



Considering the Future of Pharmaceutical Promotions in Social Media

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

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Abstract

This commentary explores the implications of increased social media marketing by drug manufacturers, based on findings in Hyosun Kim's article of the major themes in recent Food and Drug Administration (FDA) warning letters and notices of violation regarding online direct-to-consumer promotions of pharmaceuticals. Kim's rigorous analysis of FDA letters over a 10-year span highlights a relative abundance of regulatory action toward marketer-controlled websites and sponsored advertisements, compared to branded and unbranded social media messaging. However, social media marketing efforts are increasing, as is FDA attention to these efforts. This commentary explores recent developments and continuing challenges in the FDA's attempts to provide guidance and define pharmaceutical company accountability in marketer-controlled and -uncontrolled claims disseminated through social media.

Keywords: Advertising, Drug, Internet, Online, Pharmaceutical, Social Media

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Citation: Carpentier FRD. Considering the future of pharmaceutical promotions in social media: Comment on: “Trouble spots in online direct-to-consumer prescription drug promotion: a content analysis of FDA warning letters.” *Int J Health Policy Manag.* 2016;5(4):283–285. doi:10.15171/ijhpm.2016.15

Article History:

Received: 16 December 2015

Accepted: 7 February 2016

ePublished: 9 February 2016

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The United States is one of only two countries that allow direct-to-consumer advertising of prescription drugs; pharmaceutical companies are thus particularly compelled to market in the United States, spending upwards of \$4.2 billion per year targeting consumers directly.¹ In particular, online direct-to-consumer advertising of pharmaceuticals is an increasingly popular means for marketing in the United States, with expenditures estimated at \$1.86 billion for online advertising.² Use of social media, for example Facebook, Twitter, or YouTube, is increasingly a part of pharmaceutical companies' marketing strategies.³ Hyosun Kim conducted a rigorous analysis of all US Food and Drug Administration (FDA) warning letters and notices of violations issued to drug manufacturers regarding their online promotional activities to consumers over the 10-year period spanning 2005 to 2014.⁴ Of the 73 citations Kim analyzed, nearly half were in reference to a company-controlled webpage or website. A fourth of the letters concerned paid advertisements in the form of sponsored links or banner ads. Just two of the letters referred to social media messages, both of which regarded Facebook use. The common theme within the body of letters regarded information quality; lack of risk information and mischaracterized efficacy information were the most prevalent allegations, followed by incomplete product names and insufficient ingredient information. In general, Kim's findings provide a modern exemplar of the FDA's custom of regulating based on a comparison of advertising claims with medical label information.⁵ Contents of the FDA warnings also corroborate concerns among medical practitioners and the general public about

pharmaceutical advertising. Many physicians feel direct-to-consumer advertisements (DTCA) lack information about adverse side effects, monetary cost, and alternative treatment options.⁶ The majority of laypersons are skeptical of the quality of information in DTCA and feel DTCA might have negative effects on others' doctor-patient relationships and competence in their own healthcare.⁷

The fact that only two letters relating to social media were found within this 10-year span is surprising, however, given the top ten pharmaceutical companies all have Facebook pages and Twitter feeds (many of these companies also host a YouTube channel).³ Arguably, this finding suggests the current research underestimates the prevalence of incomplete and incorrect information about pharmaceuticals that exists online. Supporting this argument, four additional FDA warnings related to Facebook messages were issued in February 2015 alone, suggesting the FDA is increasing its effective vigilance of social media.

The most oft-cited allegation across the February 2015 letters plus the two letters Kim analyzed concerned unapproved claims about a drug presented by the drug manufacturer on its company-branded Facebook page. Kim categorized the two Facebook-related warnings she encountered as being marketer-influenced rather than marketer-controlled. However, the FDA has found incidents that attest to the presence of both marketer-controlled and marketer-influenced claims on Facebook and other social media. Consider Vitalab Co., Inc., which received a warning letter on October 16, 2014 for making unapproved claims about its product, Vit-Ra-Tox, via its company-authored Facebook

posts. NanoBiotech Pharma received a similar warning on February 26, 2015 for its own Facebook posts. These incidents are arguably marketer-controlled, as the posts were created by company representatives. Therefore, responsibility for this primary content lies clearly with the company, and so the FDA may take action against the company for producing and disseminating the unapproved claim.

