. This is particularly true when drug companies pay search engines like Google to increase the prominence of their sites in search results – the effect may be that more objective health information sites run by patient interest groups or medical organizations may be crowded out by information sites sponsored by the drug companies.\(^\text{23}\) In addition, the ability of pharmaceutical manufacturers to use social media platforms to target advertising increases the risk that they may target marketing at vulnerable groups, particularly persons with chronic health conditions, who are more likely to perceive their need for a particular medication.

Of course, it is worth recognizing that although various assessments of online drug advertisements have shown that they often make suspect claims and may overemphasize the benefits of the drug,\(^\text{24}\) the pharmaceutical industry is certainly not the worst offender when it comes to the production of questionable health information. The Internet is brimming with claims of miracle cures, natural remedies and new age treatments from dubious sources. Unfortunately, many consumers lack the knowledge necessary to discern between legitimate and questionable sources of health information. Self-diagnosis, in particular, can also have negative consequences when consumers trust the information they find online enough that they put off consulting a physician, which may lead to a


\(^{21}\) Ibid.

\(^{22}\) Moyer, 2012, supra note 18.

\(^{23}\) For example, when you search for “psoriasis Canada” on Google.ca, the first hit that is listed is the sponsored ad for LivingWellWithPsoriasis.com, while the Psoriasis Society of Canada website is the first true hit based on regular search parameters.

\(^{24}\) Hooper, 2011, supra note 20.
worsening of the medical condition. Many consumers will also engage in self-treatment and try remedies that they find online, many of which are unproven and may have dangerous side effects.

2 Current Regulatory Framework in Canada

As noted above, despite declining to issue specific guidelines on social media, Health Canada has clearly indicated that the existing regulations on DTCA apply to social media marketing. The primary source of regulation on DTCA is the Food and Drug Act and accompanying regulations. In addition, Health Canada has also issued a number of guidance documents to help interpret the content of the legislation.

In Canada, only two types of DTCA for prescription drugs are permitted: (1) reminder ads, which include only the brand name of the drug without any reference to health claims or hints about the product’s use, such as listing of medical specialties; and (2) disease-oriented or help-seeking ads, which do not mention a specific brand but discuss a health condition and suggest viewers or readers ask their doctor about an unspecified treatment. There is also an additional distinction made between disease-oriented and help seeking ads, which is relevant to the discussion of sponsorship identification below: a “help-seeking announcement” is defined by Health Canada as an announcement that “ask[s] patients among the general public having a particular medical disorder, or that experience a given set of symptoms, to consult a physician for discussion or treatment...”

Full product ads, such as commonly seen in the US, which include the brand name of the drug and health claims and risk information, are currently banned under the Canadian regulations.

The regulatory and review requirements for the dissemination of information about prescription drug products vary depending on the target audience. However, not all prescription drug information distributed directly to consumers is considered by Health Canada to be advertising. Rather, educational consumer health materials that meet certain criteria are considered to be “Direct-To-Consumer Information” (DTCI); DTCI that complies with the Food and Drug Act is not considered to be advertising.

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25 Ibid.
26 Ibid.
27 Patrick Massad, “Incorporating a Strategic Regulatory Though Process Into You SMM Planning... To Develop a Successful Social Media Marketing Campaign with PAAB” (Slideshow presentation delivered at the eMarketing Canada 2010 conference in Toronto, 1-2 November 2010) [Massad, 2010] at Slide 2.
28 Mintzes, 2006, supra note 1 at 8.
29 Health Canada, The Distinction Between Advertising and Other Activities (Guidance document) (Ottawa: Health Products and Food Branch, 1996) [Advertising Distinction Guidance Document] at iv. However, an important distinction arises if the message is considered to be a “help-seeking announcement” since a different set of criteria apply. In particular, a help-seeking announcement must meet the following criteria: no specific drug is identified; there is no implication that a drug is the sole treatment available for the disease or condition; and no drug manufacturer’s name is included.
and may be distributed directly to consumers.\textsuperscript{30} Both disease-oriented and help-seeking ads are generally classified as DTCl. (Note that despite the distinction made by Health Canada, for the purposes of this thesis, disease-oriented and help-seeking ads are both considered to fall under the banner of DTCA.)

To be considered as DTCA, an advertisement must be directed at consumers and, for reminder ads, must specifically identify a prescription drug product authorized for sale in Canada. Further, the advertisement must be intended for Canadian media; advertisements appearing in foreign media are not subject to Canadian regulatory requirements.\textsuperscript{31}

To set the stage for the discussion of the regulation of the Internet and social media, the following section provides a brief legislative history and overview of the current Canadian regulations on DTCA. This is followed by a more detailed description of how Health Canada distinguishes between advertising and other activities, and how this distinction plays out on the Internet and social media platforms.

\section*{2.1 Food and Drugs Act and Regulations}

In Canada, DTCA of prescription drugs is prohibited under two provisions of the federal \textit{Food and Drugs Act}, which was first enacted in 1953 as a component of the federal Criminal Code. The Act prohibits DTCA in two main ways. First, the Act places a broad prohibition on advertising prescription-only drugs to the public, which are listed in Schedule F. Secondly, s. 3(1) and Schedule A of the Act set out a number of diseases and disorders for which “treatments, preventatives or cures” cannot be advertised to the general public.\textsuperscript{32} This list includes many diseases such as depression, diabetes, asthma and heart disease which are often the subject of pharmaceutical advertising in the US. The rationale for s. 3(1) is the “recognition that people who are seriously ill may be vulnerable to unscrupulous marketing of medicines.”\textsuperscript{33} However, Schedule A has expanded somewhat unevenly over time and has often been criticized because it lacks criteria to determine which ailments are to be included.\textsuperscript{34}

Finally, Section 9 of the Act also places a general prohibition on false and misleading advertising: “No person shall ... advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.”\textsuperscript{35} The

\begin{footnotesize}
\begin{itemize}
\item[32] However, \textit{preventative} claims for Schedule A diseases may be made where these claims have been authorized by Health Canada. See Massad, 2010, supra note 27.
\item[33] Mintzes, 2006 supra note 1 at 7.
\item[34] Legislative Renewal Report, supra note 12 at 13.
\item[35] \textit{Food and Drugs Act}, R.S.C. 1985, c. F-27 at s. 9(1).
\end{itemize}
\end{footnotesize}
law also prohibits DTCA of narcotic drugs (s. 70 of the *Narcotic Control Regulations*) and controlled drugs (s. G.01.007 of the *Food and Drug Regulations*).

From a strict reading of the legislation, it might appear that all forms of advertising of prescription drugs are prohibited in Canada. However, over the last 15 years, there has been a significant shift in the interpretation of the policy governing DTCA of prescription drugs. Despite the apparent ban on DTCA, certain forms of prescription drug advertising are now becoming widespread.\(^{36}\) As will be explained further below, as a result of amendments and reinterpretation of the legislation, reminder ads and “information dissemination” are now permitted.

In 1978, an amendment to the Act introduced clause C.01.044 which approved the advertising of drug prices: “Where a person advertises to the general public a Schedule F drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.”\(^{37}\) This amendment was added to allow pharmacies to advertise prices for the purpose of competition, but does not allow for the inclusion of additional information such as text, sound or images.\(^{38}\)

Section 2 of the Act broadly defines advertising as “any representation by any means whatever for the purposes of promoting directly or indirectly the sale or disposal or any food, drug, cosmetic or device.”\(^{39}\) However, in 1996, Health Canada released a policy statement aimed at clarifying the distinction between “advertising” and “information dissemination.” It stated that Health Canada “recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access non-promotional information regarding drugs for human use.”\(^{40}\) The policy statement suggested that Health Canada was prepared to relax its interpretation of the prohibition against DTCA and gave implicit approval to disease-oriented and help-seeking advertisement for serious diseases. According to Health Canada, these messages are not considered to be advertisements; rather they are seen as providing information inviting the consumer to ask their physician about new, unidentified drug treatments.\(^{41}\)

In November 2000, another policy statement was released by Health Canada that suggested even further liberalization in the interpretation of the Act. It gave explicit approval of help-seeking and reminder advertisements, but reaffirmed that full product ads were illegal. “Reminder” ads, although

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\(^{37}\) *Food and Drug Regulations*, C.R.C., c. 870 at s. C.01.044.


\(^{39}\) *Food and Drugs Act*, *supra* note 35 at s. 2.


\(^{41}\) Legislative Renewal Report, *supra* note 34 at 4.
deemed by Health Canada to be advertisements, are considered to be within the scope of regulation C.01.044 if they only contain reference to name, price and quantity; however, if a reminder ad is accompanied by messages that allude to its intended use, then the advertisement is considered to be in violation of C.01.044.\footnote{Gardner, Mintzes & Ostry, 2003 supra note 5 at 425.}

Due to the ban on full product ads, advertisers are generally forced to choose between unbranded disease-oriented ads or branded reminder ads. Where the manufacturer runs a concurrent information-only campaign (i.e. unbranded) about the disease or condition for which the advertised prescription drug product is indicated, any similarities in terms of the theme or context, persons featured, style (e.g. music, fonts, colours, background) or wording between the branded advertisement for the prescription drug product and the unbranded communications on the disease or condition will likely be found to violate the regulations.\footnote{Ibid.} For example, in 2000, Wyeth-Ayerst Canada decided to take advantage of both by running two sets of ads for the birth-control pill Alesse in close succession. The first was a help-seeking ad that discussed the importance of birth control. The second was a reminder ad that promoted Alesse without making any claims about what the product did. The two ads were very similar in look and feel and used the same music and actors, which had the effect of linking the branded and unbranded messages. Individually, neither of these ads was prohibited. However, taken together the connection between birth control and Alesse became obvious.\footnote{Ibid.}

A full six months after the ads began airing, Health Canada finally wrote to Wyeth-Ayerst informing them that the ad campaign was considered to contravene the Food and Drugs Regulations. However, Health Canada took no other action to reprimand the drug company for this contravention\footnote{Anne Silversides, “Pharmaceutical companies are pushing the boundaries of the law against direct-to-consumer drug advertising” Eye Weekly (5 March 2001), online: Eye Weekly <http://contests.eyeweekly.com/eye/issue/issue_05.03.01/news/drugs.php >.} – a prime example of Health Canada’s lax enforcement record that will be discussed in more detail in Chapter 5. However, the one concrete development that came about as a result of the Alesse campaign was that Health Canada issued a policy statement asserting that it is prohibited to run two separate ads that taken together would violate the regulations.

### 2.2 Defining the Scope of DTCA in the Digital Age

In 1996, to help pharmaceutical advertisers distinguish between DTCI and DTCA, Health Canada issued a guidance document entitled The Distinction Between Advertising and Other Activities. According to this document, determining whether a message falls within the definition of advertising set out in the...
Food and Drug Act turns on whether “the primary purpose of the message is to promote the sale of a drug or to provide information.” To qualify as DTCI, all information presented must be factual, objective and balanced. In particular, all disease-related statements should use neutral and objective language and must accurately reflect the medical literature; all available treatment options should be treated equally; and a similar type and quality of information on safety and side effects should be presented for all treatment options. The guidance document provides that where the message is balanced with regard to risks, benefits and treatment options and can withstand a test for scientific rigour, it is less likely to be considered as promotional.

The guidance document lists seven factors that should be considered in determining whether or not the message is primarily intended to promote the sale of a drug: (1) context, (2) intended primary and secondary audience, (3) delivery, (4) sponsorship, (5) influence of the manufacturer on message content, (6) content, and (7) frequency. While the determination of whether a particular message is promotional or not will ultimately depend on each particular context, there are a few unique aspects of social media that may influence the promotional character of the message that are worth mentioning here.

When and how the message is delivered, as well as the medium chosen, can have a significant impact on the determination of its promotional content. In general, the broader the target audience, the more likely the message will be considered to be promotional. Social media platforms tend to be informal in nature and, in most cases, are widely available to a lay audience. Except in cases where a site has controlled membership (e.g. aimed at health professionals or specific patient groups), most social media sites inherently operate in an open environment. Arguably, advertisers who participate in popular social media sites such as Facebook, Twitter and YouTube do so with the express purpose of wanting to spread their message to as wide an audience as possible. As such, in most cases, the context of social media may give industry-sponsored health information a certain promotional aspect.

The guidance document asserts that “[w]here delivered by an independent party, the message is less likely to be considered as advertising.” It follows that where the pharmaceutical manufacturer delivers the message itself, the message is more likely to be considered as promotional. Similarly, the

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47 Ibid at 2.
48 Ibid at 3. Although the potential contexts for a message are diverse, the guidance document provides the example of where a message is science-based and delivered to scientists/healthcare professional by an expert, it is less likely to be considered promotional than a product-related message that is delivered by a pharmaceutical sales representative at a meeting with a limited agenda.
49 Ibid at 3.
50 Ibid at 3.
guidance document states that where the message is sponsored by an independent third party out of its general operating budget, the message is less likely to be advertising, whereas where the manufacturer pays a fee to have the message disseminated, it is more likely to be advertising.\footnote{Ibid at 3.} Moreover, “[w]here the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.”\footnote{Ibid at 3.}

Although there are numerous examples of the pharmaceutical industry teaming up with charitable causes or special interest groups as part of a social media campaign (as will be discussed below), in the majority of cases, the drug company designs, finances and delivers a social media campaign directly. Since social media channels are open and available to anyone, pharmaceutical companies are free to design and deliver their own social media campaign without having to depend on any distributions channels offered by a third party (other than the social media platform itself), which has significant advantages such as direct control over the message content; direct control over the launch, modification and, when necessary, discontinuation of a campaign; and increased brand prominence. Nonetheless, the choice by a pharmaceutical firm to design, deliver and finance social media campaigns directly raises the likelihood that the message will be considered to be DTCA.

### 2.2.1 Sponsorship Identification and Linking

An emerging dilemma that has arisen in the context of online pharmaceutical marketing is whether disease-oriented or help-seeking messages distributed via digital channels should identify the sponsoring pharmaceutical company. According to the Advertising Standards Council (ASC), in general, brochures and websites may include a simple sponsorship statement (e.g. brought to you by company X) naming the drug manufacturer; “[d]eclaration of sponsorship on an information piece by a drug manufacturer does not in and of itself render the piece promotional.”\footnote{ASC DTCI Guide, supra note 31 at 4.} However, an important distinction is made in that “help-seeking announcements” should not include a sponsorship statement and should avoid indirectly identifying the manufacturer through elements such as logos.\footnote{Ibid at 6.} As such, the determination of whether an ad is considered to be a help-seeking announcement or not is important since this type of ad cannot include a sponsorship statement, whereas a general disease-oriented ad can. However, it is often unclear whether different types of “health information” distributed through social media and other online technologies cross the line to become help-seeking announcements.
Regarding linking, the ASC specifically states that all health information websites, whether disease-oriented or help-seeking, should not provide links to a drug product or pharmaceutical manufacturer’s website.\textsuperscript{55} That is, to avoid DTCI from becoming DTCA, the manufacturer should avoid branding the website with links to their company website since such measures will likely render the site promotional. Consequently, “manufacturers need to be wary of what is linked to and from their websites.”\textsuperscript{56} However, links to third party health information websites are generally acceptable.\textsuperscript{57}

\subsection*{2.2.2 Internet Gating}

In general, patients who have been prescribed a drug are no longer considered to be members of the “general public” for the purposes of DTCA. As such, “patient information” about a drug is granted more flexibility than prescription consumer advertising and can be linked to its therapeutic use.\textsuperscript{58} Nonetheless, patients should not be exposed to promotional messages and all contents about the drug must be consistent with the Product Monograph.\textsuperscript{59}

In Canada, nearly all drug product websites that contain “patient information” are “gated” to ensure that only appropriate parties are able to access particular information. This is most often accomplished by requiring a user to enter the Drug Identification Number (DIN) assigned by Health Canada that appears on all prescription package labels to gain access.\textsuperscript{60}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{Figure1.png}
\caption{The Canadian Alesse website.}
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\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{Figure2.png}
\caption{Canadian Lipitor website.}
\end{figure}

In addition, online access can also be controlled by distributing “keys” that bypass the barrier to the targeted audience or by requiring a patient to register with a site to gain access.\textsuperscript{61} For example, the Canadian Lipitor\textsuperscript{®} website requires patients to register on the website to obtain a user name and password to enter the site. The registration requires confirmation by the user that they have a current prescription for Lipitor. However, it is worth noting that, on

\begin{itemize}
\item \textsuperscript{55} ASC DTCI Guide, supra note 31 at 4.
\item \textsuperscript{57} ASC DTCI Guide, supra note 31 at 4.
\item \textsuperscript{58} McKenzie & Parsons, 2011 supra note 56.
\item \textsuperscript{59} Pharmaceutical Advertising Advisory Board, Code of Advertising Acceptance (17 April 2009), online: PAAB <http://www.paab.ca/local/files/PAAB%20Code%20Eng%20April%202017%202009.pdf> [PAAB Code] at s. 6.4.3.
\item \textsuperscript{60} See www.alesse.ca
\item \textsuperscript{61} McKenzie & Parsons, 2011 supra note 56.
\end{itemize}
its own, a simple “attestation” from a user confirming that they have been prescribed the product will likely not be considered to be a sufficient barrier to entry. Further, any non-gated sections of a gated website are still subject to the regular consumer regulations.62

As with patient information, drug product information intended for health care professionals must also be gated. Information aimed at health care professionals is granted even more flexibility than patient information and consumer advertising, and may even include promotional claims regarding the approved therapeutic uses of the product as long the claims are consistent with the Terms of Market Authorization. Sites may be gated by requiring the health care professional to enter a password provided by the manufacturer or through moderator approval. Other drug product websites aimed at health care providers may require the user to answer a question based on medical expertise to gain access to the website. For example, the Crestor website requires health care professionals to answer the question “What is the starting dose of Crestor for most patients?”63

Unfortunately, in the end, most of these gating functions are of limited value since Canadians can easily access the US or international version of most drug product websites without having to circumvent any type of gating restriction. Moreover, many drug products sold in Canada do not have a specific Canadian version of the drug product website, so consumers will often have to access the US or international version of the website by default, which are not subject to Health Canada regulations.

3 Pharmaceutical Marketing in the Digital Age

Traditional advertising media such as print, radio and television consist almost exclusively of “push” communication where the promoter pushes unsolicited information at the consumer. Conversely, the Internet introduces the opportunity for “pull” communication where the consumer makes a demand for information from the promoter, most commonly through seeking information through an Internet search function. Moreover, in the past decade, as Internet technologies have rapidly developed, “users have migrated from passive information sources, using read-only “Web 1.0” technology, to interactive, dynamic and custom-built relationships, using “Web 2.0” technologies.”64 Today, many of the world’s most popular websites are social media sites which rely increasingly on content generated by the user.65 The rise of social media and other collaborative Internet technologies has created the

62 Ibid.
63 See www.crestor.ca. However, in an apparent glitch, no matter what dosage is entered, access to the site is granted.
65 For example, Facebook relies on users generating and sharing content through their user profiles; YouTube relies on users posting and sharing videos; Wikipedia relies on people all over the world to author, update and edit its articles.
opportunity for two-way communication where the user can interact directly with websites through user-generated content, and further, may propagate the information from the site by sharing content and links through their own social media sharing capabilities. The Internet is also becoming increasingly omnipresent as mobile devices such as iPhones and smartphones make the Internet accessible at any time, from anywhere.

Delineating the scope of social media is often an elusive task since “as social media continues to evolve and its uses change and expand, so does the definition of social media.” Nonetheless, definitions of social media commonly include characteristic references to elements such as web-based and mobile technologies used to “turn communication into interactive dialogue”, enable “the creation and exchange of user-generated content” and create “online communities to share information, ideas, personal messages, and other content.” Yet regardless of the specific definition adopted, one constant and unquestioned aspect of social media is the transformative impact the technology has had on the way that organizations, communities, and individuals communicate. Although the pharmaceutical industry has been slower than many other sectors to invest in social media technologies, this new medium is now beginning to transform the ways that drug companies interact with consumers.

