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ORIGINAL RESEARCH

Drug Familiarization and Therapeutic Misconception Via Direct-to-Consumer Information

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Abstract Promotion of prescription drugs may appear to be severely limited in some jurisdictions due to restrictions on direct-to-consumer advertising (DTCA). However, in most jurisdictions, strategies exist to raise consumer awareness about prescription drugs, notably through the deployment of direct-to-consumer information (DTCI) campaigns that encourage patients to seek help for particular medical conditions. In Canada, DTCI is presented by industry and regulated by Health Canada as being purely informational activities, but their design and integration in broader promotional campaigns raise very similar ethical concerns as those associated with DTCA. Specifically, DTCI can be an effective means of familiarizing the public with the scope and benefits of a particular prescription drug and so, like DTCA, can promote increased patient-consumer demand and thus a problematic rise in the prescribing and use of medications that may be neither the most appropriate nor the most cost-effective. Yet, with DTCI the industry is playing within the existing rules and regulations set by health regulators. To respond appropriately to this regulatory incoherence, we argue that DTCI should be regulated as a type of direct-to-consumer *indirect* advertising. Even if the case and specific regulations presented here are Canadian, the implications extend to every country that has a partial or total prohibition on DTCA.

Keywords Direct-to-consumer · Advertising · Information · Prescription drugs · Pharmaceutical industry · Public policy · Marketing campaign · Therapeutic misconception · Drug familiarization

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Introduction

The promotion of prescription drugs is a vast and complex enterprise. Pharmaceutical industry marketing departments use multilayered campaigns to reach as many patients as possible and obtain maximum exposure for their flagship products (Flowers and Melmon 1999). In Canada, drug promotion or advertising is relatively limited in comparison with the United States, because the direct-to-consumer advertising (DTCA) of prescription drugs is restricted; an advertisement cannot "make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug" (Government of Canada 2015, 871–872). This may in part explain why, as one Canadian study has shown, only a few blockbuster drugs are heavily promoted in the media, with the eight most-promoted drugs accounting for 59 percent of drug promotion (Mintzes 2006). Given these restrictions, from the industry's perspective it may be simply more cost-effective to focus on advertising only those drugs that are already well known to the public, as Canadian regulations prohibit presenting the drug's therapeutic indications. Relying on

blockbusters is likely to garner maximum consumer exposure within current regulations and thus to generate the most return on investment. However, there may be other ways for the pharmaceutical industry to build consumer awareness of its products, whether or not these are blockbusters, beyond what has traditionally been described as drug promotion or advertising.

In this paper, we use Eli Lilly's Canadian DTCI campaign "40over40" (for erectile dysfunction) as an example to show that, even if *presented* by industry and *regulated* by Health Canada as being purely informational, such campaigns are nonetheless a form of direct-to-consumer *indirect* advertising (DTCIA). These campaigns can be effective means of building familiarization with a disease and a specific drug treatment and so raise very similar ethical concerns as those associated with DTCA. They should thus be treated (i.e., restricted) like other forms of direct-to-consumer drug promotion.

Forms of Drug Promotion and Their Regulation

In Canada, as in most other developed countries around the world—with the exception of the United States and New Zealand (and there has been some intensive lobbying to relax DTCA regulations in Europe) (Arnold and Oakley 2013)—DTCA of prescription drugs is heavily restricted by health regulators. Health Canada's regulation of drug marketing permits advertising but does not allow drug manufacturers to present, in the same advertisement, a drug's benefits, risks, and other scientific claims or commercial information (Mintzes, Morgan, and Wright 2009). In the late 1990s, Health Canada relaxed its restrictions by recognizing that industry should be able to disseminate non-promotional drug information and make it broadly accessible to the public (Gardner, Mintzes, and Ostry 2003). Two types of advertising are now permitted: (1) the *reminder* ad, which presents only the drug name but not its indication, and (2) the *help-seeking* ad, which presents only the medical condition but not a drug or company name and encourages patients to consult their doctor for further information. According to Advertising Standards Canada (ASC), the reminder ad is a permissible form of DTCA, while the help-seeking ad is better labeled as direct-to-consumer information (DTCI). ASC is one of two independent organizations—alongside the Pharmaceutical Advertising Advisory Board (PAAB), whose scope is limited to the material provided to health care professionals (HCPs)—mandated by Health Canada to oversee the application of *Food and Drugs Act* provisions regarding drug promotion. But ASC's control is also limited because its remit is only over promotional activities directed at HCPs; it provides nonbinding recommendations regarding DTCA and DTCI materials submitted on a voluntary basis by pharmaceutical companies.

