

Direct-to-Consumer Advertising With Interactive Internet Media

Global Regulation and Public Health Issues

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DIRECT-TO-CONSUMER ADVERTISING (DTCA) IS LEGAL only in the United States and New Zealand and has been linked with drug overutilization, public health concerns, and higher costs.¹ Despite global proscriptions, DTCA is the most rapidly increasing form of pharmaceutical marketing, with approximately \$4 billion in US expenditures, outpacing physician marketing and research and development.²

The Internet has rapidly developed, with users moving from passive information using read-only “Web 1.0” technology to interactive tailored relationships using “Web 2.0” technology. This includes social networking sites and other interactive systems, resulting in new online DTCA marketing opportunities that transcend geopolitical borders. Currently, the US Food and Drug Administration (FDA) has not issued guidelines on this form of DTCA marketing. Yet electronic DTCA with Web 2.0 technology already has the potential for significant presence and may have unrealized public health effects.

Online DTCA Presence

There are several means by which online DTCA marketing may occur. Pharmaceutical companies may develop corporate Web pages that market their products or provide health information directly to the public. However, with integration of newer Web technology, these Web pages may also serve as launch points for access to the entire panoply of DTCA platforms.

The spectrum of social networking tools used by drug companies is as broad as those available and can include Facebook pages, Twitter accounts, blogs or RSS feeds, dedicated YouTube channels, and Apple iTunes applications sponsored by drug companies. These tools and applications are accessible globally.

The purpose of online DTCA is drug marketing. Companies may create Facebook pages, participate in Twitter health communications traffic, and have YouTube videos advertising specific drugs online. Furthermore, online DTCA can incorporate promotion strategies including patient testimonials and product information, as well as extend their influence through hosting of direct-to-consumer media on-

line and linking to favorable research data. The potential effect of online DTCA is enormous, allowing for interactive marketing to millions of potential consumers globally.

Yet these DTCA efforts may be presented as “neutral” information, despite being corporate-sponsored. This is particularly true when DTCA uses third parties (eg, bloggers, “consumer opinion leaders,” or other paid individuals/companies) to promote products without sponsorship disclosure³; presents moderated forums/sites that appear interactive but only offer 1-sided communication; and creates “unbranded Web sites,” all without sponsorship disclosure.⁴

Moreover, there is a parallel set of online DTCA marketers selling drugs. The Internet is rife with rogue online pharmacies using Web marketing tools as their primary vehicle.⁵ For example, some of these use sponsored links and search engine shopping pages and some have transitioned to social media tools, such as Facebook and Twitter. Online DTCA has emerged as an unregulated marketing tool for legitimate and illicit sources alike, and consumers lack insight on whether such information is valid.

Implications

Because hundreds of millions of individuals use the Internet for health information, it is not surprising that companies have moved into this area of marketing using online DTCA tools, spending an estimated \$1 billion.⁶ What this means, however, is that online DTCA marketing may not be limited to places where DTCA is permitted. For example, although GlaxoSmithKline’s blog site and AstraZeneca’s community Facebook page indicate that they are “intended for US residents/customers only,” non-US users have no access restrictions. Furthermore, Pfizer’s mobile applications are intended for Canadian and French audiences; Novartis targets Canadian and Korean audiences; and Roche advertises to French patients.

It also means that online DTCA is undermining traditional patient safety regulations when used by rogue online pharmacies. Consequently, online DTCA has global-

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ized DTCA to anyone, anywhere with Internet access. Rapid online DTCA development may place the FDA even further behind in attempting to regulate DTCA⁷ and illegal online sales,⁵ while global DTCA prohibitions are minimized. The combination may exacerbate negative effects that may occur with trans-border DTCA.

Patient safety may be compromised in that some DTCA may overemphasize benefits¹ and patients may not adequately assess risk. Marketing that is focused on drugs used in high volume or for chronic disease may place vulnerable patients at risk,⁸ perhaps disproportionately, because blockbuster drugs are most heavily marketed early in product life cycles when safety profiles are incomplete.¹ Heavily promoted DTCA drugs have been associated with safety advisories and FDA black box warnings.⁹ Thus, US safety concerns may become global health concerns under new online DTCA.

Patient safety is also undermined by illegal online pharmacy use of DTCA for marketing. Patients may be purchasing drugs without professional oversight; some drugs may be unapproved or have safety concerns. Some online pharmacies have been found to sell counterfeit drugs resulting in patient death and injury.⁵ These rogue sellers have been nimble in their Internet presence in illicitly selling drugs⁵; it is no surprise that they have adapted to new Web technology. This magnifies the importance of public health regulatory body warnings about purchasing drugs online and obtaining information from trusted sources.⁵

Online DTCA use by companies and illicit online pharmacies may inappropriately increase demand and compound harm by permitting self-prescribing and direct illegal purchase. Because search engines drive consumers to content, online DTCA may receive higher traffic because of repeat use or other Web site links. These sites may appear higher in search results with concomitant higher influence, allowing these DTCA sites to become a dominant source of health information, potentially displacing health care professionals.

The relatively less expensive costs and greater benefits of new online DTCA⁴ may result in more legal and illegal sellers using it for marketing. This is of particular concern in a regulatory vacuum and in areas of limited knowledge of online DTCA including sponsored links, “ad words,” Web site development and hosting, and other tools.⁸

To address these issues, a disease surveillance approach may be beneficial. United States regulators, such as an FDA and Federal Trade Commission joint task force to combat illegal web activity, should take an active role in ensuring that online DTCA is not a “global export,” as they have done for fraudulent online marketing of other health care products.¹⁰ One approach could be to require marketers, companies, Web content providers, and social media sites to actively survey and block foreign Internet protocol addresses from online DTCA content, specifically Facebook and Twitter pages. Public-private partnerships to develop filtering software can be part of this effort, which may be

shared globally. Furthermore, the public should be informed about online DTCA sources. This sponsored marketing should be disclosed, taking into account social network vagaries including short-entry limitations² and correction of user-generated content that makes unverified, negative, or clinically inappropriate comments,⁴ as well as reporting of potential adverse events.⁷

There are some potential benefits of online DTCA. Communication of patient safety risks and public health information, coordination with existing regulatory tools such as FDA risk evaluation and mitigation strategies and MedWatch, and integration of reliable information into online searches can benefit patients.⁷ Online DTCA also could be used in public-private health warnings about online drug purchasing, such as a drug company and FDA jointly issuing warnings about detected counterfeit versions of the drug, and could provide official agency links to a list of approved online pharmacies.⁵

Overall, new online interactive DTCA capabilities represent a global health challenge. The evolution in online DTCA and future forms of pharmaceutical marketing will not wait for global regulation. Instead, industry—licit and illicit—will continue to innovate and move forward in a rapidly changing digital environment. To ensure that the goals of DTCA legal proscriptions and patient safety promotion are fulfilled, online DTCA issues must be acknowledged and addressed dynamically by all stakeholders: clinicians, patients, and policy makers.

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