The increasing prominence of new Internet and social media technologies in modern communication, the growing importance of the Internet as a source health information and the fiscal realities of prescription drug marketing are all pushing the pharmaceutical industry towards digital channels. The following sections explore the trends that are driving pharmaceutical firms towards digital channels and provide a snapshot of the current presence of the industry on the Internet and social media platforms. The final section then provides specific examples of reminder and disease-oriented advertising aimed at Canadians on social media sites, including a prominent campaign that appears to violate the existing Health Canada regulations.

3.1 A New Paradigm in Pharmaceutical Advertising

According to many industry commentators, the pharmaceutical advertising industry is currently in a state of significant flux due to a number of important factors: “[t]he meteoric rise of digital information and social-media channels, the still-evolving regulatory environment, the maturing of mainstream

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66 Heidi Cohen, “30 Social Media Definitions” Actionable Marketing 101 – Social Media (9 May 2011), online: HeidiCohen.com
69 Merriam-Webster Dictionary, online ed., s.v. “social media”.

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blockbuster drugs, and fewer new drugs being brought to market all point to a major inflection point in pharmaceutical marketing.” Indeed, in the US, pharmaceutical ad spending peaked at USD$5.4 billion in 2006 and has declined every year since then to USD$4.3 billion in 2010, a drop of nearly 20% over five years. However, as in many other sectors of the economy, the primary reason for the cutback has been the recent economic recession and the slow recovery, which means that the industry simply has less to spend on marketing. As a result of increasing economic pressures, many pharmaceutical companies are being forced to turn away from traditional – and more expensive – media channels such as print and television, toward more economical “digital channels”, namely the Internet and social media platforms.

As mentioned above, another significant factor that is pushing pharmaceutical marketers towards digital channels is the growing popularity of the Internet as a source of health information. More than ever before, Canadians are turning to the Internet as one of their primary sources of health information. A Statistics Canada survey found that 70 percent of Canadian home-Internet users consulted the web for health information in 2009, up from 59 percent in 2007. Canadians now consult the Internet more for health information than they do for news, sports or online banking. Further, research has shown that the majority of people turn to the Internet first when looking for health information – not just at some point, but even before talking to their doctor, family or friends about a health question. A similar poll conducted in the US in 2010 revealed that 88% of Americans who use the Internet have consulted the web for health information. According to the same poll, 32% of adults who are online consult the Internet “often” for health information, up from 22% in 2009. A more recent survey in the US has also revealed that many consumers specifically rely on social media as a source of health information. The survey, conducted by PriceWaterhouseCooper’s Health Research Institute in February 2012, revealed that “one-third of consumers are using Facebook, Twitter and other social media sites to seek medical information, discuss symptoms and express their opinions about doctors, drugs and health insurers.” Moreover, 34% of respondents reported that information

71 Ibid at 5.
72 Ibid at 3.
73 Ibid at 7.
74 Hooper, 2011, supra note 20.
75 Ibid at 10.
76 Ibid at 4.
78 Ibid.
found through social media would affect their decision about taking a specific medication. Unsurprisingly, younger consumers were more comfortable than older consumers with seeking and sharing health information via social media. For example, more than 80% of individuals aged 18 to 24 reported they were likely to share health information through social media and nearly 90% said they would trust the information they found through social media. Overall, it is clear that “[p]atients are engaging in online conversations about medications whether pharma participates or not.”

Despite its potential dangers, the benefits of social media marketing for the pharmaceutical industry are numerous, such as “flexibility in marketing blockbuster and niche therapies, ability to reach larger audiences and target specific patients, and better financial analytics of social media and marketing return on investment,” not to mention significantly lower costs than traditional forms of advertising. Further, social media can help pharmaceutical marketers gain insights into positioning, consumer response and targeting.

In the new era of interactive Internet and social media platforms, the voice of the consumer is becoming increasingly important, which presents pharmaceutical marketers with a number of new challenges. First of all, social media allows for the creation of user-generated content, which makes drug companies uneasy if they cannot adequately control what is being said on their sponsored sites. Pharmaceutical industry representatives commonly report that they are nervous about the potential for consumers to post information on adverse drug events or off-label prescribing. However, as will be discussed in s. 4.1, industry mistrust of emerging Internet and social media technologies likely also reflects a broader fear of loss of control over their brand message as consumers may post negative or even scathing reviews of a drug product.

Unfortunately for pharmaceutical marketers, launching a successful and compliant social media marketing campaign has often proven to be a challenge. Despite numerous and repeated attempts by many pharmaceutical marketers to harness social media platforms, many campaigns have proven to be short-lived, usually due to a lack of consumer interest or real or perceived non-compliance with DTCA regulations. Further, as more and more drug companies enter the social media arena, many industry commentators report that pharmaceutical advertisers are going to have to be increasingly creative in order to attract, and hopefully hold, consumer attention. Yet while consumers have rushed ahead in searching the Internet for health information, the vast majority prefer to visit “unbranded”, third party

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80 Ibid.
82 Liang & Mackey, supra note 64 at “Discussion”.
83 Ad Age Insights, supra note 70 at 13.
websites such as WebMD or MayoClinic.com rather than sites sponsored by the pharmaceutical industry. As an illustration, according to Kantar Media, in the fourth-quarter of 2010, of the 6.5 million unique visitors to all websites about cancer, only about 4.2% were to branded sites.  

Despite the initial lag in uptake, the pharmaceutical industry is now beginning to focus more attention on the marketing opportunities offered by new Internet and social media platforms; a burgeoning number of pharmaceutical firms that are “experimenting – failing sometimes, but always trying – to reach consumers in new ways.”  

As an indication, from 2010 to 2011, investments by the pharmaceutical industry in smartphone apps, social media platforms, and wireless devices grew 78 percent. Nonetheless, investment in Internet and social media technology remains only a small fraction of the total pharmaceutical advertising market. According to Kantar Media, in the US in 2010, a total of approximately USD$203 million was spent on Internet display ads, out of a total of USD$4.3 billion spent on pharmaceutical advertising.  

Even Pfizer, the pharmaceutical company with the highest Internet advertising budget, spent only $28.6 million, or 2.8%, of its USD$967.5 million advertising budget on Internet ads in 2010. Nonetheless, despite these modest beginnings, according to eMarketer, online ad spending by pharmaceutical companies is projected to grow from $1.03 billion in 2010 to $1.86 billion in 2015.

3.2 Current Presence of Pharma in Social Media

In general, most pharmaceutical companies have had an online presence for years, most obviously in the form of corporate websites. Many companies also have a long history of placing paid search advertising on sites like Google, Yahoo and Bing, or buying display ads on medical community web pages such as WebMD. Moreover, branded product websites have been widespread since the early days of the Internet. However, new interactive “Web 2.0” technologies introduce a whole new level of complexity. In order to provide context for the discussion on the regulation of Internet and social media platforms, the following paragraphs provide an overview of the ways and extent to which the pharmaceutical industry has established itself in this new medium.

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84 Ibid at 12.
85 Ibid at 13.
87 Ad Age Insights, supra note 70 at 12.
88 Ibid at 12.
90 However, the Canadian versions of prescription drug websites are almost exclusively “gated” and require patients to enter the Drug Identification Number of the prescription drug product before being able to access the website. However, the American versions of prescription drug websites are broadly accessible to any audience, including Canadians. See discussion above in section 2.2.2.
In a 2011 study published in the Journal of Medical Internet Research, Liang and Mackey conducted a descriptive study to “assess the prevalence of DTCA of leading pharmaceutical company presence and drug product marketing in online interactive social media technologies”, which they referred to as “eDTCA 2.0”. Under their definition, “eDTCA 2.0” includes corporate social media marketing tools such as Facebook and Twitter, corporate blogs and RSS (really simple syndication) feeds that provide company-sponsored Web feed communications to users, corporate YouTube channels dedicated to marketing videos, and corporate mobile applications identified by pharmaceutical company name and copyright for smartphones and other mobile technologies. Liang and Mackey identified that all of the top ten pharmaceutical companies in the US (by sales) had a corporate presence on Facebook, Twitter, sponsored blogs, and RSS feeds. In addition, 80% (8/10) had dedicated YouTube channels and had developed health care communication-related mobile applications.

Although nearly all pharmaceutical companies have a corporate presence on social media sites – campaigns directed around their corporate profile independent of any particular drug product – there is strong divergence between companies when it comes to the level of social media engagement in campaigns featuring particular drug products or diseases. This is evident not only from the extent to which a pharmaceutical company establishes itself on popular social media platforms such as Facebook, Twitter and YouTube, but also the extent to which they integrate new interactive technologies into their standard websites. According to L2, the strongest sites use Web 2.0 technologies to amplify the site’s content through elements such as videos and interactive features with anatomic images, doctor interviews, and patient	

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91. Liang & Mackey, *supra* note 64 at “Abstract”.
92. Facebook is the most popular social networking site in the world, with more than 500 million users globally. In Canada, Facebook is the most visited website in the country after only Google. Facebook allows users to keep up with friends, upload photos and videos, and share links and posts. Drug companies can create a Facebook page or group oriented around the corporation, a drug product, disease, cause, etc., where users can post comments and share links. Facebook ads also allow drug companies to target ads to particular audiences based on information included in a user profile (e.g. age, gender, interests, etc.). Facebook also allows for the development of “Facebook apps” that allow for specialized functionalities such as quizzes, polls, maps, and games that can be shared by users. See www.facebook.com and Top Sites in Canada, online: Alexa <http://www.alex.com/topsites/ countries/CA> (last visited 7 February 2012) [Alexa].
93. Twitter is a social networking and “microblogging” service that allows account holders to broadcast messages of up to 140 characters to “followers” of the Twitter feed. Twitter is the ninth most visited website in the world and the eighth most visited in Canada. See www.twitter.com and Alexa, *ibid*.
94. YouTube is a popular video sharing site that allows users to upload, tag and share videos worldwide. YouTube is the third most visited website in the world and the fourth most visited in Canada. Drug companies can create a YouTube “channel” oriented around a particular drug product or health condition. In addition, many pharmaceutical television ads, particularly those from the US, are available on YouTube, although these are almost exclusively posted by third parties and not by the pharmaceutical companies themselves. See www.youtube.com and Alexa, *ibid*.
95. *Ibid*.
96. The top 10 pharmaceutical companies by sales were Pfizer, Merck &Co., Novartis, Sanofi-Aventis, GlaxoSmithKline, AstraZeneca, Roche, Johnson & Johnson, Eli Lilly and Abbott. See Liang and Mackey, *supra* note 64 at Table 1.
testimonials; symptom assessment surveys; doctor discussion guides; and tools to encourage compliance with a prescription.  

Some of the more recent social media marketing campaigns are now casting a wide net and creating campaigns that span multiple social media platforms at once. For example, in April 2010, Janssen launched the “Psoriasis 360” initiative as a multi-pronged social media campaign that features an interlinked website, YouTube channel, Facebook page, Twitter account and even an iPhone app, all with the same campaign logo and look and feel. The central website provides access to tools and information to help patients learn more about the disease and possible treatment options. The YouTube channel features a series of short video clips about psoriasis and allows users to post comments. The Facebook page features a newsfeed and posts and personal stories from many users living with the disease. The Twitter account “tweets” regular updates about psoriasis, and each “tweet” contains a link to the central Psoriasis360 website. And finally, the free iPhone app provides tools for both physicians and patients to assess and track the severity and impact of psoriasis.

The success of social media marketing campaigns tends to vary depending on the disease category and the target population. In general, marketing campaigns aimed at younger consumers have tended to make better use of social media and Web 2.0 technologies. In a study ranking the digital competence of pharmaceutical brands in the US published in May 2010 by the think tank L2, the authors noted that “[i]n an attempt to reach a generation raised on Google and Facebook, brand marketers... have worked to understand how to design informative and interactive web sites, incorporate community content and technology, attract users to branded sites, and test social media.” The study also ranked the pharmaceutical brands according to different disease state categories. The brands in the “Women’s Health” disease category, particularly birth control pills, were most consistently ranked with a high “digital IQ”. The success of social media and Web 2.0 marketing in this category is likely at least partially attributable to the relative youth of the target demographic (primarily women in their teens and 20s).

100 The Psorias 360 Facebook page was discontinued in May 2012.
101 See http://twitter.com/#!/psoriasis360.
103 While there is no set standard by which to measure the “success” of a social media marketing campaign, the most common standards involve such factors as the total audience reached, the length of time that the message remains in circulation, and the number of times consumers propagate the message. In general, the more people that are reached and the more the message is spread, the more successful the campaign. Of course, from the perspective of drug companies, like all advertising campaigns, the ultimate success of a social media campaign is based on the return on investment. It is worth noting that given the much lower cost of social media marketing (in comparison to traditional print, radio and television advertising), the sales generated through an online campaign would generally not need to be as high to justify the cost of the campaign.
104 L2 Think Tank, supra note 97.
and the lower “stigma” attached to birth control in comparison to more sensitive health topics (i.e. at least in Canada, more young women would likely freely admit to being on birth control than to being on medication for some other health condition). How sensitive consumers feel about publicly discussing a particular health topic ultimately has a significant impact on how willing they are to engage with social media messages related to that topic. For example, mental health is unfortunately one disease area that is still associated with significant levels of stigma and fewer patients are willing to openly discuss such conditions. Indeed, the L2 study revealed that the disease category with the lowest social media presence was Psychiatry, with none of the reviewed brands participating in social media platforms (AstraZeneca’s Seroquel, Lilly’s Cymbalta, Bristol-Myers Squibb’s Amblify and Pfizer’s Pristiq).

According to many industry commentators, the greatest challenge that most pharmaceutical companies face in entering the social media arena is learning to build more direct relationships with consumers – a significant change of direction for an industry that has often struggled with transparency. However, one way in which some pharmaceutical marketers are successfully engaging with consumers is through the development of online tools to aid adherence and compliance to a treatment regimen. For example, one brand that has shown particular success in engaging with consumers through customized online health management tools is AstraZeneca’s heartburn drug Nexium. Tools on the Nexium website include “the Trigger Checker, a searchable database of acid-reflux trigger ingredients and suggestions for milder substitutes; the Meal Planner, a weekly menu builder with heartburn-preventing recipes; and the Personal Fitness Planner, a tool that creates customized exercise plans designed by a virtual fitness trainer that can be saved on site.”105 These sorts of health management tools can be effective in attracting and retaining an audience for the site and, perhaps more importantly, of adding value to a particular brand.

Finally, one platform that is increasingly being used to host health management tools is mobile applications, which are available in online markets such as the Apple iTunes store and Android Market. Although these smartphone apps previously focused primarily on diabetes management tools, there was a rapid expansion into other disease categories in 2010, with apps emerging in an estimated 14 disease areas.106 These applications can serve a wide variety of functions such as “tools to help patients and consumers track vaccination schedules, manage infusions for treatment of hemophilia, and find

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105 ibid at 33.
106 Dolan, 2011, supra note 86.
cancer clinical trials within 150 miles of their location."¹⁰⁷ These mobile platforms allow users to access health management tools at any time, from anywhere.

### 3.3 The Branded/Unbranded Divide

In Canada, the prohibition on full-product ads forces pharmaceutical advertisers to choose between branded reminder ads or unbranded disease-oriented and help-seeking ads. Due to the strict name, price, and quantity limitations placed on branded reminder advertising, unbranded advertising has come to have a strong presence in Canadian pharmaceutical DTCA. Conversely, in the US, where full-product ads are permitted, unbranded advertising has traditionally played a less prominent role in pharmaceutical marketing campaigns, with unbranded advertising accounting for only about 4% of total DTCA in the US in 2009.¹⁰⁸ This is largely due to the fact that unbranded sites typically generate much lower traffic than a branded site and also creates the danger that a competing brand might benefit from the other’s unbranded efforts.¹⁰⁹ However, “evolving consumer health information-seeking and pharmaceutical marketing trends have prompted companies to reevaluate the role of unbranded initiatives in their promotional and customer service plans.”¹¹⁰

First, as more and more consumers turn to the Internet as a source of health information, unbranded initiatives, particularly those focused around a particular disease or condition, allow pharmaceutical companies to connect with patients throughout the stages of encounter with a disease and potentially drive them into the “marketing funnel”.¹¹¹ Even in the US where unbranded marketing efforts were traditionally viewed as much less effective than branded messages, now many pharmaceutical companies will nonetheless create unbranded education-oriented sites to market drugs before they have been approved by the FDA. While the use of these unbranded sites tends to decline once a drug is FDA-approved, almost half of brands maintain an unbranded education-oriented site to complement the disease information on their branded drug product site.¹¹²

In general, most consumers tend to trust “unbranded” information found on major third party health and medical websites more than “branded” information on industry-sponsored websites. In addition, the PriceWaterhouseCooper survey discussed above revealed that consumers were more likely to trust information posted by doctors and hospitals compared to insurers and drug companies. In particular,

¹⁰⁸ L2 Think Tank, supra note 97.
¹¹¹ L2 Think Tank, supra note 97.
only 37% of respondents said they would trust information posted by a pharmaceutical company. Nonetheless, there is still sufficient demand for unbranded health information for the pharmaceutical industry to enter the arena. Further, when unbranded marketing initiatives engage a variety of social media platforms and online marketing techniques, there are ample opportunities to push the advertisement to a wider audience than those who might actively seek information from major general health and medical websites; “[i]ntegrating campaigns both within and across channels can help leverage investment in unbranded websites more fully.”

Unbranded marketing campaigns are often better suited to social media platforms than corporate initiatives. The most successful social media campaigns tend to be those that focus on “socially-relevant” content such as causes, events, support and services; that is, “[a]n unbranded approach can offer a more human and personal way for pharmaceutical companies to participate in social media.”

In general, consumers are more likely to engage with and support a relatable cause on a social media platform than a particular pharmaceutical product. For example, a consumer would be much more likely to “like” a Facebook page aimed at raising awareness about depression than they would be to “like” a page for a branded antidepressant.

One example of successful “cause” marketing is World Contraception Day, a worldwide campaign to improve awareness of contraception to enable young people to make informed decisions on sexual and reproductive health. World Contraception Day is sponsored by Bayer HealthCare Pharmaceuticals and is supported by a coalition of 11 international NGOs, scientific and medical societies with an interest in sexual health, including the US Agency for International Development and Planned Parenthood. In addition to a website (www.your-life.com), the campaign also has an active Facebook community (www.facebook.com/yourlifecom) with almost 30,000 members. Perhaps most amusingly, the campaign has also developed a Facebook game called “Sperm Invasion” in which players must prevent pregnancy by shooting down sperm before they can fertilize an egg. By teaming up with NGOs and other organizations, Bayer is able to gain more credibility and buy-in for a campaign that raises awareness about birth control options (and hopefully may translate into more

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113 Terhune, 2012, supra note 79.
115 Ibid.
sales of Bayer’s birth control pill, Yaz). At the same time, the “cause” of World Contraception Day is a more socially relevant and marketable campaign than a campaign centred directly around a particular birth control pill. Consequently, people are more likely to respond to the campaign by sharing the message through their social networks.

While certain types of cause marketing may be positive if they raise awareness about a disease condition or raise money for a charitable cause, there are concerns that certain “causes” may be hijacked by the pharmaceutical industry for their own financial gain.\(^\text{117}\) As such, while there is clearly the potential for positive partnerships between pharmaceutical companies and the medical community and patient interest groups, there is a need for caution in ensuring that campaigns meet the same standards of scientific rigour and objectivity even where they are endorsed by patient interest groups and other health-related organizations.

