



Digital Direct-to-Consumer Advertising: A Perfect Storm of Rapid Evolution and Stagnant Regulation

Comment on “Trouble Spots in Online Direct-to-Consumer Prescription Drug Promotion: A Content Analysis of FDA Warning Letters”

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Abstract

The adoption and use of digital forms of direct-to-consumer advertising (also known as “eDTCA”) is on the rise. At the same time, the universe of eDTCA is expanding, as technology on Internet-based platforms continues to evolve, from static websites, to social media, and nearly ubiquitous use of mobile devices. However, little is known about how this unique form of pharmaceutical marketing impacts consumer behavior, public health, and overall healthcare utilization. The study by Kim analyzing US Food and Drug Administration (FDA) notices of violations (NOVs) and warning letters regarding online promotional activities takes us in the right direction, but study results raise as many questions as it does answers. Chief among these are unanswered concerns about the unique regulatory challenges posed by the “disruptive” qualities of eDTCA, and whether regulators have sufficient resources and oversight powers to proactively address potential violations. Further, the globalization of eDTCA via borderless Internet-based technologies raises larger concerns about the potential global impact of this form of health marketing unique to only the United States and New Zealand. Collectively, these challenges make it unlikely that regulatory science will be able to keep pace with the continued rapid evolution of eDTCA unless more creative policy solutions are explored.

Keywords: Direct-to-Consumer Advertising (DTCA), Social Media, Pharmaceutical Marketing, Health Communication, Regulatory Science, Food and Drug Administration (FDA)

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A recent study by Kim conducted a content analysis of notices of violations (NOVs) and warning letters issued by the U.S. Food and Drug Administration (FDA) over a 10-year period (2005–2014).¹ The study was carried out in order to identify common regulatory, public health, and patient safety challenges unique to online direct-to-consumer advertising (DTCA) of prescription drugs, a form of health marketing that is experiencing rapid growth.^{2,3} Kim’s results support findings from prior studies—namely that DTCA does not adequately communicate information to consumers in a fair and balanced manner in relation to risks versus benefits – and that this challenge extends beyond traditional media (eg, print, television, radio) into digital advertising.^{1,4,5} However, though Kim’s study introduces needed evidence on the topic, clinicians, consumers, and policy-makers continue to remain unaware of the changing dynamics of DTCA in the evolving digital media environment.

Specifically, Kim’s study raises several concerns about how online promotional activities can negatively impact public health and consumer safety. This includes its potential use in off-label promotion activities (based on study findings showing that industry sponsored links on search engines did not provide adequate drug indication information),

how the dynamic nature of these technologies can influence consumers differently than traditional forms of promotion, and how marketers may be changing DTCA tactics in order to leverage the power of these platforms to directly reach and build relationships with consumers in new and different ways. Further, the study raises more fundamental questions of whether regulatory responses by FDA are responsive and adaptive enough to address the inherent challenges faced by a universe of digital and Internet-based forms of DTCA (collectively referred to as “eDTCA”) that have the ability to transcend US borders via the Internet.^{6,7} In response, this commentary highlights some of the unique challenges faced by the emergence of eDTCA that warrant further research and exploration. It ends with a discussion about emerging challenges on the horizon, given the ability of eDTCA to globalize, and why regulatory science is unlikely to keep pace with the continued rapid growth and evolution of eDTCA.

Future Growth of eDTCA

According to a recent report by the IMS Institute for Healthcare Informatics, global spending on medicines will reach \$1.4 trillion by 2020, indicating that total pharmaceutical expenditures will undergo double-digit growth for the next

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half decade.⁸ Though “pharmerging” markets (including emerging economies of India, China, Brazil, and Indonesia) will likely account for a significant portion of this growth, the United States nevertheless continues to lead all countries in total prescription drug spending and utilization.^{8,9} This includes a 13% increase in US prescription drug expenditures in 2014 (totaling an estimated \$374 billion), representing the largest percent increase since 2001.¹⁰ Growth is attributed to the high cost of new drugs on the market (including the new hepatitis C drug sofosbuvir manufactured by Gilead Sciences and other expensive cancer and autoimmune therapeutics), fewer patent expirations for branded drugs, increased spending on specialty drugs, and the possible impact of the Affordable Care Act (ACA) on increased healthcare coverage and prescription drug spending.¹⁰

