FDA's Policy on Social Media: Why It Matters for Marketers of OTC Drugs, Food, Dietary Supplements and Cosmetics

by Kristi Wolff

Social media has proven to be not just a means of connecting with old friends, but a means of connecting with old friends and suggesting that they try new products, perhaps a new prescription drug for the treatment of chronic myelogenous leukemia.[1] Marketers of all types of products—including those regulated by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC)—use social media as a way to market their products. As social media and the laws governing it evolve, the techniques that marketers use to reach consumers and, hopefully, their extended social networks evolve as well.

FDA is expected to issue guidance and possibly regulations regarding use of social media for prescription drug and restricted medical device marketing. These policies, while only enforceable on those product categories, should be carefully examined by manufacturers of other FDA-regulated products as well, mainly over-the-counter (OTC) drugs, food, dietary supplements and cosmetics (collectively called consumer health products). As explained below, while prescription and non-prescription products are subject to differing laws and regulations, the fact that FDA regulates labeling and advertising for prescription drugs and restricted devices and that FDA shares jurisdiction over consumer health products with FTC means that social media content could be considered both labeling and advertising for all of these products. As a result, many of the same considerations apply and should be taken into account by marketers of consumer health products.

Background

FDA has been formulating its policy regarding the use of the Internet and social media to market prescription drugs and medical devices for the last several years. In 1996, FDA held a public meeting to discuss issues related to the promotion of FDA-regulated medical products on the Internet.[2] The agency sought to obtain public input regarding investigational product information, chatrooms, newsgroups and website links. Following this information gathering session, however, the FDA did not unveil social media policies or practices and did not formally revisit the issue until recently.

As anyone who has recently received a "Friend Request" can attest, there is a world of difference between social media circa 1996 and social media today. Newsgroups and chatrooms make up only a small portion of social media used by consumers and marketers. Today, sites such as Twitter, Facebook and YouTube are highly-used social media outlets, and marketers utilize this space for advertising with increasing frequency. It's true, there's an app for that.

Recognizing these changes, FDA again sought public input in late 2009 regarding the promotion of prescription medical products via the Internet and social media tools.[3] Earlier that year, the agency signaled its concern by sending warning letters to 14 drug manufacturers regarding paid search advertisements placed on Google.[4] FDA's primary concern with the paid search advertisements was that they did not meet the fair balance requirement for prescription drugs, the requirement that prescription drug advertisers present a fair balance of information regarding the efficacy as well as side effects and contraindications of the drug being advertised. For example, Bayer HealthCare Pharmaceuticals received a warning letter pertaining to several of its products, including its erectile dysfunction drug, Levitra, as well as Yaz, a birth control pill and Mirena, an intrauterine contraception system.[5] Bayer's Levitra sponsored link said only:

"Poor Blood Flow & ED; Blood Flow May Decrease with High Blood Pressure and May Lead to ED."

FDA's concern was that this ad did not disclose the risks associated with the use of Levitra and the agency expressed similar concerns regarding the paid search advertisements for Yaz and Mirena. FDA was also concerned that the advertisements for Yaz and Mirena inadequately communicated the products' indications and their efficacy. In this instance and others cited by FDA, clicking on the link transferred users to a product-branded site that did disclose the risk and limitation information. However, FDA did not believe that that was sufficient to meet the marketer's disclosure obligations.

Following this spate of warning letters, FDA appears to have maintained its position. On July 29, 2010, FDA's Division of Drug Marketing, Advertising and Communication sent an "untitled letter" to Novartis Pharmaceuticals regarding the use of a widget to promote its drug Tasigna, which is used to treat chronic or accelerated Philadelphia chromosome positive chronic myelogenous leukemia. Novartis sponsored a webpage to promote Tasigna, which featured a Facebook share widget that allowed viewers of the site to click on the widget and upload information regarding Tasigna to their personal Facebook profile pages. FDA took issue with the widget because the content uploaded did not include product risk information or sufficiently display the indication for use information. Further, the shared content included an allegedly unsubstantiated superiority claim.

In both of these instances, FDA applied its existing legal and regulatory framework to a new medium. Under the Food, Drug and Cosmetic Act, FDA has the power to regulate the labeling and advertising of prescription drugs and restricted medical devices.[6] For prescription drugs, labeling cannot be false or misleading and must disclose the relevant material facts.[7] Advertisements must present a "fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug…"[8] Under these standards, it is hard to see how the short, eye-catching phrases used in paid search advertisements can ever be used in compliance with the FDA's standard. This reality is evidenced by pharmaceutical companies' response to the warning letters, which was an 84 percent reduction in paid search advertising.[9]

The upshot of FDA's renewed public interest in social media is that FDA is expected to issue a guidance document and possibly regulations regarding the use of social media to market prescription drugs and restricted medical devices. The comment period for the recent data collection efforts closed in February 2010. Although the FDA's requests for information were specific to prescription products, several of those paraphrased below are likely applicable to marketers of non-prescription consumer health products as well, such as:

- For what online communications are manufacturers responsible?
- How can manufacturers fulfill regulatory requirements in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications?
- What parameters should apply to the posting of corrective information on Web sites controlled by third parties?
- When is the use of links appropriate? and
- Questions specific to Internet adverse event reporting.

The Marketer's Considerations

While any new guidance or regulation will apply only to prescription drugs or restricted medical device products, marketers of consumer health products should pay close attention and use FDA's policy to inform their own labeling and marketing decisions. FDA and FTC may view social media as either labeling or advertising. Set forth below are some key legal considerations for marketers of consumer health products using social media.