DTCI can be promoted through three types of media: (1) brochures and websites, (2) help-seeking advertising, and (3) social media (ASC Clearance Services 2011). For each of these, the DTCI's sponsor must comply with a set of requirements, most of which are neutral and procedural (e.g., only authorized products can be promoted, only factual information can be used, and visual aspects must be different from related DTCA). Other requirements are more ambiguous, leading to interpretation and possible circumvention, as in ASC's general definition of DTCI: "So, to ensure that your material is indeed 'information' (i.e., non-promotional) and not 'advertising' (i.e., promotional), no element can directly or indirectly promote the sale of a drug" (ASC Clearance Services 2011, 2). This definition is ambiguous and vague, particularly when one considers the commercial motivations behind a DTCI message. For companies, drug promotion is about orienting patients toward the drug's gatekeepers, that is, to encourage patients to consult their doctor in order for them to obtain a prescription to treat a condition. Also, it is important to recognize that DTCI is usually part of a broad, multilayered marketing campaign (e.g., including reminder ads, HCP-oriented activities or materials, press releases, media coverage) to promote a new drug or a new indication for an existing drug (Ofek and Sarvary 2003; Cetel 2012). DTCI thus aims at creating general disease awareness (e.g., about symptoms and associated health risks) and encouraging patients to ask their doctor about whether they might have the medical condition.

An Example of Direct-to-Consumer Information in Action

In order to have a better grasp of DTCI and its implications for health policy, it is helpful to work through a specific example of a drug promotion campaign in a particular national context. As of fall 2012, one of the most prominent drug promotion campaigns in Canada is

for erectile dysfunction (ED). Several means are used by the sponsor, Eli Lilly (manufacturer of Cialis®), to reach out to the Canadian population. A *help-seeking* television ad presents the medical condition and the burdens of living with ED, and a website called "40over40.ca" provides access to more information about treatment options. The website presents, in much more detail than the TV ad, the medical condition and its possible causes, the symptoms, and the treatments available and also encourages patients to seek medical help (Eli Lilly Canada Inc. 2011). The whole campaign is designed to fit under Health Canada's policy regarding the distinction between advertising and other informational activities, something that is also highlighted by the presence of ASC's compliance logo on the website alongside those of the Canadian Urological Association, the Réseau de médecine sexuelle du Québec (Québec's Network of Sexual Medicine), and Aboutmen.ca (Men's Health Initiative of British Columbia). The symbolic power of the ASC and other logos can help pass the message that the website is non-promotional, not considered an advertisement, and so the content is reliable (e.g., truthful, not misleading).

The campaign has been reviewed by ASC and recognized as compliant with current Canadian regulations, so the campaign's sponsor, Eli Lilly, cannot be blamed for deploying promotional strategies that one might feel are problematic. The current Canadian policies, which make a distinction between DTCA and DTCI, create an incentive for the sponsor to use these different mechanisms to promote its products. But some noticeable elements in the ED campaign demonstrate that there are important limitations in the Canadian requirements or at least with the way that they are currently applied.

First, while factual statements are required by ASC and Health Canada, the main theme of the campaign—"40over40"—is not clearly justified. This message is supposed to mean that 40 percent of men over 40 years of age suffer from some degree of ED. While this is quite a good marketing claim, its scientific rationale is problematic: The claim is not visibly supported on the website by references to the scientific literature, and the only information is an estimate that two million to three million Canadians have an ED condition (Eli Lilly Canada Inc. 2011). Moreover, 40over40 conveys the message that a "nonoptimal" erectile functionality is pathologic and so needs to be treated. A subtle and indirect performance threshold (i.e., "optimal" erectile function) is being presented that is linked to popular but scientifically unfounded views of normalcy and aging (Marshall 2010; Jones and Higgs 2010). Specifically, the message is that while younger men are not likely to have problems with their sexual function, men older than 40 can and even should expect to have problems obtaining or maintaining an erection.