3.3.1 Reminder Advertising in Social Media

To date, disease-oriented and help-seeking ads have been more common than reminder ads in social media campaigns aimed at Canadian audiences. Nonetheless, there are a growing number of reminder ad campaigns being developed. In Canada, likely the most aggressively advertised birth control pill, and indeed one of the most widely advertised prescription drugs in recent years in general, is the oral contraceptive Alesse manufactured by Pfizer. Beginning around 2000, Wyeth (later acquired by Pfizer)\(^\text{118}\) launched a wide-scale advertising campaign for Alesse that included print, television, movie theatre, transit and online advertising. However, the most recent wave of Alesse advertising centres around the “Start Something with Alesse” campaign.

Launched in 2010, the “Start Something with Alesse” initiative was one of the first Canadian pharmaceuticals campaigns to be focused online and incorporate elements of social media including a Facebook page\(^\text{119}\) and news feed.\(^\text{120}\) According to the Pfizer news release, the campaign is “[i]nspired by the resourcefulness and community focused characteristic of Generation Y (or those born between 1980 and 1999)” and is designed

\(^\text{117}\) This debate was discussed in the recent documentary film “Pink Ribbon, Inc.” See http://www.nfb.ca/film/pink_ribbons_inc_clip.
\(^\text{118}\) In October 2009, Wyeth was acquired by Pfizer, which is now the largest research-based pharmaceutical company in the world.
\(^\text{119}\) See https://www.facebook.com/startsomethingwithalesse.
“to solicit innovative proposals from young adults committed to bringing about positive change in their own lives and the lives of those around them.”\textsuperscript{121} Applicants submit their ideas through the program website. Once finalists are selected, the project descriptions are posted on the campaign website and Canadians are able to vote for their favourite entry online. The winners receive mentorship support and a $5000 grant to start their initiative.

The “Start Something with Alesse” campaign is another example of “cause” advertising that has become popular with pharmaceutical advertisers hoping to break into the social media sphere. While the idea of a campaign to reward entrepreneurially-minded youth is in itself positive, the campaign is clearly part of a larger branding effort for Alesse. Indeed, the startsomethingwithalesse.ca website contains a large banner up the right side of the screen the reads “ask your doctor about ALESSE” and provides a link to the Alesse Canadian product website (note that since the Alesse.ca website is “gated”, the information contained on the entrance page stays within the name, price, and quantity restriction). Moreover, the campaign itself was clearly designed in a way that would encourage the spreading of the message: since the winner is determined by votes from the public, entrants are encouraged to spread the word through Facebook and other social media channels, or through the “tell a friend” e-mail widget on the website, to try and get people to vote for them.

Unfortunately for Pfizer, the “Start Something with Alesse” campaign does not appear to have generated much buzz amongst consumers. To date, the Facebook page has just over a thousand fans, which is a mere blip in the Facebook universe. As such, this campaign demonstrates that meeting regulatory requirements in only the first hurdle in designing a successful social media marketing campaign.

\subsection*{3.3.2 Disease-Oriented and Help-Seeking Advertisement in Social Media}

In Canada “unbranded” disease-oriented and help-seeking ads are the most common form of pharmaceutical advertising. As discussed in s. 2.2.1, the distinction between these two types of ads is important in relation to sponsorship identification: while disease-oriented ads may include a brief sponsorship message, help-seeking ads may not identify the drug manufacturer.

To date, one of the most heavily marketed help-seeking/disease-oriented social media campaigns in Canada is the Living Well with Psoriasis\textsuperscript{122} campaign launched by

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{livingwellwithpsoriasis.png}
\caption{The Living Well with Psoriasis website features Janssen’s corporate logo in the bottom left corner.}
\end{figure}


\textsuperscript{122} See www.livingwellwithpsoriasis.com.
Janssen. This campaign is specifically targeted at a Canadian audience and features a website, Facebook page, Twitter feed and mobile app, all of which include the Janssen logo and a link to their corporate website.\textsuperscript{123} The Living Well with Psoriasis campaign has been quite successful in attracting followers in Canada, at least on Facebook; the campaign Facebook page has over 10,000 fans.\textsuperscript{124} Conversely, the corresponding Twitter feed has been a flop: the Twitter feed has only 30 followers and has not been updated since October 2011.\textsuperscript{125}

Although much of the main website is devoted to providing (relatively) neutral information about the disease itself, there are several elements of the site that clearly appear to cross the line into help-seeking announcement territory, namely:

- a “Dermatologist Finder” feature which helps users locate a dermatologist in their area based on their postal code;
- a testimonial video that concludes with the message “Take control today. Find a dermatologist who uses all treatment options”;
- a “psoriasis questionnaire” that determines the severity (“little to no impact” to “severe”) of the user’s psoriasis and encourages him or her to consult a doctor about their condition;\textsuperscript{126} and
- an online “severity calculator” (as well as a link to a downloadable app) that has an interactive diagram to allow the user to input the areas on his or her body affected by psoriasis, and then irrespective of the results, encourages the user to talk to his or her doctor about treatment options.\textsuperscript{127}

All of these features appear to “invite consumers to seek information about a specific medical condition or set of symptoms from a physician or healthcare professional or an alternate source of information” – that is, the very Health Canada definition of a help-seeking ad. If the Living Well with Psoriasis campaign is a help-seeking ad, then under the current regulations, the site should not include any sponsorship statement by Janssen or a link to their corporate website.

\textsuperscript{123} The site also includes the disclaimer "This site is intended for Canadian audiences and is published by Janssen Inc. which is solely responsible for its contents." See www.livingwellwithpsoriasis.com.
\textsuperscript{124} As of August 18, 2012. See https://www.facebook.com/livingwellwithpsoriasis.
\textsuperscript{125} As of August 18, 2012. See https://twitter.com/lwwpsoriasis.
\textsuperscript{126} If the questionnaire reports that the user’s psoriasis is "severe", the results suggest "Consider talking to your doctor about how you feel and ask them to review your treatment plan to see if you are still on the best treatment to meet your needs." Even where the questionnaire reports "little or no impact", the results suggest that "If you do have specific areas of concern, however, it might be worth discussing them with your doctor." See https://www.livingwellwithpsoriasis.com/psoriasis-questionnaire.
\textsuperscript{127} After inputting the affected areas on the diagram, the severity calculator continues on to a questionnaire that inquires if the user is currently being treated. If he or she is not, the results report that "It is important that you get the medical care you need to treat your psoriasis." If he or she is currently being treated, the questionnaire goes on to question whether the user if his or her treatment is working and if there is anything about the treatment that he or she does not like, which can lead to the result "Your doctor may be able to work with you to find a better treatment plan. It is very important that you find the treatment plan that works for you."
Currently, this potential violation of the regulations does not appear to be on Health Canada’s radar. Further, such violations are unlikely to be a priority since there is a lack of consensus over whether such sponsorship identification actually represents a threat to the health and safety of Canadians. On the one hand, allowing pharmaceutical companies to openly display sponsorship of a particular DTCA message provides a more direct marketing link between the health information and the pharmaceutical treatments offered by a particular drug company. On the other hand, sponsorship identification could increase transparency by allowing patients and consumers to be made more directly aware when a message is owned, administered or funded by a pharmaceutical company.\textsuperscript{128}

A third alternative that might serve as an appropriate compromise between the two viewpoints discussed above is to require that sites sponsored by the pharmaceutical industry feature a “disclaimer” alerting consumers that the site is sponsored by a pharmaceutical firm, but prohibiting the sponsor from actually identifying the company. This approach would have the advantage of signalling to consumers that the site is sponsored by the pharmaceutical industry (and therefore potentially subject to a certain bias), while removing some of the incentive for firms to create such campaigns in the first place since they cannot link the information to their particular company (and thus nudge consumers towards their own drug products).

4 The New Dynamics of Social Media

As discussed above, the interactive nature of social media has changed the way that the world communicates. New Internet technologies have not only increased the amount and quality of online information and the speed with which it can be accessed, but have also introduced new modes of interaction. For the purposes of pharmaceutical marketing, there are three primary aspects of social media that have changed the rules of the game: the ability of users to generate their own content; the ability of users to propagate content through their own social networks; and the unprecedented ability of promoters to target advertising based on information contained in user profiles and search history. As will be discussed in the following sections, each of these aspects of social media introduces complications that make the application of the existing regulations an uncertain process and highlights the need for more regulatory guidance from Health Canada.

\textsuperscript{128} Liang & Mackey, 2011, supra note 64 at “Reform Considerations”
4.1 User-generated Content on Industry-Sponsored Platforms

Social media is unique in that it gives consumers and patients the opportunity to directly interact with and contribute content to sites. However, user-generated content (UGC) complicates DTCA by raising questions about whether and under what conditions the drug company is responsible for the content created by third parties. In addition, as will be discussed in s. 4.1.1, some pharmaceutical advertisers report that they have been hesitant to invest in social media initiatives due to uncertainty around responsibility for reporting adverse drug reactions that may be revealed through UGC on industry-sponsored websites and social media platforms.

Although Health Canada has not yet released any specific guidelines regarding the rules for UGC, the basic rules still apply: for material to qualify as DTCI, the information presented must be “non-promotional” and “no element may directly or indirectly promote the sale of a drug.”129 This rule appears to apply regardless of the source of the content. Indeed, the guidance offered by PAAB and the ASC clearly establish that pharmaceutical companies are responsible for monitoring and controlling all content present on their sponsored Internet and social media sites, including content contributed by users and other third parties.130

Effective monitoring and administrative control of all sponsored websites is of critical importance for pharmaceutical advertisers since “[o]nce a website is determined to be advertising, the site in its entirety, including any user-generated content, is subject to regulatory control.” For disease-oriented or help-seeking messages, advertisers must keep an eye out for any UGC that might render the message promotional. For example, a post by a patient on an “informational” website that comments on his or her success with a particular drug product could render the site promotional. Similarly, for reminder ads that feature a particular drug product, any UGC that reveals more than simply the name, price and quantity of the drug could render the message non-adherent to the DTCA regulations. For example, on a Twitter feed for a particular drug, if a user post mentions even the medical specialty associated with the product, this could render the site non-adherent. Perhaps somewhat ironically, even a negative user comment that criticizes a drug product or manufacturer may render a site non-compliant if it identifies the drug product (for a disease-oriented ad) or goes beyond the name, price and quantity restriction (for a reminder ad).

The ASC cautions that drug manufacturers must recognize the inherent challenges of UGC in social media sites which may quickly render DTCI non-compliant with the Health Canada guidelines. In particular, the Council recommends: the use of the social media platform’s administrative controls to manage the level of UGC that may be posted; the proactive and regular monitoring of social media sites to remove UGC that might render the site non-compliant; and the use of disclaimers to alert consumers that content will be monitored and may be removed to maintain compliance. Of particular concern is UGC that makes reference to off-label uses and adverse events, which ASC indicates should be promptly removed from the site.

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131 McKenzie & Parsons, 2011, supra note 56.
132 Ibid.
133 ASC DTCI Guide, supra note 31 at 7.
In the absence of specific guidance from Health Canada on the particulars of responsibility for UGC, the pharmaceutical industry is beginning to implement its own measures to try and clarify responsibility for UGC, most commonly through the use of disclaimers. For example, the “Living Well with Psoriasis” Facebook Page contains a disclaimer outlining the page commenting policy and responsibility for reporting adverse events:

**COMMENTING POLICY:**

*At Janssen, we value the insight and opinions of people who wish to join or participate in the Living Well with Psoriasis community. We believe that your experiences should be heard, but we also operate in a regulated environment. Please help us by not commenting directly about specific medications.*

*While we will not monitor comments before they are posted, comments will be reviewed on an on-going basis. It may be necessary for us to remove comments if they refer to specific medications or if they could be offensive to some people.*

*The comments on this site come from members of the public and do not necessarily reflect the views of Janssen, and no endorsement or approval of their content should be implied. Comments that contain links to third-party or commercial websites may not be posted. Any websites referred to in comments are not endorsed or supported by Janssen.*

Of course, posting such a disclaimer will offer little protection unless the sponsoring pharmaceutical company actually actively follows its own stated policy.

Due to the importance of effectively monitoring and moderating industry-sponsored messages on social media sites, drug companies are understandably wary of investing in social media platforms that do not offer sufficient administrative controls. As an illustration, in May 2011, Facebook made changes to its policy that now prevent page owners from being able to have the commenting function disabled. Previously, some page owners, most notably pharmaceutical and financial companies, were able to request that the commenting feature be disabled on their sponsored pages in order to more easily avoid regulatory issues. However, in May 2011, certain pharmaceutical page owners received an e-mail from Facebook administration informing them that “Facebook will no longer allow admins of new pharma pages to disable commenting on the content their page shares with people on Facebook” and

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135 *Specifically, Facebook opened up comments on all corporate Pages, general disease awareness Pages, and unbranded campaign Pages. However, Pages that promote, talk about, or support prescription drugs or devices or pages that focus on a disease state where there is only one prescribed treatment may still have the commenting function disabled. See Matthew Snodgrass, “Facebook Page Commenting Changes” *Common Sense* (blog) (13 April 2011), online: <http://blog.wcgworld.com/2011/04/facebook-page-commenting-changes>.*
that “Pages that currently have commenting disabled will no longer have this entitlement after August 15th.”\textsuperscript{136} However, although users are no longer prevented from posting comments on page-created content, the page owner retains the ability to subsequently remove any and all user comments at their discretion. Further, the page owner can still block users from creating their own posts on the page’s wall or otherwise creating and adding their own content.\textsuperscript{137}

This change in policy prompted many pharmaceutical firms to quickly discontinue their product and disease-oriented Facebook pages. While it is unclear what prompted Facebook to make this policy change, some industry analysts have speculated that Facebook may have been concerned that “too many drug companies were creating and controlling Pages about generic themes.”\textsuperscript{138} Since Facebook is based on the concept of being an open forum, ensuring the ability to comment may have been viewed by Facebook as a means to provide a less censored environment.

For manufacturers that allow user comments on industry-sponsored sites, monitoring UGC for compliance can prove to be a daunting task. For example, in March 2012, Janssen announced the discontinuation of the Facebook page for its European Psoriasis 360 campaign (although the website, Twitter feed and YouTube channel continue). In a statement published on the Psoriasis 360 Facebook wall, the "Psoriasis 360 team" stated that "we have found ourselves removing a larger and larger proportion of posts, stifling worthwhile discussions."\textsuperscript{139} Janssen reported that in the final three months of the Facebook page, a third of all posts to the page had to be removed, the majority because they mentioned a specific prescription-only drug by name, or talked about the effectiveness of a particular treatment (or its side effects). A small minority of posts were disallowed because of the use of offensive language.\textsuperscript{140} Interestingly, the Facebook page for Janssen’s Canadian-based Living Well with Psoriasis campaign is still up and running.

Evidently, if the sponsoring manufacturer is monitoring UGC for posts that may render the site non-compliant with the regulations, they are also likely using the opportunity to remove any negative posts about their products or company, regardless of whether that particular post would raise any regulatory issues. The pharmaceutical industry has a significant stake in trying to control their brand image on


\textsuperscript{137} Note the distinction between “commenting” and “posting” on a Facebook Page. Posting involves creating a new item or topic on the Facebook page Wall, which may include such things as pictures, videos, events, links or text statements. Commenting involves writing a statement or review about a particular item or topic that has already been posted on the Page Wall and consists only of text or hyperlinks. Comments are directly associated with a particular post and appear immediately below the post in chronological order.

\textsuperscript{138} Eldon, 2011, supra note 136.


social media platforms, and user posts and comments have a strong potential to say negative things about a particular drug product. Ad Age Insights reports that in the U.S., when social media posts do mention specific pharmaceutical marketing campaigns “consumer sentiment tends to be negative – with large doses of ridicule directed at the list of potential side effects.” In addition, there have been many anecdotal reports of consumers becoming angry with pharmaceutical website moderators for removing UGC in which a user posted information about their negative experiences with a particular drug product, or negative reviews of the company in general. While many may view this type of moderating as a form of censorship, pharmaceutical companies are certainly not required to leave negative messages about their company or products on online platforms that are under their control.

4.1.1 Adverse Event Reporting

In Canada, section C.01.017 of the Food and Drug Regulations requires that drug manufacturers report all serious adverse drug reactions to the Minister of Health within 15 days of receiving or becoming aware of the information, regardless of whether the adverse reaction occurred in Canada or not. In a guidance document entitled Reporting Adverse Reactions to Marketed Health Products issued in March 2011, Health Canada indicates that drug manufacturers should screen websites under their management or responsibility for potential adverse reaction case reports. As noted by the ASC, this would include all adverse events revealed through social media sites. The guidance document further states that although pharmaceutical companies are not obligated to monitor external websites, “if a manufacturer becomes aware of an [adverse reaction] on a website that it does not manage, the [manufacturer] should review the case and determine whether it should be reported.”

Health Canada also identifies minimum criteria for an adverse reaction report: (1) an identifiable reporter (source); (2) an identifiable patient; (3) a suspect product; and (4) an adverse reaction. Where possible, it would likely be advisable for the drug manufacturer to attempt to follow up with the person making the report on the site to determine if the minimum criteria for the adverse reaction report can be discovered and whether the reaction has already been reported to the proper authorities.

141 Ad Age Insights, supra note 70 at 13.
142 Food and Drug Regulations, supra note 37 at s. C.01.017.
144 ASC DTGI Guide, supra note 31 at 7.
145 Adverse Reactions Guidance Documents, supra note 143 at 16.
146 Ibid at 11.
As with other forms of UGC, many pharmaceutical advertisers are now including disclaimers on websites and social media pages addressing adverse event reporting. For example, the Living Well with Psoriasis Facebook page includes the following statement:

**ADVERSE EVENTS**

This site is not intended for the reporting of adverse events of any kind. If you wish to report an adverse event, please write to us at dsscan@its.jnj.com or call us toll free at 1-800-567-3331.147

Presumably, any adverse event reported to the drug company via phone or e-mail would subsequently be referred to the appropriate authorities at Health Canada, as required by the regulations.

Although there is still significant uncertainty around what form and amount of information posted on a social media site would trigger the duty to report an adverse drug event, the pharmaceutical industry is cautious enough to be motivated to sidestep the issue by disabling commenting functions. Interestingly, industry commentators in the US have reported that the primary reason that pharmaceutical companies wish to disable the commenting function on Facebook pages is because of FDA regulations that require them to report any “adverse events” that they become aware of.148 However, once again the pharmaceutical industry’s expressed concerns about adverse event reporting are likely, at least in part, a decoy argument to try and draw attention away from the fact that, from the perspective of drug companies, the greatest threat posed by UGC is in fact negative publicity.

### 4.1.2 Social Media “Testimonials”

Some drug companies, particularly in US-based marketing, have launched promotional campaigns that try to harness the interactive nature of social media by inviting consumers to share “testimonials” on their experiences with a particular disease or drug product. As an example, in February 2009, AstraZeneca launched the “My Asthma Story” campaign, which centred around a branded YouTube channel for its asthma drug Symbicort. The channel featured testimonial videos from “ordinary people” sharing their stories about coping with the challenges of asthma, with each video demonstrating how Symbicort

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147 See Living Well with Psoriasis Facebook page, *supra* note 134.
became an integral part of their regimen to manage asthma.\textsuperscript{149} The accompanying website\textsuperscript{150} invited Symbicort users to upload videos about their own experiences with the drug. According to AstraZeneca, submitted videos were reviewed by a panel of legal, regulatory and compliance experts, with selected videos appearing on the Symbicort YouTube channel.\textsuperscript{151}

Although many industry commentators initially praised the ingenuity of the My Asthma Story campaign, the campaign was abruptly discontinued in 2010, likely over fears of regulatory non-compliance. In particular, it can be a challenge to meet the FDA rules around “fair balance”\textsuperscript{152} in the patient testimonial video format. As an illustration, in a similar campaign developed by Sanofi-Aventis called whyinsulin.com, to comply with the FDA regulations, patient testimonial videos were interrupted by a blue screen featuring “important safety information”, which significantly detracted from the authenticity of the videos.\textsuperscript{153}

Although campaigns like My Asthma Story that are centred around a specific branded drug product would not be permitted under the Health Canada regulations since they would go beyond the name, price and quantity restriction for reminder ads, there are nonetheless other ways that Canadian advertisers may make use of patient “testimonial” content gathered through social media. For example, Janssen recently announced an initiative around its Canadian Living Well with Psoriasis campaign: the “Are You a Living Well Champion?” contest invites users with psoriasis to write an essay or upload a photo or video that depicts how they are “living well” despite their psoriasis for a chance to win $10,000 (e.g. “Maybe you became a school teacher, ran the Boston Marathon or did extreme kayaking.”) The top 20 entries will be placed on the website and the winner will be determined based on online votes. As another interesting example, Pfizer recently launched a health awareness campaign in Europe called “Can you feel my pain?” that utilizes the popular photo sharing site Flickr to invite users to post photos depicting what it is like to live with chronic pain.\textsuperscript{154}

\textsuperscript{149} Some risk information scrolled across the bottom margin of the videos while they played, with a link to full product information appearing near the top of the channel page. Videos on the YouTube channel were not open for commenting.