Understand the Relevant Regulatory Jurisdiction: FDA regulates product labeling, broadly defined as "all labels and other written, printed or graphic" materials "upon" or "accompanying" an article.[10] FDA may also consider product websites or sites that link to sponsored social media pages to be labeling, particularly where product packaging directs consumers to visit a particular website. Marketers of consumer health products should stay informed about FDA's position regarding labeling and its limitations, if any, with respect to social media.

Identify the Issues: Marketers also need to be aware of consumers posting information about adverse experiences due to product usage to determine whether the adverse event descriptions constitute adverse event reports, one of the issues on which FDA sought comment. Manufacturers must address adverse event reports when they become aware of them. Given the highly unrestricted use of consumer posts on social media, marketers' monitoring obligations are not entirely clear at the present time. Failing to properly identify and address a consumer's description of symptoms that constitute an adverse event report could have regulatory implications and legal implications in the form of a personal injury lawsuit depending on the level of harm experienced.

In addition to consumers reporting adverse events, marketers should also be on the lookout for consumers posting information regarding product quality that could signal the need for a recall. While many consumers will still opt to call the customer service telephone number listed on the label, as social media pushes further into consumers' daily modes of communication, it is entirely foreseeable that a consumer could post information regarding product quality on a company sponsored social media outlet. Furthermore, with the recent passage of food safety legislation, there is an emphasis on the prevention of foodborne illness outbreaks. Manufacturers must consider not only the operational ways in which they can prevent outbreaks, but their means of identifying quality concerns that may signal bigger problems.

Related to FDA's expected social media policy, FTC issued updated Endorsement and Testimonial Guides in late 2009. The Endorsement and Testimonial Guides govern the use of endorsements and testimonials in the advertising of consumer health products, including traditional advertising, social media and blogs. Marketers utilizing social media and consumer generated content should be sure to incorporate the requirements and restrictions set forth in the Endorsement and Testimonial Guides into any social media or campaign or any advertising campaign involving endorsements or testimonials.

Assess the Risk and Plan to Address It: One risk that companies face when advertising on social media is loss of control over the content. Unfortunately, the fact that content is consumer generated does not necessarily shield a marketer from potential regulatory or legal liability. Indeed, when FTC issued its Guides Concerning the Use of Endorsements and Testimonials in Advertising, the Commission specifically noted that "advertiser's lack of control over [a] specific statement made via these new forms of consumer-generated media" does not necessarily mean the advertiser is not responsible for the content.[11] Unlike a company-hosted site, marketers cannot control the terms and conditions, filters, takedown policy, privacy policy or even the ability to post content when using social media.

To account for this risk, marketers must be proactive and determine up front how to handle scenarios in which consumer generated content may create legal risk. For example, a consumer may post a statement about a product that cannot be supported with evidence. Marketers should have a plan in place to address this and other scenarios before launching the social media campaign. Further, marketers must monitor the social media sites that they sponsor in order to avoid the appearance that the company implicitly adopts statements that it knows are not supported. If a marketer recognizes that consumers are posting unsupported product claims on a company-sponsored outlet, such as a Facebook page, and the company fails to act, FDA or FTC could interpret this as the company adopting the consumers' statements as labeling or advertising and use this in an enforcement action. Marketers of consumer health products should use FDA's upcoming social media guidance to inform corporate website monitoring and social media response plans.

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As tempting as it is for marketers to compartmentalize FDA's actions into pertaining only to specific categories of products, this would be a mistake with regard to social media. While FDA has jurisdiction over labeling and advertising of prescription drug and restricted medical device products, many of the issues that FDA raised as concerns in its September 21, 2009 Federal Register notice can also be applied to consumer health products. It is likely that much of the policy and rationale expressed in the upcoming social media guidance will apply across categories as well.

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1 *See* Letter from Karen R. Rulli, FDA Division of Drug Marketing, Advertising and Communications to Lisa Drucker, Director, Regulatory Affairs – Oncology, Novartis Pharmaceuticals Corporation (July 29, 2010). As described further above, the FDA took issue with Novartis's use of a Facebook share widget on its product branded website for Tasigna, a drug used to treat chronic myelogenous leukemia.

2 *See* 61 Fed. Reg. 48707 (Sept. 16, 1996).

3 *See* 74 Fed. Reg. 48083 (Sept. 21, 2009).

4 Clifford, Stephanie "*F.D.A. Rules on Drug Ads Sow Confusion as Applied to Web*" New York Times (April 16, 2009), available at: http://www.nytimes.com/2009/04/17/business/media/17adco.html.

5 Letter from Shefali Doshi, M.D., Regulatory Review Officer, FDA Division of Drug Marketing, Advertising and Communications to Fadwa Almanakly, Associate Director, Global Regulatory Affairs, Bayer Healthcare Pharmaceuticals, Inc. (April 2, 2009), available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm055773.htm

6 *See* 21 U.S.C. §§ 352 and 353b.

7 *See* id. at § 352(a).

8 21 C.F.R. § 202.1(e)(5)(ii).

9 *See* Bnet.com "Pharma Reduced Paid Search by 84% Following FDA Warnings" (October 7, 2009), available at: http://www.bnet.com/blog/drug-business/pharma-reduced-paid-search-by-84-following-fda-warnings/3159.

10 21 U.S.C. § 321(m).

11 74 Fed. Reg. 53,124, 53,126 (Oct. 15, 2009).