The consequences of this shift from what is considered normal to abnormal function are particularly obvious in the "Self-Assessment Quiz" presented on the 40over40.ca website (see Table 1), which encourages patients to consult a physician if their result is lower than the defined "abnormal" threshold (i.e., lower than 22 points out of 25) (Eli Lilly Canada Inc. 2014).

Second, as recommended by ASC's guidelines (i.e., separating disease information and the name of the drug or manufacturer), the sponsor's identity in the ED campaign is not at all obvious. Viewers of the website need to be attentive and look under the "Privacy Statement," "Terms and Conditions," "Disclaimer," "Copyright," or "Accessibility" sections at the bottom of the page, which are in the smallest font and thus the least noticeable content on the website. The issue is that the campaign is an *industry*—and not a *government*-sponsored public health awareness or information activity. Providing clear details about the sponsor's identity would likely help people: (1) critically assess the general message being conveyed by the campaign, (2) evaluate the specific information presented and its relevance to their particular health needs, and (3) judge the credibility of the information provider. Yet, the very policies that were supposedly designed to protect the public from potentially manipulative DTCA in fact discourage or even prohibit industry sponsors from being transparent about their identity, with the result that it may be very difficult to distinguish between an industry-sponsored DTCI marketing campaign and a government-sponsored public health campaign.

Third, one of the requirements for a campaign to be considered non-promotional is that there be a balance between the treatment presented (e.g., drug and nondrug options) and that a particular drug not be overemphasized. In the 40over40 case, some of the visual design favors the sponsor's drug, Cialis®, which is presented in first place (Option A) at the top of the page in the "Treatment Options" section and has twice as much space (two columns) as any other treatment option (e.g., other ED drugs, pumps, or injections). There is no non-promotional rationale behind this ranking. Cialis® is the first drug presented and the only

Table 1 "40over40" Self-Assessment Quiz (Questions, Answers, and Weighting) (Eli Lilly Canada Inc. 2014)

Take this self-assessment quiz to find out if you may have ED

#	Questions	Answers	Points
1	*How do you rate your confidence that you can get and keep an erection?*	*Very low*	1
		Low	2
		Moderate	3
		High	4
		Very high	5
2	*When you had erections with sexual stimulation, how often were your erections hard enough for penetration?*	*No sexual activity*	0
		Almost never or never	1
		A few times (much less than half the time)	2
		Sometimes (almost half the time)	3
		Most times (much more than half the time)	4
		Almost always or always	5
3	*During sexual intercourse, how often were you able to maintain your erections after your penetrated your partner?*	*Did not attempt intercourse*	0
		Almost never or never	1
		A few times (much less than half the time)	2
		Sometimes (almost half the time)	3
		Most times (much more than half the time)	4
		Almost always or always	5
4	*During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?*	*Did not attempt intercourse*	0
		Extremely Difficult	1
		Very Difficult	2
		Difficult	3
		Slightly Difficult	4
		Not Difficult	5
5	*When you attempted intercourse, how often was it satisfactory for you?*	*Did not attempt intercourse*	0
		Almost never or never	1
		A few times (much less than half the time)	2
		Sometimes (almost half the time)	3
		Most times (much more than half the time)	4
		Almost always or always	5

treatment to hold more than one indication, making it apparently more versatile and potent than the other drugs. Further, the non-oral options, which are presented much further down on the page, are surgical or require a fairly complex apparatus to be inserted into or used on the penis and thus are clearly much less desirable (e.g., "Involves drawing blood into the penis," "Involves the surgical insertion of a prosthesis"); there is no presentation of psychosocial options, such as sexual counseling or psychotherapy. Interestingly, the two tables (for the oral and non-oral options) present differently the rare side effects and contraindications: The table for the oral options uses a different shading, making the side effects and contraindications seem not even part of the table, while with regard to the non-oral options all of the side effects and contraindications have the same shading as the rest of the table. The website's visual aspect thus reinforces in the viewer's mind (1) the benefits of drug therapy in general over other options and (2) the sponsor's drug, which is arguably the primary objective of this promotional campaign.