\textsuperscript{150} Ben Corner, “AZ launches branded YouTube channel, testimonial site” Medical Marketing and Media (6 February 2009), online: MMM <http://www.mmm-online.com/az-launches-branded-youtube-channel-testimonial-site/article/127046/>.

\textsuperscript{151} Ibid.

\textsuperscript{152} In DTCA, “fair balance” refers to the presentation of accurate and fair assessment of the risks as well as the benefits of the drug. Specifically, the FDA defines fair balance as “the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety.” See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 202.1(e)(7)(viii)).


\textsuperscript{154} See http://www.flickr.com/groups/can-you-feel-my-pain/ The site states: “We are looking for inspiring photos that illustrate “what your pain is like on a good day and what your pain is like on a bad day.” What does chronic pain feel like? What does it look like? Share your thoughts, feelings, and experiences about chronic pain using photos.”
One danger that arises when pharmaceutical advertising combines with UGC is the potential for consumers to be misled about the source of the information. The Internet often seems to be filled with “people just like us” who face similar health challenges.\textsuperscript{155} However, appearances can be deceiving. Pharmaceutical companies often monitor patients’ online social media activities in an attempt to target them for advertising. Moreover, “unbranded websites and paid ‘independent’ health bloggers target people who are looking for the experience of other fellow sufferers.”\textsuperscript{156} As an illustration, in November 2010, a complaint filed with the U.S. Federal Trade Commission alleged that Sanofi-Aventis had paid spokespeople to pose as typical consumers on the whyinsulin.com website. Subsequently, the whyinsulin.com website was taken down in 2011.

Another potential complication introduced by UGC is the potential for health care professionals or other “experts” to promote a particular drug product through their personal blog or website. Although patients and consumers are clearly permitted to write about and share their own experiences with a particular drug product through social media and other online technologies, the situation becomes problematic where there is any sponsorship relationship between the propagator and the pharmaceutical industry since this is essentially a form of indirect DTCA. Moreover, even where a physician or other health care professional has no affiliation with the pharmaceutical manufacturer, they may be restricted from promoting specific health products on their personal sites. As an illustration, in July 2011, Health Canada issued an advisory on its website entitled “Health Products Advertising on Physician Web Sites — Questions and Answers.” The advisory warned physicians that “if physician Web sites promote specific products, they must comply with the [Food and Drugs] Act and its associated regulations.” The specific reason for issuing the advisory was that:

\begin{quote}
“\textit{Health Canada has received complaints regarding direct-to-consumer advertising of prescription drugs on Web sites of some cosmetic surgeons. In addressing the complaints, it was noted that this practice was widespread. Health Canada suspects that physicians may not be aware of the federal advertising prohibitions or their application to physician advertising.”}\textsuperscript{157}
\end{quote}

Health Canada also contacted the provincial and territorial medical licensing bodies to get their assistance in educating physicians about federal advertising regulations for prescription drugs.\textsuperscript{158}


\textsuperscript{156} Ibid.


Another potential violation of DTCA regulations might arise if celebrities or other influential figures discuss their successes with a particular pharmaceutical product. As an example, a drug company in the US entered into a partnership with a professional race car driver, who also happened to be an avid Twitter user and diabetic. The race car driver began to “tweet” about his success with two insulin products produced by the drug company, but also included the drug’s generic name and a link to information about the drug’s risks and benefits.\(^\text{159}\) However, although this type of ad might be permitted in the US, it would likely violate Canada’s DTCA restrictions since it mentions a specific drug product. Nonetheless, a drug company in Canada could sponsor a celebrity or well-known scientific or medical expert to spread the word about a disease-oriented or help-seeking message through his or her social media streams.

### 4.2 Consumer Propagation and Viral Marketing

One of the most unique features of social media technologies is the ability for everyday users to become a broadcast source, either through creating their own message or propagating a message from another source. Arguably, this is the feature of social media that has most transformed online communication. The use of social networks to achieve marketing objectives can sometimes rise to the level of “viral marketing” when the self-replicating nature of popular messages in social media is analogous to the spread of viruses, particularly computer viruses.

The key to a successful viral marketing campaign is to create “viral messages” that have a high probability of being presented and spread by individuals through their social media connections within a short period of time. The ultimate goal of most online marketing campaigns is to “go viral” – that is, to create a message that is so unique, funny, shocking or otherwise memorable that everyone will share it with everyone else.\(^\text{160}\) In addition, viral marketing is likely the most borderless form of advertising since it follows lines of social connectivity that reach every corner of the globe. Further, it has a tendency to turn up messages even after they have been banned or discontinued in their original medium. For example, a controversial ad for a banned drug may still turn up on YouTube and be subject to mass distribution. Indeed, American TV ads for the withdrawn arthritis drug Vioxx are still widely available on YouTube.


\(^{160}\) While there is no specific measure to determine when a message has spread enough to be considered as “viral”, as an example, popular YouTube videos will often receive more than 5 million views within a few weeks or months. However, “viral” success is not simple measured by viewership, but may also consider such aspects as how much buzz the message creates in the media or through online discussion, how much the message is parodied or incorporated into other messages, and how long the message is shared for and remains popular. See Megan O’Neill, “What Makes a Video ‘Viral’?” Social Times (9 May 2011), online: Social Times <http://socialtimes.com/what-makes-a-video-viral_b61409>.
It is important to note that a marketer cannot simply create a “viral” campaign; a campaign “only becomes viral if people share it with others and those people do the same.” Rather, all a marketer can do is to take certain measures to increase the likelihood that the content will go viral, such as creating a simple, low commitment but memorable message and getting the right people to talk about it.

The Health Canada guidance document *The Distinction between Advertising and Other Activities* indicates that “[w]here the same message is delivered repeatedly, the message is more likely to be considered as advertising.” Although in traditional forms of push media such as television, radio and print, the advertiser alone controls the frequency of the message through their advertising budget, with social media the frequency of message delivery depends significantly upon consumer participation and propagation. Obviously, with social media the advertiser controls certain elements of the frequency of the message, such as the presence of the message on multiple social media sites concurrently and targeted advertisements on the Internet and social media sites. However, another important consideration in assessing the frequency of a message is the aggressiveness with which the advertiser tries to incentivize consumers to spread the message through their social networks. As such, in the context of social media, an assessment of message frequency should arguably take into account the measures taken by the advertiser to try to push the message to a wider audience.

It has become common practice for websites in all sectors of the economy to include “widgets” that allow users to share a website or page through popular social media sites such as Twitter, Facebook and LinkedIn with a single click. Such widgets are intended to allow a particular website or message to be propagated as easily as possible. Many pharmaceutical websites, particularly those oriented toward a particular cause or disease, often include these widgets.

In an effort to encourage consumers to spread a sponsored message through their own social networks, many pharmaceutical marketers incorporate a variety of different incentives into their social media campaigns; advertisers may run contests, make donations to a charity based on the number of times the message is shared, or design games or apps to increase the entertainment factor of the site. For example, Sunovion has created a Facebook app around its sleep medication Lunesta called “Follow

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163 For example, many campaigns such as Janssen’s Living Well with Psoriasis campaign feature a website, a Facebook page, a Twitter feed, a YouTube channel and iPhone/smartphone apps.
the Wings”. To encourage users to share the game, Sunovion has teamed up with the charity CARE and has pledged to contribute $1 to CARE the first time a user plays the game and every time a user shares the game with a friend. As another example, in Pfizer’s “Start Something with Alesse” campaign mentioned above, the winner of the contest is determined based on votes from online consumers, which encourages contestants to share the message broadly through their social networks in order to gain votes.

Videos are one of the most common types of messages to go viral. A good example of an attempt to create a viral video is Roche’s Big Blue Test campaign. Started in 2009, this “unbranded” campaign aims to raise awareness about the importance of exercise in connection with diabetes management. To encourage people to share the message, the program sponsor, Roche Diabetes Care (makers of ACCU-CHEK® diabetes products and services) pledged to make a donation for every view received (up to a maximum of $75,000) to provide diabetes medication and supplies to children in the world’s poorest countries. By November 2010, the campaign’s YouTube video had received more than 100,000 views, making it one of the most widely viewed pharmaceutical social media campaigns to date. The success of this campaign is also likely due to the fact that the campaign involved a strong educational message about the importance of exercise in diabetes management. As discussed above, such “unbranded” messages generally have much stronger penetration in social media spheres than branded messages.

Viral marketing is almost certainly the most difficult form of “marketing” to regulate since it is the consumers themselves, rather than the promoter, who are primarily responsible for the propagation of the message. As a result, it is one area of DTCA that will probably have to remain largely unregulated. Any attempts at regulation would probably have to be limited to rules restricting the drug company from participating in the further propagation of viral messages, or rules around targeting such campaigns. Unfortunately, attempting to regulate viral marketing raises the spectre of censorship because restricting the practice would likely require clamping down on the ability of individuals to freely spread messages on the Internet.

4.3 Targeted Marketing

Although traditional advertising media do allow limited forms of targeted marketing (e.g. advertising arthritis pain medication in a magazine aimed at seniors), social media technologies represent an unprecedented opportunity to corner the target audience. Social media

164 “Follow the Wings” uses Lunesta’s butterfly logo as a “player” that must be moved around to collect coins and flowers and avoid obstacles.
sites give promoters the opportunity to target their advertisements to particular audiences based on information from users' profiles and online activity; advertisers can target not only based on demographic information and interests listed in a user's profile, but may even advertise to friends and connections of users who have shown an interest in their page. Likely the most well-known example of targeted advertising is Facebook ads, which allow advertisers to target based on information such as age, location, gender, work, education and relationship status. As another example, the popular professional networking site LinkedIn allows advertisers to target marketing based on such parameters as job title, job function, industry, company name and company size, or LinkedIn Group.

The pricing scheme for Facebook advertisements, and many similar social media sites, is based on two different methods: Cost Per Click (CPC), which allows the advertiser to specify a certain amount that they are willing to pay each time a user clicks on their ad, and Cost Per Thousand Impressions (CPM), which allows the advertiser to specify how much they are willing to pay for 1000 impressions (i.e. views) of their ad. Under the CPM model, the advertiser can ensure maximum impact per dollar by correctly targeting their ads to an interested audience.

There is a diversity of ways in which the pharmaceutical industry could use these targeted marketing opportunities to narrow the focus of their advertising campaigns to those users who are most likely to have an interest in their products. For example, advertisers could promote birth control pills to women between the ages of 14-40, or arthritis pain medication or cholesterol lowering drugs to persons over age 50. There are even potential benefits to such targeted marketing since it could be used to route advertisements to more appropriate audiences – for instance, excluding children under the age of 18 from seeing the ads. However, there is a dark flipside to this if certain drugs are specifically targeted at vulnerable groups such as children or the elderly. For example, targeted marketing might raise controversy if, for example, they promoted sleeping pills or anti-anxiety drugs to students in high-stress majors such as law and medicine.

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165 "Promote Your Business with Ads” Facebook for Business, online: Facebook <https://www.facebook.com/business#!/business/ads/> [Facebook Ads] at Step 2. According to the Facebook advertising guide, promoters can target users based on:
- Location, Language, Education, and Work
- Age, Gender, Birthday, and Relationship Status
- Likes & Interests
- Friends of Connections: Friends of Connections targeting allows you to target the friends of users already connected to your Page or App to reach a more relevant audience. To use this, simply look for the Friends of Connection check box under the Connections on Facebook section of the ad creation interface.
- Connections: Connections targeting allows you to target your ad to current fans of your Page for promoting special offers and driving customer loyalty.

Facebook also offers the option to target students at specific colleges or universities, or students with a particular major. See "Ads: Targeting Options”, online: Facebook <https://www.facebook.com/help/?page=863>.

166 "Frequently Asked Questions” LinkedIn Ads, online: LinkedIn <http://partner.linkedin.com/ads/faqs/?utm_source=li&utm_medium=el&utm_campaign=gate-c>.

167 Facebook Ads, supra note 165 at Step 4.
One aspect of targeted marketing that is likely to raise the most concern is campaigns aimed at children and youth. The Canadian Association of Broadcasters' *Broadcast Code for Advertising to Children* prohibits the advertising of “[d]rugs, proprietary medicines and vitamins in any pharmaceutical form” to children under 12 years of age. However, there are no specific prohibitions against marketing drugs to teenagers. Perhaps the most obvious example of prescription drug advertising aimed at teenagers is birth control or anti-acne medications.

Ultimately, given the potential for pharmaceutical advertisers to use targeted marketing to direct their online campaigns at particular groups or demographics, this is clearly another area of social media marketing that could benefit from greater regulatory guidance. In particular, Health Canada should set out rules that prohibit pharmaceutical advertisers from targeting ads at vulnerable groups, particularly children under the age of 18 or the mentally incompetent. Of course, defining who constitutes a "vulnerable" population will be no simple task since regulators must avoid being overly paternalistic and treating certain groups as being less competent to make health-related decisions. A more tenable approach might be to articulate a series of principles around targeted marketing to help guide acceptable targeting practices. For instance, knowingly targeting a population where their use of the drug is likely to constitute off-label use of the product would likely be inappropriate. Nonetheless, an assessment of the appropriateness of a given targeting scheme may ultimately have to be made on a case-by-case basis.

### 4.3.1 Search Engine Advertising

Another form of targeted marketing that has transformed online commerce in recent years is sponsored search engine advertising where promoters pay search engines such as Google, Bing and Yahoo! for traffic from the search engine to their website. Most commonly, the sponsored search results are driven based on specific key words that a promoter chooses to associate with their ad. However, with the newest wave of sponsored search results, search engines like Google actually provide “personalized ads” by collecting and compiling information about a user’s online activities in order to show consumers ads related to websites visited, recent searches and clicks, or information

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from e-mail inboxes. According to L2, approximately 70% of pharmaceutical brands engage in paid search advertising on Google or Bing.

Sponsored search ads allow major search engines to sponsor their current infrastructure (for example, such advertising allows Google to sponsor free services such as Google Maps, Gmail, Google Pages, Google Calendar, Google Docs, etc.). At the same time, sponsored search is a tool that is key to the success of many businesses; without it, many online businesses that have little or no presence in natural web search results would have no way to generate online traffic to their websites.

However, sponsored search results have also generated a fair amount of criticism. The US Federal Trade Commission has reported that search engines do not adequately label sponsored links, and various studies have shown that searchers are often unaware of the distinction between sponsored links and non-sponsored links. And while the same studies reported that searchers who are aware of the distinction tend to find sponsored links to be less relevant, there are nonetheless a significant number of consumers who are persuaded to click on sponsored links instead of the natural search results (indeed, if this were not the case, advertisers would not invest in sponsored links). As such, online advertisers have a clear potential to manipulate the information that consumers access online.

The potential for sponsored search results to influence the information accessed by consumers searching for health information online is easily demonstrated by typing common health topics into any search engine. For example, entering the term “birth control” on Bing produces a sponsored link for the emergency contraceptive pill Plan B as one of the first three “results” that appear on the top of the screen. Similarly, entering the term “psoriasis” in Google produces a sponsored link for Janssen’s Living Well with Psoriasis campaign.

As with any other form of pharmaceutical DTCA, search engine sponsored link advertisement and the keywords that generate these links are subject to the Health Canada regulations. Guidance from PAAB suggests that for websites for Schedule F drugs, the aggregate of the keywords, sponsored link, the landing page (i.e. the page accessed by a web browser upon following a link) and its URL may not go beyond the name, price and quantity restriction. Similarly, for websites for drugs for the treatment of Schedule A diseases, the aggregate of the keywords, sponsored link, the landing page and its URL may

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170 Ads Preferences, online: Google <https://www.google.com/settings/ads/preferences/?hl=en>. The Google Ads Preference Manager even allows users to manage their ad preferences by blocking certain advertisers. Users also have the option to opt out of ad personalization entirely.

171 L2 Think Tank, supra note 97 at 16.

172 Jansen & Mullen, 2008, supra note 169 at 115.

173 Note that the above example of Plan B falls outside of the DTCA restrictions since Plan B is available from a pharmacist without a prescription.
not allude to the therapeutic use. Finally, for disease-oriented websites, the keywords, sponsored link, the landing page and its URL may not contain the drug name. However, these restrictions do not currently apply to organic keyword results.

4.3.2 Rogue Advertisers

At this point, it is also worth mentioning that the pharmaceutical industry is certainly not the only group using targeted marketing and search engine advertising to promote the sale of prescription drugs. Another form of pharmaceutical DTCA that presents a significant public health risk is illegal online pharmacies that use sponsored search results to advertise illicit pharmaceutical products. Illegal online pharmacies present a wide range of safety concerns, including:

- they are may not be licensed or subject to proper regulatory oversight and many allow medications to be purchased without a prescription;\(^{175}\)
- they may sell expired, mislabelled, or counterfeit medications,\(^{176}\) or may sell drugs that are not approved for sale in Canada or that have been withdrawn from the market due to safety concerns;\(^{177}\)
- they may offer inadequate security and leave patient data open to breaches of confidentiality;\(^{178}\) and
- many online pharmacies are not actually located in the country that is claimed.

Ordering drugs online also means that patients miss the opportunity to have direct contact with a pharmacist, who can provide valuable information such as reviewing drug safety information and identifying possible drug contraindications and adverse side effects.\(^{179}\)

Although legitimate online pharmacies do exist, the staggering majority of online drug retailers are not properly accredited. As an illustration, LegitScript, the leading Internet pharmacy verification and Internet enforcement service in the US, reports that of the more than 40,000 active Internet pharmacies monitored, only 2-3% are identified as legitimate.\(^ {180}\) Further, LegitScript reports that “well over 90% of Internet pharmacies are outright illegal, selling prescription drugs without a valid

\(^{174}\) Massad, 2010, supra note 27.
\(^{175}\) Liang & Mackey, 2011, supra note 64 at “Rogue eDTCA 2.0”.
\(^{177}\) Liang & Mackey, 2011, supra note 64 at “Rogue eDTCA 2.0”
\(^{178}\) WebMD, supra note 176.
\(^{179}\) Ibid.
\(^{180}\) LegitScript employs a series of Internet pharmacy verification standards, including pharmacy licensure, registration, validity of prescription, and privacy protection. See Legitscript Internet pharmacy verification standards, online: LegitScript <http://www.legitscript.com/standards>.
prescription; offering unregulated and potentially unsafe pharmaceuticals; and/or lacking required pharmacy licenses.\textsuperscript{181}

For years illegal online pharmacies succeeded in circumventing search engine mandates for legitimacy verification and used search engine-sponsored links to illegally market prescription drugs. Following investigations by regulatory authorities, major search engine operators, namely Google, Yahoo! and Bing, adopted recommendations requiring online pharmacies to provide VIPPS\textsuperscript{182} accreditation. However, although this step helped eliminate sponsored links for illegal online pharmacies on the major search engines, online pharmacies are increasingly infiltrating social media platforms, most notably Facebook.\textsuperscript{183}

In one of the largest forfeitures in US history, in August 2011, Google agreed to a USD $500 million settlement to avoid prosecution by the US Justice Department on charges that the company had knowingly accepted illegal advertisement from “Canadian” online pharmacies for years.\textsuperscript{184} Although the company claimed that they had rigorous controls in place to prevent unlicensed online pharmacies from advertising on Google, a criminal probe revealed that some Google insiders had turned a blind eye to the tactics used by illicit pharmacies to circumvent these controls. Some internal documents even suggested that Google had been actively working with illicit advertisers to prevent their ads from being disqualified. In particular, the US government alleged that “Google was aware that it was violating U.S. law since at least 2003 and provided ‘customer support’ to some Canadian online pharmacies until 2009 to help them reach U.S. customers.”\textsuperscript{185}

As part of the settlement, Google accepted responsibility for helping “Canadian" online pharmacies to target ads at US customers. However, despite being the most trafficked website in the world, Google is only one of several search engines; other major search engines such as Bing and Yahoo have also been reported to run ads from illicit online drug sellers. Nonetheless, the Google settlement has likely sent a strong message to these other search engines to ensure enforcement of ad controls on illicit online pharmacies.