Accountability for claims are less clear when the content is not directly marketer-controlled, which Kim refers to as marketer-influenced. On December 11, 2012, AMARC Enterprises received a warning for endorsing, via a Facebook “like,” an unapproved claim about its product, Poly-MVA for pets, which had been posted on another company’s Facebook page. In this case, the origin of the claim is unclear, as it is not possible from viewing the claim to ascertain whether AMARC might have authored the content or encouraged the other company to create and disseminate the claim. Similarly, Zarbee’s, manufacturer of a natural cough remedy, received an FDA warning on June 27, 2014 for “liking” unapproved claims posted to the company’s Facebook wall by third parties (Zarbee’s was also warned about their Twitter posts implying their product was a drug rather than a dietary supplement). In June 2014, the FDA issued a draft report of social media guidelines to address third party misinformation.^{8,9} Relevant to the determination of authorship, the FDA indicated that it considers a company’s responsibility for a claim to increase, the closer the company is to the creation or endorsement of the claim.⁹ A second report focusing on Twitter was also issued in June 2014, indicating that a company may embed a direct link within a message that directs a user to additional information about the product.¹⁰ However, in the initial message and in the linked information, risk information must be complete and be afforded the same prominence as benefit information.¹⁰ Furthermore, all information and links must be branded.¹⁰ The overriding suggestion by the FDA in these reports is for pharmaceutical companies to consider avoiding use of the medium if there is concern of noncompliance or an inability to comply.⁸⁻¹⁰

These points can most easily be evaluated and enforced when a message has clearly been posted by the company. However, as is evident in the recent body of allegations, a great deal of ambiguity surrounds social media, and regulators will likely continue to struggle with defining the company’s agency, and therefore responsibility, in pharmaceutical messages disseminated outside the company’s branded media channels.¹¹ Yet, as Kim concludes, it is vital that the FDA increase its monitoring of social media either directly or through a third-party system. Health information continues to be one of the most frequently sought topics on the internet.¹² In social media specifically, health information is widely shared; over 80% of young adults have disclosed health information and have sought health information at least once through a social media channel.¹³ Consumers who actively seek out online health information tend to believe the information to be credible, irrespective of whether a medical expert has actually authored the information.¹⁴ Unlike their perceptions of other methods of DTCA, consumers are less skeptical of online information unless they are expressly motivated to recognize the intent of these messages as persuasive.¹⁵ Thus, marketer-influenced messages, especially

if unbranded, are particularly problematic for both consumers and regulators, as these messages often appear to be word-of-mouth information offered by a fellow layperson.¹⁶ In fact, the message might be originating from a compensated blogger or brand ambassador, as was the case with celebrity Kim Kardashian’s paid endorsement of morning sickness drug, Diclegis, disseminated via Instagram post.¹⁷ Diclegis manufacturer, Duchesnay, Inc., received an FDA warning about this incident on August 7, 2015.

It is likely that the use of unbranded content by pharmaceutical companies will continue to grow, given that consumers tend to trust information from unbranded sources more than they trust branded sources.¹³ To the extent that the messages are either marketer-influenced or simply favorable toward a company product, these messages can serve as a conduit to attract users to the company’s branded information.¹¹ Thus, the potential to drive consumers toward this branded information might overcome current hesitations of some pharmaceuticals to capitalize on third party social media messaging outside their marketing campaigns, despite the understanding that this messaging, though potentially advantageous, is nonetheless uncontrollable.¹⁷ Both companies and regulators will likely remain concerned, however, about the potential misinformation and encouragement of misuse (eg, off-label use) of a drug in user-generated social media messages, which can harm public health as well as company marketing efforts.^{18,19}

Perhaps more attractive to companies, Facebook and/or other social media offer venues for marketer-controlled, marketer-influenced, or simply advantageous cause-related marketing opportunities, such that users interested in a social issue (eg, childhood obesity, heart disease) might be converted to potential consumers of a relevant product (eg, cholesterol lowering medication).²⁰ Again, cause-related virtual spaces might or might not be formally branded and might or might not be managed by the pharmaceutical company. The onus thus falls to regulators to identify when a cause-related space is, in fact, a component of a company’s social media marketing campaign, just as regulators and companies alike will be challenged in determining when claims offered via messages outside marketer control become the responsibility of the company. According to the FDA’s 2014 draft guidance on third party misinformation, pharmaceutical companies will not be held responsible for user-generated content.⁸ However, as the FDA increases its guidance on how it will consider accountability of online messages, pharmaceutical companies might be increasingly tempted to leverage favorable user-generated messages, which may further obfuscate the distinction between controlled and uncontrolled content.¹⁷ A replication of Kim’s content analysis of FDA warnings ten years from now would be very informative in examining how successful the FDA becomes in detecting drug manufacturer accountability in online unapproved claims, assuming pharmaceutical companies continue the trend toward online and social media marketing.

Ethical issues

Not applicable.

Competing interests

Author declares that she has no competing interests.

Author's contribution

FRDC is the single author of the paper.

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