Despite these problems with the DTCI campaign for ED, ASC judged that the 40over40 campaign was compliant with its guidelines and that the information and its

presentation were non-promotional. The line is thus very thin and flexible between what is accepted as non-promotional by ASC and Health Canada's core requirement that in non-promotional activities "no emphasis is placed on one drug product" (Health Canada 2005, iii). Table 2 presents our analysis of the case in light of *The Distinction Between Advertising and Other Activities*, Health Canada's guidance document (Health Canada 2005).

Following the Health Canada guidance regarding advertising, our analysis shows that most considerations point toward the 40over40 campaign as being promotional and not purely informational. But as the Health Canada document clearly states: "No one factor in itself will determine whether or not a particular message is advertising" (Health Canada 2005, 3). We can thus assume that the nuance here is that the 40over40 campaign has been identified as non-promotional because it promotes a variety of drug treatments rather than only the sponsor's drug.

Familiarization Through Direct-to-Consumer Information

The effectiveness of DTCI campaigns depends on both the content of the message and how it is conveyed through the mass media, and as with most advertising campaigns, DTCI has as its goal to habituate the public/consumers to accept a certain realty as being true and relevant for them (Belch and Belch 2008). In being presented as an informational message, DTCI can build consumer confidence and increase the credibility and thus the persuasive effect of the message (Briñol, Petty, and Tormala 2004), a process that we call *familiarization*.

There are subtle ways that a well-designed DTCI campaign can familiarize the public with a particular condition and so influence subsequent information- and treatment-seeking behavior. Specifically, in making informational activities (i.e., help-seeking ads) part of a large, multilayered campaign that includes promotional activities (i.e., reminder ads), a drug sponsor can:

(1) build general awareness about a particular disease being an important public health problem;
(2) convince a diverse audience that they may suffer from a specific disease (i.e., have related symptoms) and so should consult their physician;
(3) suggest that solutions to health problems are best addressed by medical (i.e., pharmacological) treatments, even if the general content of a campaign is disease-related as required by Health Canada (Health Canada 2005)—and this is where the bias is particularly subtle, reinforcing what some scholars have called "pharmaceuticalization" (Bell and Figert 2012) that Abraham defines as "the process by which social, behavioral or bodily conditions are treated, or deemed to be in need of treatment/intervention, with pharmaceuticals by physicians, patients, or both" (Abraham 2010, 604);
(4) direct viewers to consider drugs as a better option than other treatments (e.g., pills over pumps and injections, no mention of counseling or psychotherapy);
(5) orient the viewer to a specific drug (e.g., the sponsor's drug may have as much detail as other drugs but be presented first) so that patients can then request a prescription from their physicians (Limbu and Torres 2009); and
(6) hide commercial interests by downplaying the sponsor's identity, because even if no emphasis should be placed on one drug (an ASC requirement), viewers can reasonably be expected to have difficulty in differentiating the DTCI campaign from a government-sponsored public health campaign.

To summarize, a DTCI campaign can provide information about a medical condition that is defined in such a way that the pharmaceutical treatment is seen as the best solution; patients come for information and stay for the pharmaceutical treatment. But only the necessity of seeking medical treatment is conveyed in DTCI; the benefits and the risks of a drug are often vague or even absent. Underlying familiarization is another process in marketing called *evaluative conditioning*, which can induce people to create or reinforce beliefs that a certain drug is the best/only solution to a medical condition (Biegler and Vargas 2013), even when clinical research may show that effective treatment requires a combination of approaches (e.g., pharmacological and psychosocial) (Althof 2006; Berry 2012; Waldinger 2008).