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\textsuperscript{181} A Message from LegitScript’s Founder and President, online: LegitScript <http://www.legitscript.com/johnhorton>. Note that LegitScript only verifies the legitimacy of online pharmacies located in the U.S. and does not certify Canadian pharmacies.

\textsuperscript{182} The VIPPS (Verified Internet Pharmacy Practice Sites) program, established by the National Association of Boards of Pharmacy in the US, consists of a series of licensing and inspection requirements that pharmacies must comply with to receive certification. Once an online pharmacy is approved, the site may display the VIPPS hyperlink seal. See VIPPS information and verification site, online: National Association of Boards of Pharmacy <http://vipps.nabp.net/>.

\textsuperscript{183} Liang & Mackey, 2011, supra note 64.


\textsuperscript{185} Ibid.
While illegal online pharmacies are less of a concern in Canada than in the US since lower brand-name drug prices and broader public drug programs in Canada reduce or eliminate the incentive for consumers to try to find cheaper drugs online, the issue of illegitimate sources of pharmaceutical advertising certainly exists in Canada. Moreover, if Canadian pharmacies are actually participating in targeting US consumers and selling pharmaceutical products online without a prescription, Health Canada certainly has a stake in regulating such illegitimate and even illegal activities.

5 Regulatory Approaches

According to Epps, “[r]egulatory regimes are best seen as occupying a continuum, with pure forms of government regulation and self-regulation at opposite ends.” In a system of direct government oversight, the government is responsible for all aspects of regulation and administration of the regulated activity; this system is often referred to as classic “command and control” regulation. Direct government regulation can also exist in combination with other systems of governance, most commonly industry self-regulation or third party oversight, as will be discussed below.

Under the current regulatory system, Health Canada is responsible for interpreting and enforcing drug advertising regulations, including establishing policies to effectively regulate marketed health products, issuing guidelines for the interpretation of the regulations; and overseeing regulated advertising activities. However, Health Canada does not directly review DTCA materials for compliance with the regulations. Rather, the preclearance of advertising for marketed health products is carried out through a self-regulatory and voluntary system in which independent preclearance agencies review and preclear advertising material to help advertisers ensure compliance with the regulatory provisions of the Food and Drugs Act, the Controlled Drugs and Substances Act and respective regulations. Advertising preclearance agencies use Health Canada’s guidance documents and their own codes of

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187 Ibid at 78.
189 Health Canada, Health Canada and Advertising Preclearance Agencies’ Roles Related to Health Product Advertising (Guidance document) (Ottawa: Health Canada, 2010) [Preclearance Guidance Document]. According to this document, “[t]he board of directors or advisory bodies of these agencies may include stakeholders from academia, consumer groups, the media, advertising agencies, the pharmaceutical industry, and healthcare professional associations. Health Canada acts as an ex-officio observer and advisor to these boards and advisory bodies, without relinquishing any part of its authority under the F&DA and Regulations. Although Health Canada works in collaboration with these agencies, it does not endorse them.”
190 Independent preclearance agencies are defined as “independent entities which review and pre-clear advertising material to help interested parties ensure compliance with the advertising provisions of federal legislation, the various Health Canada guidance documents, as well as their own codes of advertising.” See ibid.
advertising to ensure that advertising material is “accurate, balanced and evidence-based” and is consistent with the Terms of Market Authorization191 for the health product.

While all advertising preclearance agencies, including the ASC and PAAB, offer mechanisms to resolve complaints on advertising for authorized health products, Health Canada is directly responsible for handling any complaints about prescription drug advertising and information aimed directly at Canadian consumers.192 Any complaints of this nature received by an advertising preclearance agency must be referred to Health Canada.193 Within Health Canada, complaints are investigated by the Health Products and Food Branch Inspectorate. However, the Branch will generally not proceed against an advertiser unless it can demonstrate that the ad is deceptive or poses significant risk to the health of Canadians.194 With respect to enforcement, Health Canada has indicated that “its efforts range from education and voluntary compliance to warning letters and prosecutions that could result in fines, injunctions or imprisonment.”195

Since 1996, Health Canada has conducted three major consultations with stakeholders concerning changes to the legislation banning DTCA of prescription drugs. These consultations have involved a broad range of stakeholders including community and consumer groups, patient groups, academia, industry, media and health professionals. Although no new legislation has been enacted, these consultations have highlighted a number of proposals for regulatory reform. In the most recent consultations in 2005, there was agreement that clear criteria must be developed to help determine what constitutes balanced and correct information and that Health Canada has a vital role to play in helping to establish these policies and standards.

5.1 Direct Government Regulation

As mentioned above, during discussions with Health Canada in April 2009, the PAAB outlined the issue of social media marketing and raised the idea of Health Canada creating guidelines for the pharmaceutical industry’s use of social media. However, Health Canada declined to issue any such

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191 The Terms of Market Authorization consists of all labelling information and accompanying material that was submitted with the product during regulatory review as authorization. See ibid.
192 Preclearance Guidance Document, supra note 189. Complaints related to DTCA of prescription drugs and Schedule D drugs (biologics, including vaccines) are submitted to the Regulatory Advertising and Risk Communications Section of Marketed Health Products Directorate. Complaints related to advertising of unauthorized health products are submitted to the Health Products and Food Branch Inspectorate for compliance verification.
193 Ibid.
195 Ibid at 9.
specific guidance. At subsequent meetings between Health Canada and the advertising preclearance agencies in 2010\textsuperscript{196} and 2011\textsuperscript{197}, Health Canada once again confirmed they are not currently developing guidance documents for social media advertising. Rather, Health Canada reiterated that existing regulatory advertising provisions apply indiscriminately to all media. They also noted that they have provided guidance on the use of social media to various stakeholders, and participated in the PAAB’s 2009 workshops on Social Media Marketing. However, Health Canada stated that they would consider adding statements in guidance documents to inform stakeholders that advertising provisions apply to all media and would provide input when PAAB revises its Code to reflect social media.\textsuperscript{198}

The debate over whether or not government regulators should issue specific guidelines to address the social media context has also arisen in the US. In November 2009, the FDA held hearings to learn about the unique challenges of marketing pharmaceutical products via social media and the Internet. Following these hearings, the FDA made a number of public announcements about its intention to develop social media guidance, even placing an item called “Promotion of Prescription Drug Products Using Social Media Tools” on its 2010 agenda.\textsuperscript{199} Yet all of 2010 and most of 2011 passed before the FDA finally released its first social media guidance in December 2011. However, social media was only a side topic of the guidance, which was in fact about responding to requests for off-label information and only touched on certain aspects of social media within that discussion.\textsuperscript{200} According to many industry commentators, “[a]ll mention and discussion of a grand, all-encompassing social media guidance has disappeared” and it’s highly unlikely that a major statement on the use of social media as a whole will be on the FDA’s agenda again anytime soon.\textsuperscript{201} As such, pharmaceutical marketers in the US are now scaling back their expectations on FDA guidance.

Although the FDA appears to have moved away from its original intention to issue context-specific guidelines, the fact that social media and Internet technologies are now part and parcel of its discussion of regulated communications is, nonetheless, a major step forward.\textsuperscript{202} Some industry analysts now speculate that the inclusion of social media in the off-label marketing guidance is an indication that the FDA will be including discussion of social media in future guidance documents. Indeed, in October 2011, and FDA spokeswoman reported that “[p]olicy and guidance development for promotion of FDA-

\textsuperscript{196} 2010 Record of Discussions, supra note 218.
\textsuperscript{197} 2011 Record of Discussions, supra note 158.
\textsuperscript{198} Ibid.
\textsuperscript{200} Ibid.
\textsuperscript{202} Ibid.
regulated medical products using the internet and social media tools are among our highest priorities” and that the FDA is currently in the process of developing multiple draft guidances that touch on these issues.203

Another jurisdiction that appears to have backed away from issuing specific social media guidelines is the UK. The Association of the British Pharmaceutical Industry (ABPI) has convened a digital media working group to assist its member companies in applying its Code of Practice to the social media context. Although this working group originally considered developing specific social media guidance and case study examples to illustrate different ways of using social media, in more recent meetings the working group decided that producing new guidance would only increase confusion levels. In January 2012, an ABPI spokeswoman stated that “With the rapid pace of change in digital media, if we had bowed to pressure and produced guidance 12 months ago, this would have been out of date as soon as we’d written it.”204 Instead, like the FDA, the ABPI has taken a more stepwise approach and in June 2011, ABPI’s Pharmacovigilance Expert Network issued adverse event and product complaint guidance notes that covered blogs, tweets and other online medical communities.

Overall, while many stakeholders are still placing pressure on pharmaceutical regulators to issue comprehensive guidance on digital communications, there is no clear consensus in the industry that this is the best approach. In the end, the rapidly changing nature of social media and new Internet technologies creates significant concerns that comprehensive guidelines would be complex to design and would require frequent updating, and might ultimately create more confusion than clarity. Consequently, the pharmaceutical industry is largely being left to push the boundaries and scope of digital media on their own, while still working to stay within regulatory guidelines.

Considering the experiences of pharmaceutical regulators in the US and the UK, it appears unlikely that Health Canada will issue specific social media guidance in the foreseeable future. Nonetheless, Health Canada appears to be a bit behind in the game since the aspect of social media has yet to be included in any Health Canada guidance document. As will be discussed below, to date it has been the preclearance agencies, rather than Health Canada, that have stepped up to the plate in terms of offering industry guidance on how to conduct social media marketing campaigns within Health Canada’s regulatory restrictions.

203 Ad Age Insights, supra note 70 at 11.
As a starting point, Health Canada should follow the example of its British and American counterparts and include aspects of social media in new guidance documents. Further, key components of existing guidance documents should be updated to incorporate the social media context. In particular, Health Canada should include an updated definition of “the Internet” in the 1996 guidance document *The Distinction Between Advertising and Other Activities*. Currently, the only definition of the Internet is as an example of “interactive electronic databases”, which are defined as “electronic information systems that provide menus through which the consumer can control the level of information detail accessed upon request.” However, considering the extensive evolution of Internet technologies in the last 15 years, most modern online and social media technologies go far beyond the scope of the definition of interactive electronic databases. In addition, the guidance document should also be updated to include social media examples.

### 5.1.1 Enforcement Issues

Proponents of direct government regulation argue that it offers a number of advantages “in terms of visibility, credibility, accountability, compulsory application to all... greater likelihood of rigorous standards being developed, cost spreading... and availability of a range of sanctions.” Unfortunately, many of these purported benefits fail to play out in practice. In recent years, a significant amount of criticism has been directed against Health Canada for its lack of enforcement of advertising regulations. According to Gardner et al., “[r]esponse to complaints tends to be slow, probably reflecting Health Canada’s undercapacity to regulate DTCA, and, arguably, ineffectual.” They point to the example of a television advertisement for the drug Zyban which was allowed to run for four months even though Health Canada was aware that the ad included product claim information in contravention of the regulations. Further, some sources report that no company has been fined or had any other sanctions imposed against it by Health Canada for any promotional violation, including DTCA, since 1978.

In 2004, the House of Commons Standing Committee on Health released a report entitled *Opening the Medicine Cabinet* which highlighted concerns over Health Canada’s passive stance on the enforcement of the DTCA regulations, stating that “Health Canada has abrogated its clear responsibility to enforce the existing rules.” As such, the Committee called on Health Canada to immediately enforce the current prohibitions on all industry-sponsored DTCA on prescription drugs and recommended that they

205 Advertising Distinction Guidance Document, supra note 29 at iv.
206 Gardner, Mintzes & Ostry, 2003, supra note 5.
207 Ibid.
209 Standing Committee on Health Report, supra note 194 at 10.
“dedicate specific resources to the Health Products and Food Branch Inspectorate for vigorous enforcement of the direct-to-consumer advertising regulations on prescription drugs, including active surveillance of all relevant media, identification of potential infractions, appropriate corrective action, and production of annual public reports…”\(^{210}\)

Canada is certainly not the only country that has struggled with direct regulation of pharmaceutical advertising. Lexchin points out that “fiscal pressures in almost all countries have prevented government agencies from effectively policing pharmaceutical promotion.”\(^{211}\) Given the considerable return on investment that the pharmaceutical industry can achieve from sales generated through DTCA, government regulatory bodies generally lack the resources necessary to implement strict enough sanctions to make it economically rational for firms to adhere to regulations. Further, government regulators are often criticized for lacking the expertise necessary to regulate the industry. Lexchin points to the challenges faced by the FDA in attempting to directly regulate DTCA in the US: the FDA is chronically under-funded; staff are consistently overwhelmed by the volume of material that they have to deal with; and they are becoming increasingly unwilling to confront firms guilty of promotional violations due to an inability to adequately reprimand violators.\(^{212}\)

Another potential explanation for Health Canada’s lack of enforcement of existing DTCA regulation may be drawn from the economic theory of regulatory capture developed by George Stigler, a Nobel laureate economist. According to his theory, regulatory capture occurs when a regulatory agency, which was formed to act in the public interest, eventually acts in ways that benefit the very industry it is supposed to be regulating, rather than the public. The reason for this is simple: “a regulated industry has a far larger stake in regulatory decisions than any other group in society. As a result, regulated companies spend lavishly on lobbyists and lawyers and, over time, turn the regulatory process to their advantage.”\(^{213}\)

In Canada, the regulatory system responsible for approving prescription drugs is largely funded by the pharmaceutical industry through a user-fee system. Through these financial contributions, the pharmaceutical industry has gained significant influence within the drug regulatory system and uses this influence to request a disproportionate distribution of funding towards fast drug approval, rather

\(^{210}\) Ibid at 11.
\(^{211}\) Lexchin Affidavit, supra note 9.
\(^{212}\) Ibid at para. 113.
than long-term safety monitoring.\textsuperscript{214} Non-enforcement of legislation by government may be seen “as a soft way of managing the pressure from industry.”\textsuperscript{215} Alternatively, non-enforcement may simply stem from an unwillingness to take on the pharmaceutical industry in costly and time-consuming legal battles.\textsuperscript{216}

Although in the eight years since the release of the House of Commons Standing Committee on Health report few substantive changes have been made in the way that the DTCA regulations are enforced, Health Canada has been credited with improving its response times to complaints – at least for those referred by the advertising preclearance agencies. In general, response times have improved year over year.\textsuperscript{217} Moreover, at an April 2010 meeting between Health Canada and the advertising preclearance agencies, the meeting attendees acknowledged that advertising issues that are referred to Health Canada from the advertising preclearance agencies are “not straightforward and often require consultation among various areas within Health Canada”, and further “often require policy work, issue analysis, or legal advice, which can all be time consuming.”\textsuperscript{218} Further, urgent issues, such as advertising for unauthorized products, are addressed on a priority basis, particularly if they present a health risk.\textsuperscript{219}

Even if Health Canada did regularly levy sanctions for breaches of the DTCA regulations, the maximum penalties allowed under the \textit{Food and Drugs Act} are trivial at best. Section 31 of the \textit{Food and Drugs Act} provides that for a contravention of the Act or its regulations, a party is liable for a maximum fine of $5000, a term of imprisonment of up to three years, or both.\textsuperscript{220} Although a prison term of three years could be considered as fairly substantial, since corporations cannot be imprisoned, this sanction is rarely applicable to pharmaceutical companies.\textsuperscript{221} Therefore, the pharmaceutical industry is unlikely to be deterred from breaching the DTCA regulations by the threat of either jail time or a maximum fine of $5000. Interestingly, the one type of offence under the \textit{Food and Drug Act} and regulations that is subject to much more substantial fines is those offences related to food. In particular, under s. 31.1,

\textsuperscript{214} Epps, 2007, supra note 186.
\textsuperscript{215} UK Parliament, Select Committee on Health, Memorandum by Professor Les Toop and Dr Dee Richards (Written Evidence) (22 March 2005), online: UK Parliament <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42we21.htm>.
\textsuperscript{216} Ibid.
\textsuperscript{217} 2011 Record of Discussions, supra note 158.
\textsuperscript{219} Ibid.
\textsuperscript{220} See \textit{Food and Drugs Act}, supra note 35 at s. 31. In particular, the party is liable for:
(a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both; and
(b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.
\textsuperscript{221} Except where personal liability can be found on the part of individual members of the corporation, which only occurs in exceptional circumstances.
any person who “contravenes any provision of this Act or the regulations, as it relates to food” is liable for a fine of up to $250,000, a term of imprisonment of up to three years, or both.222 Although addressing offences that relate to the quality and safety of food are understandably given significant importance, the discrepancy between the fines for food-related offences and other types of offences is striking – maximum fines for food-related offences are in fact fifty times higher than for other offences. Arguably, offences that relate to the quality and safety of drug products should be given at least equal weight to those related to food.

While increasing the maximum available fines for breaches of DTCA regulations is certainly not a complete solution – particularly in light of Health Canada’s marked lapse in imposing fines for such contraventions – the fact that fines of up to $250,000 are already available for food-related offences shows that there is certainly space to contemplate higher fines for drug-related offences. Moreover, the fact that an offending drug company could be found guilty of multiple counts of a breach, and consequently be subject to multiple fines, also increases the potential deterrent effect of higher maximum fines. That said, given the substantial financial resources of many large pharmaceutical companies, or more directly, the massive revenues that may be generated from drug products promoted through DTCA, there are strong arguments to be made that the maximum penalty provisions should be pushed far beyond $250,000 if they are to have any significant deterrent effect.

Another important aspect of deterrence is “public shaming” – that is, ensuring that the circumstances of the contravention become a matter of public record. At a meeting between Health Canada and the Canadian advertising preclearance agencies in April 2009, the ASC and PAAB noted that both agencies have recommended that Health Canada publish final rulings on advertising complaints that have been resolved in order to “increase transparency, discourage noncompliance, and to share information regarding past experiences and precedents.”223 Although Health Canada acknowledged the potential advantages of posting this information online, they noted that they face significant limitations due to the need to comply with the Privacy Act – the only exception being where the information is related to a significant impact on public health. However, Health Canada emphasized that they currently post recalls, warning letters and advisories and are developing the Compliance and Transparency Initiative (CTI) which may include publishing outcomes of Health Canada’s compliance work or generating

222 See Food and Drugs Act, supra note 35 at s. 31.1.
summary reports without specific details on the complaints to show what actions are taken to resolve the advertising complaints.224

Given the lack of enforcement of existing regulations in traditional media, there is understandably a significant amount of scepticism about the ability of Health Canada to effectively regulate DTCA on Internet and social media platforms; Health Canada appears to have neither the resources nor the political will to dedicate much attention to enforcing regulation on the Internet. Unfortunately, both the insubstantiality of the available sanctions and Health Canada’s lack of enforcement has led many drug companies to adopt an “it’s easier to ask forgiveness than permission” approach to advertising. That is, many drug companies are increasingly pushing the envelope with their DTCA campaigns in order to test the limits of what is permitted.