Coincidentally, the United States – the largest consumer market for prescription drugs – is one of only *two* developed countries (the other New Zealand) that currently legally allows DTCA.¹¹ This means that continued growth in US national prescription drug spending will likely fuel further spending on DTCA, especially given increased scrutiny to physician-directed promotion due to transparency requirements enacted as part of the ACA.^{6,12,13} Within the overall category of DTCA, a recent study found that Internet-based DTCA was the only subcategory that experienced rapid growth (an estimated 109% increase) from 2005-2009.² Yet, the ascendance of eDTCA should come as no surprise, with surveys conducted by the Pew Research Center showing that 72% of Internet users actively search for health information online.¹⁴ Hence, the combination of increased drug spending and widespread use of the Internet by consumers to search for health information, has created the perfect storm for eDTCA to emerge as a more prominent and influential form of health and drug marketing.^{6,15,16}

Regulatory Challenges of eDTCA

The rise in the use of health information technology has been described as a “disruptive” phenomenon.¹⁷ eDTCA also reflects these same “disruptive” qualities in the context of health communications. Kim’s study reports that FDA characterizes eDTCA as highly interactive, rich in multimedia and user-generated content, interacts socially with consumers, and that eDTCA campaigns are often strategically coordinated and interlinked through shared online resources.¹ Yet, technology innovation and market disruption are difficult areas for regulators to proactively address through enforcement, policy and rule-making. FDA is no exception and has struggled to achieve the correct balance of regulatory oversight given the unique challenges associated with eDTCA and the constantly changing nature of Internet technologies. Instead of pursuing comprehensive regulation, FDA has relied on issuing draft non-binding industry guidance to address issues on a piecemeal basis including (1) responding to unsolicited requests about off-label information including via the Internet and social media (2011); (2) product name placement, size, and prominence in Internet advertising (2013); (3) voluntary correction of misinformation on the Internet and social media platforms by firms (2014); and (4) structuring promotion for Internet and social media platforms with character space limitations (eg, Twitter) (2014).¹⁸⁻²¹ Though draft guidance

is aimed at providing regulatory clarity, it can also lead to confusion, hence necessitating the examination of NOV/warning letters in Kim’s study and others.²²⁻²⁵

However, Kim’s piece does not fully assess the relationship between content of NOV/warning letters and how it tracks with the timing of FDA regulatory guidance issued during the 10-year study period. This is an important component in assessing whether regulatory intervention (through the combination of warning/violation letters *and* issuance of industry guidance) has had its desired impact: primarily clarifying for manufacturers what forms of eDTCA content will trigger a violation, ensuring manufacturers correct existing deficiencies, and dissuading these activities in future marketing practices. Furthermore, NOV/warning letters are likely not representative of past and ongoing eDTCA industry trends. Specifically, it is unclear how the FDA conducts surveillance and monitoring of eDTCA (including its sampling methodology for digital advertisements) and how it prioritizes enforcement activities through its Office of Prescription Drug Promotion (OPDP), especially since the OPDP has historically lacked necessary funding to carry out its operational mandates.²²

One striking example of the potential limitations of NOV/warning letters as a secondary data source in order to understand eDTCA trends is Kim’s finding that only two FDA actions targeted social media (both on Facebook).¹ This result seems peculiar especially given the high-degree of popularity of social media in health communications, prior studies that have reported near universal use of these platforms (including Facebook, Twitter, and YouTube) by large pharmaceutical firms, and another study that found a majority of eDTCA drug product claims emphasized benefits over risks.^{7,15,16} Further, study findings that violations occurred simultaneous across several different industry digital assets (including sponsored search links, online videos, and on company websites) emphasizes the need to assess how the *entire* online environment is collectively being used to influence the consumer through exposure to different marketing channels, multimedia, and targeted messaging.