Parallels can be made with the literature on DTCA, both in terms of the issues raised and also the fact that proponents and detractors do not share the same vision about the influences and consequences of drug

Table 2 Considerations for determining whether an activity is promotional (advertising) or non-promotional (informational), based on *The Distinction Between Advertising and Other Activities* (DAOA) (Health Canada 2005)

Considerations	DAOA Test	Case Specificities	Most Probable Case Activity Type
What is the context in which the message is disseminated?	Is it a science-based message delivered [by an expert] or is it a product-related message delivered to a group […] with a limited agenda?	Message via television ads and website; same as for Public Health campaign.	Either Promotional or Non-Promotional
Who are the primary and secondary audiences?	Where they are different, the message to the secondary audience is more likely to be advertising.	Due to its wide TV and Internet diffusion, audience is mass market; same as for Public Health campaign.	Either Promotional or Non-Promotional
Who delivers the message (the provider)?	Where delivered by an independent party, the message is less likely to be considered as advertising.	Drug Sponsor through TV spots and website.	Mostly promotional
Who sponsors the message and how?	Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.	Drug Sponsor, but not overly visible.	Promotional
What influence does a drug manufacturer have on the message content?	Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.	Drug Sponsor is responsible for all the content.	Promotional
What is the content of the message?	Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?	Scientific rigour is vague or deficient; treatment-oriented rather than disease prevention or management.	Mostly promotional
With what frequency is the message delivered?	Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.	Frequency determined by the Sponsor and limited only by Sponsor's marketing budget.	Promotional

advertising and promotion. On one side, proponents of DTCA argue that it informs patients of available treatments and empowers them to seek help and weigh options (Hollon 1999; Peyrot et al. 1998; Wong-Rieger 2009; Holmer 1999). On the other side, opponents of DTCA have argued that: (1) advertisements affect patient discourse, making patients more inclined to discuss the advertisements they have seen than the condition they might have (Hughes-Morgan et al. 2010); (2) DTCA has a harmful impact on the patient–physician relationship (Stange 2007; Peyrot et al. 1998); and (3) patients would be less insistent if they were more aware of the risks, thereby reducing attractiveness of drug treatments induced by DTCA (Karlowicz 2009). Arguably, the same debate applies to DTCI, as it is a way to transmit information to patients to help them better assess their needs and understand their symptoms, but it also has the potential to influence or shape certain behaviors. Whether in DTCI or in DTCA, we agree with those scholars who argue that the information contained in drug promotion is not sufficient for—and may even undermine—peoples' ability to make an informed choice about a treatment (Atkin and Beltramini 2007; Kessler and Levy 2007).

Misconception as an Active Mechanism

Within a multilayered campaign such as 40over40, each element has its own effect on consumers, and familiarization is triggered by repetitive advertising such as television spots, whether they are reminder ads or help-seeking ads. Consumers may be passive recipients of information when watching TV, but if reference to the disease incites them to visit the 40over40 website, then they have become active seekers of information; it is through this multiple exposure that consumers can become habituated or familiarized with the product. Such familiarity can, we suggest, open the door to a type of therapeutic misconception (TM) among consumers.

A concept developed in research ethics with regard to clinical trials, Henderson and colleagues explain that TM exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial (Henderson et al. 2007, 1736).

TM thus involves a potentially very problematic misunderstanding on the part of a patient/research participant regarding the scope of a physician/researcher's professional activity (e.g., both clinical and researcher roles) and expectations about receiving treatment that is in the patient's best interest. That is, patients may foreground their physician's duty to act in their best interest and so assume that they were recruited into the study because it will help in treating their condition or that, in the context of a randomized-controlled trial, they will nonetheless receive the active drug. TM jeopardizes a patient's ability to give voluntary informed consent to participate in a clinical study and so must be mitigated, for example, by separating the physician/researcher role in recruitment and information provision.