Overall, although there a clear need for reform in the enforcement of Canada’s DTCA regulations, a more detailed discussion of this issue is beyond the scope of this thesis. While Health Canada will continue to play an important, if somewhat ineffective, role in the provision and enforcement of DTCA regulations in both traditional and digital mediums, there is a concurrent need to consider other avenues besides direct government regulation for the effective regulation of pharmaceutical social media marketing. Indeed, as will be discussed in the following sections, both industry self-regulation and independent third party oversight may arguably be better suited for the enforcement of DTCA regulations in the Internet and social media context.

5.2 Independent Third-Party Oversight

Health Canada mandates two agencies to review and preclear advertising materials for prescription drugs directed at consumers: the ASC and the PAAB. Specifically, these two agencies “provide advisory opinions on messages directed to consumers for prescription drugs and on educational material discussing a medical condition or disease.”225 In addition, advertising material that is distributed to physicians or to patients through physicians is reviewed and precleared by the PAAB in accordance with the PAAB Code of Advertising Acceptance.

One potential advantage of third-party oversight is that independent agencies generally have more flexibility in their structure and mandate than government regulators, and may enjoy a less adversarial relationship with the pharmaceutical industry. During the most recent round of stakeholder

224 Ibid.  
consultations on regulatory reforms to the DTCA regulations in 2005, there was wide support for the idea that preclearance should be conducted by “an independent, trustworthy third party, staffed by experts from different fields and informed by consumers.” Stakeholders also noted that there was a corresponding need for any regulatory body to have clear authority to levy sanctions and to report violations to the public. However, Lexchin cautions that in New Zealand, where DTCA is largely governed by the independent Advertising Standards Complaints Board, such regulation is often ineffective because the board lacks the power to make decisions binding and enforceable. Indeed, this is already a difficulty faced by the PAAB since the organization has no authority to levy financial penalties on companies that breach its code and companies are rarely ordered to run corrective advertising. In addition, Lexchin points out that although the PAAB is independent of the pharmaceutical industry, the majority of members on its board come from organizations that benefit financially, either directly or indirectly, from advertising.

While Health Canada has not yet issued any guidance specific to social media, in the fall of 2011 the ASC updated its DTCA and DTCI guidance materials to include tips for social media marketing in an effort to “help advertisers ensure compliance with the Food and Drugs Act and Regulations when creating direct-to-consumer prescription drug messaging.” These guidance materials include the DTCA Rx Checklist, which helps advertisers to comply with Section C.01.044 of the Regulations under the Food and Drugs Act., and the DTCI Guide, which helps advertisers to meet the criteria set out in the Health Canada guidance document The Distinction Between Advertising and Other Activities. Both of these documents have been cited throughout this paper. In addition, in November 2010, the PAAB Chief Review Officer, Patrick Massad, made a presentation at the eMarketing Canada conference entitled “Incorporating a Strategic Regulatory Thought Process Into Your SMM Planning”. This presentation, which offers detailed guidance on the approach that pharmaceutical marketers should take when planning social media promotional activity, is available for reference on the PAAB website.

Since preclearance is not mandatory, advertisements may technically be released to the general public without being reviewed by government regulators or their delegated bodies. However, although the system is voluntary in that the review and preclearance of DTCA materials is not strictly legally required by Health Canada, most broadcasting and mass-media outlets in Canada will not publish an

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226 Legislative Renewal Report, supra note 34 at 13.
227 Lexchin Affidavit, supra note 9.
228 Lexchin Affidavit, supra note 9.
231 Gardner, Mintzes & Ostry, 2003, supra note 5.
advertisement without ASC or PAAB approval. Further, preclearance of physician materials and adherence to the PAAB Code is mandated for all members of Canada’s Research-based Pharmaceutical Companies (Rx&D). Promotional material that has been successfully precleared by the PAAB or the ASC may be marked with the PAAB or ASC logo, respectively, to signify the approval of each preclearance agency.

While preclearance is standard practice for traditional media such as print, radio and television, preclearance of consumer-directed online materials appears to be less frequent. For example, while the Canadian drug product websites for blockbuster drugs such as Nexium® (AstraZeneca), Singulair® (Merck) and Lantus (Sanofi-Aventis) all bear the PAAB seal of approval, the websites for other major drugs such as Lipitor® (Pfizer) and Advair® (Bristol-Meyers Squibb) do not. Moreover, the vast majority of pharmaceutical promotional materials on social media platforms do not bear either the PAAB or ASC seal of approval. Thus, while PAAB or ASC review appears to be common practice for DTCA materials in traditional media – likely due in large part to media outlet rules that require such review before publication – many drug product websites, and the vast majority of social media campaigns, do not undergo such preclearance review.

Due to the potential for DTCA materials to be released to the public without being subject to any type of review, some commentators have suggested that advertising preclearance of DTCA materials by the PAAB or ASC should be mandatory, rather than voluntary. Groups such as the Canadian Treatment Action Council argue that “[t]o ensure that advertisements are accurate and contain balanced information, they should be subject to mandatory preclearance by a… organization with a mandatory, transparent reporting system for violations.” Regis argues that another advantage of mandatory preclearance would be the possibility for Health Canada to require a mention of approval in ads that successfully make it through the preclearance process, which would help distinguish Canadian ads from their American counterparts, as well as indicate which drugs are available in Canada. She further suggests that to relieve Health Canada of any additional costs, this preclearance service could be

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232 Baker-Blais, supra note 30.
233 Ibid. All major brand name pharmaceutical manufacturers in Canada are members of Canada’s Research-Based Pharmaceutical Companies (Rx&D), an association of 50 leading research-based pharmaceutical companies, which has an Rx&D Code of Conduct which all member advertisements must comply with.
234 However, it is unclear if these sites do not bear the PAAB logo because they have not been reviewed by PAAB, or because the manufacturer did not choose to include the logo on the website.
235 Based on my own review of Internet material in June 2012.
237 Catherine Regis, “Direct-to-consumer advertising for prescription drugs in Canada: beyond good or evil” (2005) 14(2) Health Law Rev. 28. Regis also notes that “there would have to be mention of the limits of what such approval entails, so that patients clearly understand the role of Health Canada.”
financed by the pharmaceutical companies through a user fee system, as is done now under the voluntary system.²³⁸

Although many pharmaceutical companies already take advantage of the voluntary “advisory opinion” services offered by the PAAB and ASC, the industry would likely protest against a mandatory preclearance system due to increased cost, delay and loss of control. Further, both the ASC and PAAB would likely have to significantly increase their resources to accommodate the increased workload created by a mandatory preclearance requirement.

A mandatory preclearance system would have a particularly strong impact in the context of the Internet and social media since online media currently have a very low level of preclearance activity because unlike traditional media outlets, web hosting companies and social media platforms do not have any policies that require DTCA materials to be precleared prior to posting. Further, drug companies are likely aware that Health Canada has so far not treated the Internet and social media platforms as a priority, so online campaigns are probably less likely to be scrutinized than campaigns in traditional media. However, unless preclearance is mandated for all DTCA material, including for online and social media campaigns, drug companies have no particular incentive to submit their social media marketing campaigns for preclearance unless they have truly pressing questions about compliance.

Even without a mandatory preclearance requirement, the absence of specific social media guidance from Health Canada likely means that the interpretive guidance prepared by the ASC and PAAB already holds significant influence with pharmaceutical marketers; to date, the DTCL and DTCA guidance prepared by ASC and social media marketing workshops organized by the PAAB are really the only authoritative resources available. Although some pharmaceutical companies have been exploring social media marketing for several years, the release of the ASC and PAAB social media guidance materials has likely been an important step in giving many companies the confidence to enter this new medium.

Overall, the advertising preclearance agencies could potentially have an important role to play in the regulation of Internet and social media marketing campaigns, especially considering that these agencies are already developing expertise in this area – and have certainly done far more than Health Canada thus far. However, as long as preclearance of DTCA materials remains voluntary, many pharmaceutical advertisers will likely continue to forgo preclearance of their online marketing campaigns simply

²³⁸ Ibid.
because they can – and because they likely have little fear of reprisal from Health Canada even if they do contravene the regulations. Arguably, implementing mandatory preclearance of all DTCA materials would be one of the most straight-forward ways to pre-empt contraventions of the DTCA regulations, particularly in the Internet and social media context where few other advertising controls exist.

5.3 Industry Self-Regulation

In general, self-regulation refers to a regime where the industry or profession rather than the government is responsible for regulation. However, the term “self-regulation” can encompass a range of regulatory scenarios: “[a]t one end of the spectrum, the term is used quite narrowly, to refer only to those instances where the government has formally delegated the power to regulate... At the other end of the spectrum, the term is used when the private sector perceives the need to regulate itself for whatever reason...”

Systems of self-regulation commonly exist in combination with government regulation, with an industry or profession being given authority to govern itself while still relying on a state agency to carry out certain functions such as administration and adjudication of complaints. While self-regulatory bodies are usually granted a fair amount of autonomy with respect to rulemaking, monitoring, enforcement and sanctions, government will usually retain ultimate authority at some level.

There are a number of advantages that are commonly claimed for self-regulation. First, self-regulatory bodies often have more expertise and technical knowledge of practices in their industry than government regulators or independent agencies. Self-regulation may be more cost-effective in terms of the formulation and interpretation of standards, monitoring and enforcement, and also allows for administrative costs to be internalized by the industry and thus make no demands on taxpayer funds. In addition, self-regulation often allows for greater flexibility than direct government oversight as a result of less formal rules and processes. Finally, self-regulation also tends to reduce the adversarial stance between government and industry.

In Canada, pharmaceutical industry self-regulation stems not from delegated government power, but from within the private sector itself. Since DTCA is primarily the domain of innovative pharmaceutical


240 Epps, 2007, supra note 186 at 78.

241 Ibid at 78.

242 Ibid at 78.

243 Ibid at 80.
companies, the most important self-regulatory body as it relates to DTCA is Rx&D, which has established a Code of Ethical Practices to govern the relationship between its member companies and various stakeholders. The new 2012 version of the Code introduces a number of important revisions. Previous versions of the Code required members to comply with the PAAB Code of Advertising Acceptance and the Guidelines for General Advertising published by the Canadian Association of Medical Publishers – both of which dealt specifically with advertising and promotion aimed at healthcare professionals. But the new 2012 version of the Rx&D Code now requires all members to comply with all applicable provisions of the Health Canada regulations, the PAAB Code of Advertising Acceptance and the ASC Code of Advertising Standards. A breach of any of the above codes of regulations may be deemed by the Rx&D Industry Practices Review Committee (IPRC) to constitute a breach of the Rx&D Code of Ethical Practices. Many of the complaints that come before the IPRC are referred by the PAAB.

Since both the Health Canada regulations and the ASC Code include provisions that deal with advertising and promotional activities aimed at consumers, the recent revisions to the Code seem to indicate that the IPRC may now begin to field complaints that relate to DTCA. Further, the newly added “Scope” section of the Code states that the “Code applies to the activities of all Member employees who interest Stakeholders for the purpose of commercializing prescription drugs.” “Stakeholder” is specifically defined as including health care professionals, government or any other individual or organization “who has an interest in or is impacted by the activities of a Member company”, which presumably would include a consumer who purchases a prescription drug product.

All complaints of Rx&D Code infractions since 2006 are published on the Rx&D website for a period of 24 months. However, few details are provided on these cases and specific names of the companies and products involved are only published where a breach is found by the IPRC. Consequently, the deterrent impact of publishing infractions on the Rx&D website is likely to be limited since the

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244 Although the Canadian Generic Pharmaceutical Association (CGPA) adopted a Code of Marketing Conduct in 2008, generic drug companies generally make little or no investment in the type of DTCA that is the subject of this thesis. As such, the CGPA Code will not be discussed.
246 The Industry Practices Review Committers is the body within Rx&D responsible for adjudicating complaints of breaches of the Code of Ethical Practices. See s. 19 of Code of Ethical Practices. Prior to 2008, a violation of the PAAB or ASC code was an automatic Rx&D Code infraction. However, the section was changed in two significant respects: (1) infractions of PAAB and ASC Codes can only be violations of the Rx&D Code if IPRC receives and is guided by information provided regarding the infractions of the other codes; and (2) once referred, the decision on whether or not there has been an infraction of the Rx&D Code is left to the IPRC. See 2012 Rx&D Code, infra note 253.
247 2010 Rx&D Code, supra note 245 at s. 7.
248 Ibid at s. 8.
249 Ibid at s. 19.7.
summaries listed provide few details on each allegation or violation and the finding of an infraction is not publicized in any other way.

In the past five years, only 18 complaints have been filed with the IPRC. While the IPRC found breaches of the Code in 10 of these cases,\(^{250}\) the number of complaints heard by the IPRC is surprisingly low considering that Rx&D has 50 member companies that together invest more than $1 billion in drug research and development each year.\(^{251}\) The penalties for members found by the IPRC to be in violation of the Code during a given calendar year were recently increased in the new 2012 version of the code. Under the new Code, penalties have been increased from $10,000 to $25,000 for a first infraction, from $15,000 to $25,000 for a second infraction, from $25,000 to $50,000 for a third infraction, and from $50,000 to $100,000 for each additional infraction.\(^{252}\) In addition to a fine, upon a third violation, the CEO of the member company must appear before the Rx&D Board of Directors and provide a detailed explanation of the violations and a comprehensive written action plan to ensure remediation. The set fine for a first violation, and for subsequent violations, is fixed regardless of the severity of the breach (however, the IPRC has the discretion to count any violation as two violations).\(^{253}\)

The majority of the complaints before the IPRC are brought by pharmaceutical companies against competing firms. Arguably, in a highly competitive industry such as pharmaceutical sales, “the desire of individual companies to prevent competitors from gaining an edge can be harnessed to serve the public interest...”\(^{254}\) However, Lexchin argues that although self-regulation can inhibit competition to some degree, he points to a number of drawbacks with an existing Rx&D Code:

- the code relies on complaints of breaches before it takes actions, rather than proactively monitoring compliance;
- the majority of the members of the committee come from the pharmaceutical industry;
- fines for non-compliance are relatively small;
- there is no mechanism for regular review; and
- companies can avoid being governed by the code if they withdraw from Rx&D.\(^{255}\)

Further, many critics point to “the tension inherent in self-regulatory regimes between on the one hand, the public interest, and on the other, private interests that would otherwise be threatened by

\(^{251}\) The IPRC heard three cases in 2011, three cases in 2010, two cases in 2009, six cases in 2008 and one case in each of 2006 and 2007. See ibid.  
\(^{252}\) 2012 Rx&D Code, infra note 253 at s. 19.7.  
\(^{253}\) Canada’s Research-Based Pharmaceutical Companies, Code of Ethical Practices (2012), online: Rx&D  
\(^{254}\) Lexchin Affidavit, supra note 9 at para. 103.  
\(^{255}\) Ibid.
This tension may lead to weaker regulatory standards, ineffective enforcement and lenient sanctions. Self-regulation may also suffer from a lack of consumer representation or consultation.

Rx&D’s recent expansion of the scope of its Code of Ethical Practices and the increase in fine amounts is certainly an encouraging sign that industry self-regulation could have a larger role to play in the enforcement of DTCA regulations. Nonetheless, there are additional changes that could be made to the Code to increase its effectiveness. First of all, Rx&D should make its decisions more widely available to increase the deterrent effect of the finding of an infraction and to help establish a clearer case precedent of what sorts of activities will be found to contravene the Code. Further, the 24-month time limit on the posting should be removed so the precedent set by each IPRC decision can be permanently available on the public record. In addition, to improve transparency of the process, IPRC should have a broader range of representatives, including members of the public.

While industry self-regulation is certainly not a substitute for direct government regulation, there is certainly potential for the two systems to work in tandem, particularly given the partial void that has been left by Health Canada’s lack of enforcement activities. Moreover, self-regulation is one area that has the potential to work well in the Internet and social media context. As an emerging form of pharmaceutical marketing, many drug companies are paying close attention to the activities of their competitors in planning their own social media campaigns. As such, many drug companies may be eager to “rat out” a competing firm if they feel their competitor is pushing the rules too far and gaining an unfair marketing advantage. That said, such industry self-reporting is unlikely to take off unless and until Health Canada more clearly articulates how existing DTCA rules apply in the Internet and social media context. In particular, although a breach of the Food and Drugs Act or its regulations can constitute a breach of the Rx&D Code of Ethical Practices, as long as the rules of the game are unclear, neither Rx&D nor its members will have much confidence to act against a potential infringing firm.

6 Beyond Regulation

The response to the pharmaceutical industry’s burgeoning interest in social media should not simply be limited to restricting or regulating the advertising of drug products via digital media. After all, social media is equally available to health care professionals, advocacy groups, government and consumers as a tool to spread their own health information and such resources should be developed as an alternative to pharmaceutical industry

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256 Epps, 2007, supra note 186 at 81.
promotion. To round out the discussion on the regulation of DTCA on Internet and social media platforms, the following sections discuss how these new Internet and social media technologies can also be used not only to provide consumers with access to reliable health information, but also for public health benefits such as improving adverse event reporting.

6.1 Dissemination of Consumer Health Product Information

There is no doubt that Canadian consumers want access to more information about drugs and their effectiveness. During the most recent Health Canada consultations on amendments to the legislation banning DTCA in 2005, there was a clear emphasis among stakeholders on the need for health information that was independent from advertisements aimed at promoting sales. In particular, participants supported the establishment of a neutral health information website as well as a 1-800 number. In particular, the vast majority of participants emphasized that consumers (and practitioners) “need and deserve clear, balanced and neutral information in order to make informed choices about their health...”

In a policy statement released in March 2003, the Canadian Medical Association (CMA) similarly asserted that in order to make informed decisions about their health, consumers have a right to accurate information on prescription medications and other therapeutic interventions. The CMA, which is on record as opposing DTCA, added that “consumer drug information should be provided in such a way as to minimize the impact of vested commercial interests on the information content...

Pharmaceutical manufacturers and patient or consumer groups can be valuable partners in this process but must not be the sole providers of information.”

In addition to “health information” sites sponsored by the pharmaceutical industry, there are two other major sources of consumer health information used by Canadians: third-party health information sites developed by private companies, special interest groups and health care organizations; and health information sites sponsored by government departments or public institutions. In Canada, most third-party health information sites are run by special interest groups such as the Canadian Diabetes Association or the Heart and Stroke Foundation and focus only on one specific disease area. Consequently, most Canadians seeking more general health information online end up consulting third-party health information sites which are based in the US. This has important implications since most of the prescription drug information provided is based on FDA, rather than Health Canada approval, and

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257 Legislative Renewal Report, supra note 34 at 3.
258 CMA Policy: Principles for Providing Information about Prescription Drugs to Consumers (March 2003) online: Canadian Medical Association <http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD03-06.pdf> [CMA Policy].
perhaps more significantly, Canadian consumers are often exposed to American full product ads on these sites.

Section 6.1.1 explores the extent to which Canadians are turning to US-based sites for health information and the potential for growth in Canadian-based third-party health information sites to prevent consumers from looking south of the border. Then, section 6.1.2 discusses the extent to which the federal and provincial governments are involved in providing health information online and argues that government should play a stronger role in providing access to balanced, objective information on prescription drugs approved for sale in Canada.