Other minor findings in Kim’s study making up a smaller percentage of NOV/warning letter content characteristics should also raise alarms. This includes pharmaceutical companies directly contacting consumers via email (in the case of 2 letters analyzed) and their attempt to use these same consumers to propagate their DTCA via social media.¹ This blunt form of “marketer controlled” DTCA by attempting to use patients as “third-party endorsers” raises privacy concerns regarding the use of protected health information (PHI) and could possibly violate the US Health Insurance Portability and Accountability Act (HIPAA) (if the information is categorized as PHI and the patient has not adequately consented to use and disclosure for the purposes of marketing.) These violations may also be a byproduct of a DTCA channel that has been largely neglected in pharmaceutical marketing research: the use of branded and unbranded patient engagement portals operated under the control of a pharmaceutical firm (or their intermediaries) that create online environments where manufacturers can control interactions between current and prospective consumers.²⁶ These patient engagement portals directly sign up consumers (usually via email registration), may

offer free services or treatment guidance, and often include online patient coaches/advocates, but also simultaneously serve as veiled marketing platforms for eDTCA.²⁶

Lastly, a set of new violations added in the study's analysis (ie, indication information and violation of product labeling), highlights the dangerous possibility that manufacturers may be engaged in illegal off-label promotion by failing to provide adequate information on drug dosage or the specific patient population that can be treated per the approved FDA indication.^{1,27,28} Though manufacturers may argue that space and character limitations (such as sponsored search engine links) preclude them from communicating this information effectively, omission of such information appears to be in direct violation of FDA regulations that prohibit manufacturers from promoting drugs off-label.^{29,30} This risk could be accentuated by a recent 2015 federal district court decision in *Amarin vs. FDA*, that ruled that manufacturers have the constitutionally protected right to engage in "truthful" and "non-misleading" off-label communication, a decision that may embolden industry use of eDTCA for off-label promotion.³⁰⁻³³

Global Implications

Another important concern raised by Kim is the risk that eDTCA communication that violates FDA rules, guidance and regulations, could also impact populations outside the United States. Specifically, Kim notes that Facebook pages subject to FDA warning/violation letters appeared to be accessible to non-US consumers.¹ This observation confirms findings from prior studies that have identified lack of US domestic DTCA regulation as an enabling factor for global dissemination of DTCA via Internet-based technologies.^{6,7,9,16,34} Currently, there are no appropriate controls to limit international DTCA dissemination, a responsibility that arguably falls on the shoulders of drug manufacturers and the FDA who act to generate and regulate eDTCA content.

In response to this clear regulatory gap, policy experimentation emanating from Canada may represent a future strategy to address the globalization of eDTCA. Canadian researchers have long recognized the potential public health risks associated with the international spread of DTCA, as originally identified in studies examining the impact of cross-border transmission of US TV DTCA satellite broadcasts on prescription drug utilization and patient safety.³⁵⁻³⁷ In addition, Canadian stakeholders have begun to recognize the unique threat posed by eDTCA for Canadian public health.¹⁵ As an example, In 2013, the British Columbia Medical Association and others called for Health Canada to appoint a watchdog to block DTCA ads transmitted via the Internet and social media.³⁸ This could theoretically be accomplished by implementing technical tools already utilized for preventing access to Internet content in certain jurisdictions, such as blocking foreign IP addresses or requiring Internet service providers/manufacturers to limit user access and online transmission.³⁸ Such an approach is consistent with current law as well as policy provisions generally prohibiting DTCA in Canada and a host of other countries.^{9,15,16,36}

Conclusions

With pharmaceutical spending enjoying strong growth and millions of people searching for health information online,

eDTCA likely represents the next frontier for pharmaceutical marketing.¹³ Yet this marketing medium remains highly controversial given the rising costs of prescription drugs, a point underscored by a recent vote by the American Medical Association in support of a DTCA ban.³⁹ Despite eDTCA's rapid growth and maturation, regulatory responses seem to be several steps behind industry activities, who can no longer afford to wait for FDA to give them sufficient guidance on how to engage with their patients online.^{15,16} This includes revised 2015 FDA draft guidance that calls for the use of a "Drug Facts" box or Q&A to better communicate risk information to consumers.⁴⁰ Specifically, revised draft guidance appears to continue FDA's antiquated trend of overemphasizing traditional media in DTCA regulatory efforts and may lack flexibility in addressing the dynamic challenges faced by eDTCA.^{11,40} As categories of eDTCA continue to expand in a 21st century digital health landscape populated by growing numbers of "e-patients," it is crucial that clinicians, researchers, policy-makers, and the public better understand the true scope and influence of eDTCA and how it impacts how they "consume" health.

Ethical issues

Not applicable.

Competing interests

Author reports no conflicts of interest and no funding sources associated with this paper.

Author's contribution

TKM is the single author of the paper.

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