In the context of DTCI, we argue that a similar therapeutic misconception can occur when consumers see DTCI campaigns as well-intentioned mechanisms for raising public awareness about an important health condition and disseminating scientifically valid information about appropriate treatment options. As consumers are already habituated to official government public health campaigns that aim to promote and encourage particular behaviors deemed to be in the public's interest (e.g., smoking cessation, exercise), consumers may fail to see the commercial interests behind the DTCI campaign—and which may not be the same as the consumer's interest—that justify a company's significant financial investment. Because DTCI is required by Canadian regulation to be free from apparent links between disease/medical condition and therapeutic options, a form of TM is arguably fostered.

Well-designed DTCI campaigns exploit patients' trust in medical science and the health care system, misconceptions about disease incidence and risks/benefits of drugs, and legitimate desires to find appropriate treatments for conditions to which they have become sensitized. In this case, TM is triggered by consumers' interest in finding more information about their condition (or that of family members) and possible treatments, so their apparent free and voluntary engagement (watching the TV ads and seeking more information online) blinds them to other information—e.g., risk information, the identity and nature of the sponsor—that would be necessary to critically assess the value and veracity of the message. As has been argued in the case of research (Cunningham and Iyer 2005), it is not sufficient to rely on individual autonomy or to argue that people simply need to be more media-savvy (although

such critical capacities are important); it is up to clinicians, researchers, industry, and government to create a context that will make TM less likely so that the *information* component in DTCI lives up to its name, that is, the information is neutral and unbiased and so enables consumers to freely choose.

As Canadian DTCI regulations require the sponsor's identity to be hidden or at least not be used in a promotional fashion, they also hide the commercial marketing aspect of DTCI and thus the motivations behind the message. Without the explicit connection between the message conveyed and the sponsor's commercial interests, consumers are less able to resist the power of the messages advanced in campaigns such as 40over40 and so will likely associate a certain pill as the solution to their symptoms, regardless of the other factors that may be involved in their condition. As a result, the process of familiarization and eventual therapeutic misconception on the part of the general public becomes hard to counter, something that is completely opposite to the spirit of the health policies and regulations that were supposed to control direct-to-consumer activities involving pharmaceutical drugs.

Conclusion

Direct-to-consumer information can have an important—and, we argue, problematic—impact on patients' imaginary and expectations, but the situation is complex and those responsible are not necessarily the usual suspects. In particular, the pharmaceutical industry, which has legitimately been subject to much critique with regard to DTCA, is not solely to blame in the context of DTCI in Canada. After all, pharmaceutical companies are only playing within the rules set by Health Canada, since the latter relaxed its policies and delegated much of its authority to third-parties (ASC and the PAAB) who have limited coercive power regarding drug advertising. Clearly, the message from government has been that DTCI is both a legal and an approved means to advertise indirectly, by reinforcing a message conveyed by other activities in a multilayered media campaign (e.g., TV ads, disease-related websites, pharmaceutical representative visits to physicians). Regulators should instead acknowledge that DTCI is an effective way for industry to meet its promotional objectives and is a form of direct-to-consumer *indirect* advertising (DTCIA) that builds familiarization and entrenches patients in therapeutic misconceptions.

Even if the case and specific regulations presented here are Canadian, the implications of DTCIA have a much wider impact. In fact, every country that has a partial or total prohibition on DTCA (i.e., every developed country with the exception of the United States and New Zealand) may face the same situation experienced in Canada, whether or not they have explicit DTCI policies. The solutions to the problems associated with DTCIA, and especially the potential for TM, are multiple. But lessons can be learned from analyses of consumer perspectives and the experience with research ethics. Regulation and guidelines need to be implemented to address actual direct-to-consumer activities, ensuring better disclosure of the interests underlying informational campaigns, reducing the risk of and scope for misinterpretation, and thus fostering consumer understanding and informed choice. More generally, the development of comprehensive and reliable sources of health information (i.e., additional information from health agencies and academia) and the requirement that agencies (such as ASC in Canada) verify the scientific rigor of claims in DTCI could help in disseminating a broader range of scientific evidence about the benefits, adverse effects, and appropriate uses of pharmaceutical drugs. Unfortunately, this is exactly what the current DTCI regulations in Canada are designed *not to* do.

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