### 6.1.1 Third-Party Health Information Websites

Many health information websites are established and maintained by independent organizations that have no direct ties to government or the pharmaceutical industry. These sites range from large, general health information sites and portals that provide articles and links on a wide range of health topics, to small sites focused on particular diseases or health conditions. Third-party sites are usually financed by advertising, third-party contributions and sponsorships. In the US, in particular, many health information sites are created in association with well-known hospitals or health care organizations such as the Mayo Clinic.

With more than 110 million unique users each month, US-based WebMD\(^{259}\) is the most popular third-party consumer health information website in both the US and Canada.\(^{260}\) Other popular third-party consumer health information websites include MedicineNet\(^{261}\) (a subsidiary of WebMD), MayoClinic.com\(^{262}\), HealthCentral.com\(^{263}\) and KidsHealth.org.\(^{264}\) In addition, there are a number of

\(^{259}\)WebMD’s Alexa traffic rank in Canada is 468 (as of April 4, 2012) based on the number of Canadian visitors to the site. See [http://www.alex.com/siteinfo/webmd.com](http://www.alex.com/siteinfo/webmd.com)


\(^{261}\)MedicineNet.com ([http://www.medicinenet.com/](http://www.medicinenet.com/)) is owned and operated by WebMD and part of the WebMD Network. The content is produced and edited by a nationally recognized network of over 70 U.S. Board Certified Physicians. Additional feature include Web videos, daily health news, an email newsletter and a symptom checker. See Consumer and Patient Health Information Section, 2010 CAPHIS Top 100 List Health Websites You Can Trust (2010), online: CAPHIS <http://caphis.mlanet.org/consumer/top100all.pdf> [CAPHIS, 2010].

\(^{262}\)Mayo Clinic ([http://www.mayoclinic.com/](http://www.mayoclinic.com/)) provides easy-to-understand health and medical information, including a number of healthy living guides and helpful resources such as Health Tools, Treatment Decision Guides, blogs and podcast, and Ask a Specialist feature. Mayo Clinic experts review website content for accuracy. See *ibid*. MayoClinic.com’s Alexa traffic rank in Canada (as of April 4, 2012) was 722 based on the number of Canadian visitors to the site — see [http://www.alex.com/siteinfo/mayoclinic.com](http://www.alex.com/siteinfo/mayoclinic.com).

\(^{263}\)Health Central Alexa traffic rank in Canada (as of April 4, 2012) was 1992 based on the number of Canadian visitors to the site — see [http://www.alex.com/siteinfo/healthcentral.com](http://www.alex.com/siteinfo/healthcentral.com).

consumer information websites such as Drugs.com\textsuperscript{265} and RxList.com\textsuperscript{266} that focus specifically on providing information on drugs, both prescription and non-prescription.

Overall, the majority of the popular general health information websites accessed by English-speaking Canadians are based in the US. In contrast, as noted above, most third-party consumer health information websites based in Canada focus on specific disease areas. (As will be discussed below, the one major exception to this trend is the popular French-language site Passeportsanté.net.\textsuperscript{267}) As a result, much of the health information that Canadians access online (at least English-speaking Canadians) is subject to regulation by the FDA rather than by Health Canada.

Although the health information available on reputable third-party sites like WebMD is frequently reviewed for accuracy and timeliness by physicians and other qualified health professionals, the fact remains that the majority of these third-party sites are funded predominantly through advertising revenue. WebMD, in particular, has been the subject of controversy, with critics charging that its content steers readers toward drugs manufactured by advertisers such as Eli Lilly.\textsuperscript{268} Since the majority of the most popular third-party consumer health information websites are based in the US, they are also subject to American regulations that permit full-product DTCA. As such, Canadians accessing health information on US-based websites are much more likely to encounter DTCA for prescription drugs than if accessing Canadian or even international sites where DTCA is more restricted. As with search engines like Google and Bing, WebMD search results display sponsored ads on top of and alongside natural search results. But more significantly, WebMD sometimes features banner ads for prescription drugs directly

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{cymbalta_webmd.png}
\caption{Ads for the pain medication Cymbalta on WebMD.}
\end{figure}

\textsuperscript{265} According to the site, “Drugs.com is the most popular, comprehensive and up-to-date source of drug information online. Providing free, accurate and independent advice on more than 24,000 prescription drugs, over-the-counter medicines & natural products.” Drug.com’s Alexa traffic rank in Canada (as of April 4, 2012) was 1514 based on the number of Canadian visitors to the site — see http://www.alexa.com/siteinfo/drugs.com.

\textsuperscript{266} RxList: The Internet Drug Index (http://www.rxlist.com) has information about prescription and non-prescription drugs, herbs, and supplements, searchable by generic and brand name. Additional tools include a pill identifier tool, information and slide shows about diseases and health topics, and a medical dictionary. See CAPHIS, 2010, supra note 261. The site’s Alexa traffic rank in Canada (as of April 4, 2012) was 6707 based on the number of Canadian visitors to the site — see http://www.alexa.com/siteinfo/rxlist.com.

\textsuperscript{267} Although the ranking is likely skewed because of the English-speaking majority, Passeport Santé’s Alexa traffic rank in Canada: 2843 (as of April 4\textsuperscript{th}, 2012) was 2843 based on the number of Canadian visitors to the site — see http://www.alexa.com/siteinfo/passeportsante.net (comparatively, the sites Alexa traffic rank in France was 976).

next to articles discussing the health condition for which the advertised drug is prescribed. For example, a WebMD article discussing tips for reducing chronic pain has featured not one but two banner ads for Eli Lilly’s pain medication Cymbalta®.

Interestingly, despite maintaining its position as the most popular third-party consumer health information website in the world, WebMD suffered significant financial losses in 2011, with stock prices falling by 55% from May to October 2011.269 The company largely attributes this decline to a drop in ad revenue due to pharmaceutical companies’ recent loss of patent protection for several major drugs. However, some industry commentators also attribute WebMD’s recent decline to the failure of the company to evolve along with broader trends which suggest consumers are turning to other sources for health information – particularly social media.270 As stated by one commentator, “the biggest threat to WebMD’s business model may be Facebook and Twitter.”271

In contrast to WebMD, the Québec-based site Passeport santé, which is the leading French-language health information site in Canada, has embraced the evolution towards social media by launching successful Facebook and Twitter pages in association with the main website.272 The site attracts more than three million unique visitors each month, including over 400,000 Canadians. The Passeport santé Facebook page has over 17,000 fans and is frequently mentioned in user posts; Passeport santé regularly features interesting health-related articles that users can “like”, post comments on, and share with friends, which has been successful in generating significant traffic to the page. Similarly, the Passeport santé Twitter feed, which has over 4000 followers, generates traffic by “tweeting” about and linking to interesting health-related articles that are available on the main website.

Although US-based sites are certainly a valid source of health information, Canadian sites offer the advantage of providing information that is specific to Canada, such as Canadian health statistics and information related to Health Canada approvals. While many disease or condition-specific websites such as the Heart and Stroke Foundation website are funded directly by the sponsoring organization and do not require ad revenue, other third-party sites like Passeport santé are largely financed through advertising. Nonetheless, since these sites are based in Canada, they are subject to Health Canada’s tighter regulations on pharmaceutical DTCA.

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269 Ibid.
270 Ibid.
271 Ibid.
272 Passeport santé is also popular in France and other French-speaking countries/regions in Western Europe and Africa. See http://www.alexa.com/siteinfo/passeportsante.net.
Passeport santé serves as the prime example of a successful Canada-based third-party consumer health information site. However, the success of this site in comparison to sites in English-speaking Canada is likely largely attributable to the fact that it is not directly competing with US-based sites. Further, the site has launched a successful social media campaign and appears poised for future expansion, not just in Canada, but within many French-speaking communities around the world. Although there is the potential for a Canadian-based third party health information site to take off in the future, such a site would likely face many hurdles considering that the market already appears to be largely saturated with US-based sites. Further, Canada’s stricter DTCA rules might make it more difficult for a Canadian-based site to attract advertisers in comparison to their American counterparts. As such, government-sponsored sites, which are discussed in the next section, are likely a more tenable option for providing Canadians with access to comprehensive information on prescription drugs, at least in the foreseeable future.

6.1.2 Government-sponsored Health Information Websites

In addition to third-party health information sites, many national and regional governmental organizations maintain websites and portals providing reputable health information. One major benefit of government-sponsored sites is that they do not rely on advertising revenue, which is particularly a problem on US-based third party sites that are subject to less strict pharmaceutical DTCA rules. However, government-sponsored sites in both the US and Canada continue to be less popular than their third-party counterparts.

The US government has been particularly active in funding initiatives to compile online consumer health information resources. For example, the National Institutes of Health (NIH), the US government department in charge of medical research, has developed the MedlinePlus website which offers more than 18,000 links to accurate and current medical information that has been evaluated by the National Library of Medicine. The National Library of Medicine has also created the NLM Drug Portal, which provides a comprehensive database of prescription and non-prescription drugs, including vitamins and supplements. In addition, the US Department of Health and Human Services has established the Healthfinder website, which provides links to selected information and websites from over 1500 health-related organizations. Unfortunately, although all of these websites provide high-

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273 MedlinePlus (http://www.nlm.nih.gov/medlineplus/) provides drug information, an illustrated medical dictionary, the latest health news, directories of doctors, dentists and hospitals, surgery videos, and interactive health tutorials. The GoLocal initiative adds links to local resources in more than 18 states with hospital information available in the other states. See CAPHIS, 2010, supra note 261.

274 NLM Drug Portal (http://druginfo.nlm.nih.gov/drugportal/drugportal.jsp) allows users to search by generic or brand name and obtain information from the NLM databases, the FDA, and other government sources.” See ibid.

275 Healthfinder (http://www.healthfinder.gov/) provides such tools as the Drug Interaction Checker, Online Checkups, and health newsletters in Spanish and English. See ibid.
quality and reputable health information free from advertising, they all generate significantly less traffic than their third-party counterparts such as WebMD and MayoClinic.com.  

Healthfinder is one US Government-sponsored health information website that has taken the leap into the social media sphere, with associated Facebook and Twitter accounts as well as an RSS feed and e-mail updates. While the healthfinder.gov Facebook page has only a modest following of just over 1600 fans, the Twitter feed has been very successful and has over 160,000 followers. The site receives very few Canadian visitors. Unfortunately, despite a dedicated Twitter following, the Healthfinder website continues to suffer from low levels of Internet traffic.

The Canadian federal and provincial governments have been much less active in developing online consumer health information resources than their American counterparts. Likely the most successful government-sponsored consumer health information site in Canada is the Public Health Agency of Canada website. Since one of the mandates of the Public Health Agency is to advocate for effective disease prevention and health promotion programs and activities, the organization website provides information on a range of public health topics, from infectious and chronic diseases to food safety and emergency preparedness. However, because of the organization’s specific public health mandate, the site does not provide as wide a range of health topics as other general health information sites – and provides very little information on drugs; the site is not designed as a comprehensive consumer health information resource. The Public Health Agency has also done a good job of engaging with social media platforms: the website features links to a Facebook page, Twitter feed, YouTube channel and an RSS feed, as well as a mobile version of the website and sharing widgets. While the popularity of these social media sites is only moderate, the site is nonetheless among the more social media-savvy of government initiatives in Canada.

Likely the most comprehensive government-sponsored consumer health information website in Canada is the HealthLink BC website developed by the BC Government. HealthLink BC is the gateway to access non-emergency health information and services in BC, namely “a collection of print and online resources, including the BC Health Guide Handbook, which puts health and health care system know-how into the hands and homes of British Columbians.” The HealthLink BC website includes a specific

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276 For example, healthfinder.gov has an US Alexa traffic rank of 23,791 (as of April 6, 2012). While the main NIH website itself gets a high level of traffic (Alexa traffic rank 172 in the US and 233 in Canada), there is no specific traffic information available on Alexa for MedlinePlus or the NLM Drug Portal since both are subsets of the main NIH website.

277 The Public Health Agency of Canada has 3600 Facebook fans, almost 9000 Twitter followers, but only 94 YouTube channel subscribers (as of April 7, 2012).

section on medications where consumers can enter either the generic or brand name of a drug product to receive information about the drug’s use and its side effects. Unfortunately, the website suffers from fairly low levels of traffic.\textsuperscript{279} The HealthLink BC website does not currently have a presence on social media sites like Facebook and Twitter, and further, is not optimized for sharing on these sites.

While HealthLink BC has potential since it offers the advantages of Canadian-centric health information free from advertising, the site fails to attract many of its potential users – perhaps due at least in part to a lack of engagement with social media platforms. Further, it would be inefficient for each provincial government to maintain its own, largely redundant, health information site. While it is positive that BC has taken the lead on this sort of initiative, greater efficiency (and funding) could be achieved through a cooperative effort with the federal and other provincial governments. Given the current absence of a comprehensive third-party consumer health information site in English-speaking Canada, there is certainly space for this type of initiative to grow and hopefully capture some of the consumer audience that currently turns to US-based health information sites.

In 2002, the high-profile Romanow Report\textsuperscript{280} on the future of health care in Canada expressed clear opposition to DTCA and recommended the establishment of a National Drug Agency, which among its various roles would “communicate evidence-based information and guidance to both health professionals and to patients, using various media including the Internet.”\textsuperscript{281} While Health Canada provides access to its online Drug Product Database\textsuperscript{282} which offers detailed information about all drugs approved for use in Canada, including links to a PDF of the Product Monograph, much of the information provided is quite technical in nature and is not targeted at consumers (in comparison, the NLM Drug Portal in the US is more user-friendly and comprehensive). While Health Canada has discussed the possibility of creating a Therapeutic Products Register (repository) that would include labelling information, Product Monographs, Summary Basis of Decision documents, risk

\begin{itemize}
\item \textsuperscript{279} Although it is expected that a BC-centric website would have lower levels of traffic nationally, the current Alexa traffic ranking of HealthLink BC in Canada is 15,751 (as of April 7\textsuperscript{th}, 2012), which is significantly lower than Canadian traffic levels to US-based third-party consumer health information sites such as WebMD and MayoClinic.com.
\item \textsuperscript{280} The Royal Commission on the Future of Health Care in Canada, also known as the Romanow Report, was a committee study led by former Saskatchewan premiere Roy Romanow on the future of health care in Canada. The committee recommended sweeping changes to Canada’s health care system, which were outlined in the Commission’s Final Report, Building on Values: The Future of Health Care in Canada, which was released in November 2002. See Commission on the Future of Health Care in Canada: The Romanow Commission, \textit{Building on Values: The Future of Health Care in Canada} (Ottawa: Government of Canada Publications, 2002).
\item \textsuperscript{281} Ibid at 202.
\item \textsuperscript{282} The Drug Product Database "contains product specific information on drugs approved for use in Canada. The database is managed by Health Canada and includes human pharmaceutical and biological drugs, veterinary drugs and disinfectant products. It contains approximately 15,000 products which companies have notified Health Canada as being marketed." See Health Canada, \textit{Drug Product Database}, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>.
\end{itemize}
communications, etc., to serve as a publicly-accessible resource for health professionals, patients and the public, this initiative remains at the proposal stage.\footnote{283 2009 Record of Discussions, supra note 223.}

Considering that Health Canada already makes a wide range of drug product information available through the Drug Products Database – they have even been including prescribing information online since July 2011 – there are many opportunities to make this information more easily available to consumers through a user-friendly interface accessible through a single government-sponsored health information portal. This would be an important step forward in providing Canadians with access to reliable and neutral online health information, particularly on drug products that are approved for sale in Canada. While the idea of creating a Therapeutic Products Register is already on Health Canada’s agenda, this item should be moved forward. However, any government-sponsored drug product information website would likely be most effective when coupled with general health information website. Considering that the Public Health Agency has already taken on the role of providing health information to consumers, and has done a good job in engaging with social media platforms and new Internet technologies, the Agency is arguably well-positioned to take a leading role in providing access to more comprehensive consumer health information in cooperation with the provincial governments.

Ultimately, if and hopefully when the Canadian government gets a general health information site up and running, efforts must be made to properly promote the site to Canadians through marketing campaigns that include intelligent use of social media. Unless Canadians are made aware of the domestic online health information resources available to them, they will likely continue to go south of the border for their health information.

\section*{6.2 Harnessing Social Media for Public Health}

In addition to “health information” prepared by pharmaceutical industry sponsors, and more comprehensive drug information resources developed by third party and government organizations discussed above, an increasingly important, but often ignored, source of health information is from consumers themselves. While most of this thesis has focused on the pharmaceutical industry’s use of social media in their own promotional campaigns, an important complement to this discussion is consumers’ own use of social media to share their experiences with and perceptions of prescription drugs. While many patients and consumers share their own experiences with prescription drugs through personal blogs and websites, many more consumers share this information through online
patient communities that are aimed specifically at connecting patients with similar health experiences and concerns.

Perhaps the area of drug information that has garnered the most consumer-driven content is that of adverse drug event reporting. Since adverse drug events arise from individual reactions to drug products, it makes sense that consumers may feel they are well-positioned to report this information themselves. As such, many online patient communities have dedicated sections to indicate or discuss adverse drug events, and other sites are designed entirely around the reporting of adverse drug events. Some sites even include existing adverse events data that has been reported to regulatory authorities such as Health Canada and the FDA and present it in a form that is more accessible to the general public. As will be discussed below, the increasing availability of adverse events data can potentially be used to detect potential problems with drugs already on the market sooner, and hopefully, prevent adverse events before they occur.

6.2.1 Learning from Online Patient Communities

One of the most ground-breaking ways in which social media and new interactive technologies have transformed consumer access to health information is through online patient communities. While many of these sites are outwardly similar peer-to-peer patient support communities, both disease-specific and more general, others offer distinctive features that push the boundaries of the more traditional online patient support groups. For example, AskaPatient.com features often detailed reviews of various medications by patients who have taken the drug. Patients can rate a drug from 1 (low: “I would not recommend taking this medicine”) to 5 (high: “this medicine cured me or helped me a great deal”). Other sites like healthEtreatment.com also feature patient reviews of medications, but promote much more interaction and direct communication between patients through online patient communities and by actively encouraging patients to share the site through social media platforms like Facebook, Twitter and LinkedIn. The site also features a list of active clinical trials related to particular medical conditions, as well as links to find more information about these trials. HealthTap is another interesting new take on online patient communities: the website allows patients to ask questions of


285 See http://www.askapatient.com. According to the website description, “There is more to know than what the ads say. Learn from the experience of real people who have taken drug treatments. Share your side effects or success stories. Take control of your health by being informed and asking questions. AskaPatient.com provides tools for the empowered patient”. Patient reviews are listed in a database that can be sorted by rating, reason for taking the drug, side effects, sex, age, and duration/dosage. The site also provides a link to FDA warnings and alerts for a particular drug, and allows users to compare the reviews for similar drug products.

286 See http://www.healthetreatment.com. The website features the slogan “Share your experience. Learn from others. Feel better. According to Shaywitz, “HealthTheTreatment, a website that explicitly aspires to be the Trip Advisor or Yelp of chronic diseases, solicits and concisely presents patient experiences and ratings, so that you can immediately see, for a particular condition, what therapies other patients have received and how they felt the various treatment options worked for them.” See Shaywitz, 2012, supra note 284.
physicians, who are then able to earn status points by providing answers that other physicians agree with.\textsuperscript{287}

One of the earliest and most successful online patient communities is PatientsLikeMe.com. Founded in 2004, the site originally focussed specifically on Lou Gehrig’s disease (ALS), but the site has since evolved into a broader community attracting a wide range of patients.\textsuperscript{288} According to the website, PatientsLikeMe is committed to “providing a better, more effective way for you to share your real-world health experiences in order to help yourself, other patients like you and organizations that focus on your conditions.”\textsuperscript{289} What really makes PatientsLikeMe unique is that the site is data-driven – members are able to input data on their conditions, treatment history, side effects, symptoms, etc., which results in a detailed longitudinal record organized into charts and graphs. PatientsLikeMe has also been integrated with ClinicalTrials.gov\textsuperscript{290} to develop a clinical trials matching tool to help patients find trials that they might be eligible for.\textsuperscript{291}

PatientsLikeMe also has an in-house team of research scientists who have authored more than a dozen peer-reviewed scientific articles based on the data compiled through the site.\textsuperscript{292} For example, in 2010, a group of researchers from PatientsLikeMe published a study in the Journal of Medical Internet Research which showed that based on the results of a survey, PatientsLikeMe users reported a variety of benefits from using the site, including feeling better informed about their treatment decisions, better communication with their healthcare providers, and improved quality of life.\textsuperscript{293}

As with third-party health information websites, the majority of online patient communities frequented by Canadians are based in the US. And while there is nothing wrong with Canadians turning to US-based sites for health information – indeed, arguments could be made that more is to be gained from pooling information from a wider range of patients – there are perhaps missed opportunities to promote information that is specific to the Canadian drug regulatory process. As will be discussed in the next section, there are also significant concerns about the quality of adverse events data reported through

\textsuperscript{287} See https://www.healthtap.com. The site offers a peer-based reputation system: users post questions and doctors post brief answers. Fellow physicians can show they agree with the advice offered by clicking “Agree,” and users can show their appreciation with a “Thank” button. Users are able to see the number of doctors who agree, who the approving doctors are, as well as their HealthTap “reputation level,” which is built by being active on the site.

\textsuperscript{288} Shaywitz, 2012, supra note 284.

\textsuperscript{289} About PatientsLikeMe, online: PatientsLikeMe <http://www.patientslikeme.com/about>.

\textsuperscript{290} According to the site, “ClinicalTrials.gov is a registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial’s purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals.” See http://clinicaltrials.gov.

\textsuperscript{291} See the Clinical Trials Tool at http://www.patientslikeme.com/clinical_trials.

\textsuperscript{292} See Research Tools, online: PatientsLikeMe <http://www.patientslikeme.com/research>.

online patient communities and the potential for events to be double reported, or not reported to regulatory authorities at all.

### 6.2.2 Improving Adverse Drug Reaction Reporting and Discussion through Social Media

The reporting of adverse drug events plays a critical role in helping to ensure the safety and efficacy of prescription drugs approved for sale in Canada. However, as stated in a recent article in the *Canadian Medical Association Journal*, “[f]or years, obtaining hard information about the incidence rates of adverse effects related to a specific drug was all but impossible as pharmaceutical manufacturers and governments seemed inclined to hide all manner of dirty linen, as if providing such information to patients was an altogether too dangerous thing.”

But as consumers have increasingly demanded more information on decisions that affect their health and well-being, governments are beginning to respond by making reports on adverse events more accessible. For example, in 2005, Health Canada made its MedEffect database publicly available, and in the US, the FDA releases statistical reports on cases in its Adverse Event Reporting System.

While the MedEffect initiative allows consumers to directly report adverse events to Health Canada online, many consumers are simply unaware that the MedEffect site exists. Moreover, the database is not user-friendly and the data it contains is not necessarily in a form that is useful to consumers or even health researchers. As such, the MedEffect website is arguably under-utilized. (It is worth noting that the FDA Adverse Event Reporting System is not searchable by the general public).

Due to the limitations on the adverse events data maintained by governments, some privately developed databases such as Adverse Events, Inc. (AEI) are stepping in to meet the growing consumer demand for such information. AEI uses data taken from the FDA to create a database on side effects associated with FDA-approved prescription medications. Users can search the database for specific drugs to find the percentage of respondents that reported a specific adverse effect or the percentage that found a drug to be ineffective. According to their website, AEI has “created a unique set of online tools that are optimized to provide un-paralleled access to adverse event information on over 4,000 drugs, in an easy to understand and navigate format.” Users can also pay to gain access to even more detailed information, such as the relationships between adverse events and patient

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297 For example, while the database displays records listing the date, age, gender, drug product and specific adverse reactions, this information is only available in tabular form and the site does not provide any composite reporting options. See Sysak, 2012, supra note 294.
298 See Adverse Events, About Us, online: AdverseEvents <http://www.adverseevents.com/about.php>.
299 See ibid.
demographics or prescription regimens, or outcomes such as hospitalization or death. These tools can be used to track potential trends and problems in the pharmaceutical industry.

One of the most recent initiatives to improve the reporting of adverse events and the availability of the resulting data is the website RxISK.org. The website, which is still in beta testing, is described as the first free website (not sponsored by the pharmaceutical industry or advertising) to provide a means to easily report side effects “to assist in individual patient care and to help other patients by identifying problems and possible solutions earlier than is currently happening.” RxISK.org is proposed to be funded by selling subscriptions to the anonymized, aggregated data collected through the site. The initial basis for the RxISK adverse events database will be current data supplied by the FDA, with new adverse events data to be contributed by patients from around the world – this information will be anonymized and added to the database in real time.

As discussed in the previous section, many online patient communities feature databases of consumer-generated reviews on their experiences with particular drug products, which often include data on adverse drug reactions. A 2010 study conducted by researchers at PatientsLikeMe suggested that "[o]nline patient communities structured around quantitative outcome data have the potential to provide an observational environment to monitor such drug usage and its consequences." In particular, based on the results of a small Italian study that reported that lithium carbonate had the potential to slow the progress of ALS, the study followed hundreds of PatientsLikeMe users who began to take lithium under the supervision of their physicians. Although the study was unable to replicate the promising findings of the Italian researchers, the authors observed that “[a]lthough observational studies using unblinded data are not a substitute for double-blind randomized control trials, this study reached the same conclusion as subsequent randomized trials, suggesting that data reported by patients over the internet may be useful for accelerating clinical discovery and evaluating the effectiveness of drugs already in use.”

Even outside of online patient communities, there is evidence to suggest that monitoring online consumer discussion of health conditions and medication use may help to highlight potential trends and problems early on. For example, in 2010, a report by the online business intelligence firm Wool

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300 For example, while the database displays records listing the date, age, gender, drug product and specific adverse reaction, this information is only available in tabular form and the site does not provide any composite reporting options. See Sysak, 2012, supra note 294.
302 Ibid.
304 Ibid at 411.
Labs analyzed seven years of social media data around the decline of GlaxoSmithKline’s diabetes drug Avandia to determine “how patients speak about Avandia in open conversations publicly available on the Internet and the opportunity it presents for pharmaceutical brands and the FDA to listen and to learn.” The report found that patients began discussing the risks of Avandia in online forums and blogs well before a meta-analysis linked the drug to a higher risk of heart attack. However, company officials failed to acknowledge such concerns, which contributed to a serious loss of trust in the product and the manufacturer. Concerns about adverse events subsequently led the FDA and Health Canada to place significant restrictions on the use of Avandia, and prompted the European Medicines Agency to suspend the drug from the European market. According to the Wool Labs report, the Avandia case offers an important lesson to GSK and other pharmaceutical companies: social media can serve as a powerful tool to monitor patient reactions and hopefully detect potential problems early on before they escalate.

To the extent that these new online platforms add value to the existing adverse events data maintained by drug regulatory authorities, they can arguably be viewed as a positive trend. However, despite the promise of using interactive online technologies as a source of data on adverse drug events, critics are sceptical of the quality of such information and its ultimate utility. On the one hand, even with respect to data gathered through MedEffect and the FDA Adverse Events Reporting System, many critics express concern that “[s]uch ‘un-edited’ reporting might result in skewed data that will be of limited scientific use and will further muddle a picture if accessed by consumers… There is nothing worse than an uninformed person attempting to draw conclusions from (low quality) data.” On the other hand, databases of patient reported adverse events may have value if they provide patients with an opportunity to report adverse effects and make a potential contribution to research.

While there is clearly a need for caution, the move towards greater disclosure of adverse events information appears to be inevitable. Moreover, as consumers increasingly seek health information online, this demand will only increase – consumers believe that they are entitled to such information. Given that there are already multiple databases reporting on adverse drug events, and that more are likely to enter the field, there is a need to ensure a certain level of coordination between the reporting

308 Ibid.
309 Ibid.
310 Ibid.
of an adverse event to an independent database or online patient community, and reporting to drug regulatory authorities; while consumers should be free to participate in online reporting systems, they should not do so to the exclusion of official drug regulatory databases. As such, online adverse event reporting initiatives should be encouraged to refer users to the official reporting authorities in their home jurisdiction.

6.3 A Note on Technical Measures

Unless and until the US tightens up its restrictions of pharmaceutical DTCA, Canadians will continue to be exposed to US-based pharmaceutical advertising. As such, one potential solution that is sometimes suggested is implementing various technical measures to block US-based ads from being viewed by Canadians. For example, this could be achieved through IP blocking, which blocks a specific IP address or range of addresses from being able to access a particular website. However, the only reasonable way to prevent Canadians from accessing American drug product information online would be for the US-based pharmaceutical product sites to undertake the initiative to block foreign-based IP addresses from accessing their sites. Otherwise, the only other alternative would be to institute China-style censorship measures to prevent Canadians from being able to access foreign-based health information, which would be both expensive and technically complex, not to mention politically untenable. Overall, it is one thing to restrict the types of promotional messages that pharmaceutical advertisers can direct at consumers, but it is another thing entirely to censor Canadians from being able to access pharmaceutical product information that is freely accessible in another jurisdiction. Currently, such censorship does not exist in any domain in Canada, and would most likely be unconstitutional.

A more tenable approach might be to implement automatic forwarding to the drug information website for a specific country. For example, if a consumer accessed the American version of a drug product website, they could be automatically forwarded to the equivalent Canadian site, or alternatively, a popup could appear and advise the consumer that there is a Canadian site available at the listed link. Regardless, to be feasible, such technical measures would have to be implemented from the US-based site. Since drug companies have no incentive to restrict access to their drug product information – indeed, their interest lies in making such information widely available – such technical measures would likely only be put in place as the result of an international cooperative effort amongst

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311 An IP (Internet Protocol) address is a number that is assigned to each device, such as a computer, tablet or printer, that participates in a computer network. IP addresses are used to both identify a computer and to map its location – i.e. a computer’s location can be devised from its IP address. IP address blocking technology is commonly used to prevent people with non-US based IP addresses from being able to access copyrighted content online, namely TV and movie services such as Hulu and Netflix, which are only intended for an American audience.
drug regulators to restrict access to prescription drug sites to domestic audiences. While this approach is less problematic than the full censorship approach discussed above, it is still unlikely to gain much support since it could involve significant technical and regulatory overhead, and is unlikely to be very popular with the general public who do not like to have their access to information restricted.

In the end, technical measures do exist that could be used to enforce the DTCA regulations and prevent Canadians from accessing US-based or other foreign pharmaceutical advertising that does not comply with the Health Canada regulations. However, given the importance of access to information in Canadian society and the significance of the Internet as an open forum free from censorship, such measures are unlikely to play more than a minor supporting role in the enforcement of DTCA regulations.

7 Conclusion

The increasing prominence of new Internet and social media technologies in modern communication, the growing importance of the Internet as a source of health information and the fiscal realities of prescription drug marketing are all pushing the pharmaceutical industry towards digital channels. Despite a slow start, pharmaceutical social media marketing is now becoming widespread and is only expected to increase in the future. And while Health Canada has made it clear that the existing DTCA regulations apply to the Internet and social media context, this new medium remains an uncertain landscape for both pharmaceutical advertisers and regulators.

Pharmaceutical advertisers are realizing that meeting regulatory restrictions is only the first hurdle in designing a successful social media marketing campaign; the real challenge for many drug companies is developing a campaign that actually grabs the attention of fickle consumers. Pharmaceutical advertisers are quickly learning that consumers are more likely to engage with and support an “unbranded” educational message on a social media platform, particularly where it is coupled with a relatable cause, than a particular branded pharmaceutical product. While the effectiveness of a social media initiative depends on a variety of factors such as disease category, brand goals, product situation and the regulatory environment, there are several recent trends that suggest the growing importance of unbranded advertising as a useful complement to other marketing initiatives. Ultimately, in the rapidly evolving world of social media, drug companies will have to be increasingly creative if they want to stay relevant, particularly as more and more competitors enter the social media sphere.
To date, Health Canada has offered little guidance as to how the existing DTCA regulations translate into the Internet and social media context. Indeed, so far it has been the advertising preclearance agencies that have stepped up and provided guidance to pharmaceutical marketers on how to construct a compliant social media marketing campaign. And while the guidance offered by the PAAB and the ASC is certainly a welcome first step, it is not a substitute for direct guidance from Health Canada. Indeed, unless and until Health Canada sets out clearer rules on how the existing DTCA regulations apply to digital media, the advertising preclearance agencies and Rx&D will be less likely to pursue complaints against drug companies for social media marketing.

While the experiences of drug regulators in the US and the UK suggest that the issuance of detailed social media guidelines is likely more trouble than its worth, both of these jurisdictions now include aspects of social media in more general guidance documents. As such, Health Canada appears to be lagging behind its counterparts in these countries in addressing the issue of social media marketing. In particular, there are a number of unique aspects of social media – namely user-generated content, consumer propagation and targeted marketed – that make the application of the existing regulations to this new medium an uncertain process.

First, the rules around sponsorship identification along the disease-oriented to help-seeking ad continuum remain ill-defined, and some current campaigns such as Janssen’s “Living Well with Psoriasis” campaign appear to be in violation of the existing rules. This is one area in which the regulations are in need of clarification, or better yet, revision. The current rules on sponsorship identification don’t really make all that much sense, particularly since there are strong arguments that consumers have a right to know who in sponsoring a particular “health information” campaign. Requiring pharmaceutical advertisers to include a “disclaimer” on all health information campaigns which states that the message is sponsored by a pharmaceutical company, but not allowing the particular sponsoring company to be identified by name, might be a creative way to balance some of the competing concerns around sponsorship identification.

User-generated content is likely the single greatest obstacle that pharmaceutical advertisers face in launching social media campaigns due to the need to closely monitor posted content for both regulatory compliance and negative handling of the brand image. While the rules around user-generated content are quite clear – manufacturers are responsible for site content, regardless of its source – there is a need for more specific guidance around the duty to report adverse events and acceptable use of UGC in promotional activities. Further, considering the important role of consumer propagation in social media marketing, Health Canada should establish the principle that measures
taken by pharmaceutical advertisers to incentivize consumers to propagate a message through their social networks increase the promotional nature of a campaign in distinguishing between DTCA and DTCl.

Finally, the ability of advertisers to target their social media campaigns at a particular audience has both positive and negative aspects; while such targeting may be useful for directing promotional material towards a more appropriate audience, the same tactics may become dangerous if they are used to target vulnerable populations, particularly adolescents. As such, Health Canada should set out some general principles regarding appropriate targeted marketing practices, particularly as they relate to vulnerable populations.

As highlighted above, the enforcement of DTCA regulations, even in traditional media such as print, radio and television, has often proven to be a challenge – which raises serious questions about the ability of Health Canada to effectively regulate the Internet and social media sphere. While the exact reasons for Health Canada's lack of enforcement activities is unclear, the trend is likely at least partially explained by resource limitations, regulatory capture by the pharmaceutical industry and a reluctance to engage in lengthy and expensive legal battles with an industry well known for its dogged legal wrangling. Nonetheless, despite few substantive regulatory changes, in recent years Health Canada has been credited with improving its response times to complaints and is currently working on initiatives to improve the transparency of the complaints process. Nonetheless, irrespective of any improvement in response times, Health Canada’s lax enforcement record and the weak penalty provisions under the Food and Drugs Act mean that pharmaceutical companies have little to deter them from pushing the limits of the DTCA regulations. Overall, given that pharmaceutical advertising on Internet and social media platforms does not currently appear to be a priority for Health Canada, direct government regulation alone is unlikely to be sufficient to ensure compliance with the DTCA regulations.

The advertising preclearance agencies appear to be well-positioned to play a leading role in the regulation of Internet and social media platforms. Indeed, both the PAAB and the ASC have already done far more than Health Canada in issuing guidance to industry on how to develop a compliant social media campaign, and thus seem ready to further develop their expertise in this field. However, under the current voluntary preclearance system, both the PAAB and the ASC lack the authority to levy financial penalties against drug companies, and more significantly, have little power where drug companies choose not to seek out an advisory opinion. Given that Internet and social media sites do not require DTCA to go through any sort of preclearance, online pharmaceutical advertisements are much less likely to be subject to preclearance review than ads in traditional media. As such, instituting a
system of mandatory preclearance may be one of the most effective ways to pre-empt violations of the DTCA regulation on Internet and social media platforms. Although implementing such a mandatory preclearance system would increase the workload of the advertising preclearance agencies – and would certainly be unpopular with the pharmaceutical industry – since the preclearance system is funded through user fees, this approach would not place any additional strain on public resources.

The final regulatory approach that may have a role to play is industry self-regulation. Although the Rx&D Code of Ethical Practices originally only governed the relationship between member companies and health care professionals, the new 2012 version of the Code appears to significantly expand the scope of industry self-regulation – namely by expanding the definition of relevant stakeholders and including violations of the Health Canada regulations and advertising preclearance agency codes as potential violations of the Rx&D Code. Further, given that social media is still largely unchartered territory for the pharmaceutical industry, drug firms will likely be paying close attention to the activities of their competitors in this new medium – and may be more than happy to complain to Rx&D if they feel another company is gaining an unfair advantage by pushing the limits of the DTCA regulations too far. Nonetheless, industry self-regulation still has significant weaknesses and should only serve as a complement to the more central enforcement activities of Health Canada and the advertising preclearance agencies.

In addition to effectively regulating DTCA, another important aspect of promoting public health is ensuring that consumers have access to reliable and unbiased sources of health information. As more and more consumers go online for health information, it is not only pharmaceutical marketers who should be looking to invest in Internet and social media platforms; the federal and provincial governments should team up to develop a Canadian-centric online health information portal that includes both general health information and information on prescription drug products. In many ways, the foundations for such a government-sponsored resource already exist. In particular, the HealthLink BC website sponsored by the BC government represents exactly the sort of site that could be rolled out across the country, and with more resources from the federal and other provincial governments, the site could hopefully be expanded and more widely promoted to Canadians – perhaps with the Public Health Agency of Canada taking the lead.

Considering that Health Canada already makes a fair amount of drug product and adverse drug event information available online through the Drug Product Database and the MedEffect site, there is already a wealth of prescription drug information that could be linked into a government-sponsored health information site. Of course, as they currently exist, the Drug Product Database and MedEffect
site are not very user friendly, so the development of Health Canada’s planned Therapeutic Products Register would be a positive step in making the prescription drug information available through Health Canada much more accessible to the general public. Ultimately, any government-sponsored health information site must be properly promoted in order to make Canadians aware that they have a Canadian alternative to the US-based health information sites. Any such promotional campaign would likely benefit from intelligent use of social media and search engine advertising.

As a final note, while this thesis has focused primarily on the Canadian perspective on DTCA, another important – and highly complex – issue relates to the need for some form of international cooperation in the regulation of online pharmaceutical advertising. Given the borderless nature of the Internet and social media, this is certainly not an issue that Canada can hope to regulate independently. Indeed, numerous examples throughout this paper have highlighted just how often Canadians are exposed to US-based pharmaceutical advertising through the Internet. And while Canadians may certainly be exposed to advertising aimed at, for example, a European audience, this generally presents less of a concern from a regulatory perspective since nearly all industrialized countries – with the exception of the US and New Zealand312 – do not allow full-product DTCA. Thus, the effective regulation of online pharmaceutical marketing may ultimately depend on some sort of international framework on DTCA. Of course, the cooperation of the US in such an international framework would be the most important – but also the most challenging – aspect of any such agreement.

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312 Although New Zealand does allow DTCA, given the smallness of the New Zealand market and its geographic distance from Canada, in general, Canadians receive virtually no exposure to New Zealand pharmaceutical advertising.