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# FDA AND PROMOTION OF MEDICAL PRODUCTS USING THE INTERNET AND SOCIAL MEDIA TOOLS

Internet and social media tools such as Google searches, Twitter, Facebook, and Wikipedia have become important routes for consumers to obtain information about health and medical treatments. Companies that make or market US Food and Drug Administration- (FDA-) regulated products are increasingly using these tools to promote their products and to provide other important information to consumers and healthcare professionals. While the Internet and social media provide significant benefits to consumers, industry, healthcare professionals, and the public as a whole, these forms of media present new legal and regulatory challenges with respect to promotional labeling and advertising, third-party communications about a company's products, and potential adverse events identified in blogs, chat rooms, and other forms of social media. On November 12–13, 2009, FDA held a public hearing on the promotion of FDA-regulated medical products using the Internet and social media tools to hear from industry leaders, consumers, public interest groups, and media professionals about the opportunities that these new technologies offer, as well as the regulatory and compliance challenges that industry and FDA will have to address in the face of constant innovation in the use and availability of these media.

The hearing, which was moderated by Thomas Abrams, Director of FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC), followed a panel-style format in which pre-selected speakers gave prepared remarks with accompanying slide presentations. The FDA panel members, which included legal and regulatory professionals, asked questions of the speakers, but did not otherwise provide prepared remarks or invite questions or participation from the audience. Promotional issues were covered on the first day and adverse event reporting on the second day.

Speakers made oral presentations addressing the following issues posed by FDA in the Federal Register notice announcing the hearing:[1]

1. For what online communications are manufacturers, packers, or distributors accountable?
2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, postmarketing submission 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 (e.g., microblogs, mobile technology)?

1 74 Fed. Reg. 48083 (Sept. 21, 2009).

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3. What parameters should apply to the posting of corrective information on websites controlled by third parties?
4. When is the use of links appropriate?
5. Questions specific to Internet adverse event reporting (e.g., how are entities with postmarketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to monitoring adverse event information about their products? How is adverse event information from these sources being received, reviewed, and processed? What challenges are presented in handling adverse event information from these sources? What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?).

## PROMOTION AND ADVERTISING

Internet companies and regulated industry representatives discussed the need to differentiate Internet and social media from other forms of labeling or advertising because, unlike traditional promotional labeling and print or broadcast advertisements, Internet and social media users have a greater ability to control, alter, and respond to the promotional messages and other product information they receive. For example, one speaker discussed the potential regulatory challenges presented by new technologies such as Google Sidewiki, a browser sidebar that enables users to post comments and view other third-party comments alongside any webpage. Speakers such as Eli Lilly, sanofi-aventis, and Pharmaceutical Research and Manufacturers of America (PhRMA) agreed that manufacturers should be accountable for online content they control, but noted that manufacturers should not have a broad obligation to police or remove all forms of third-party content about their products. The prevailing view was that manufacturers should be accountable in the following ways:

- Manufacturers should be responsible for any content located on company sites, third-party sites on which they have a company page (e.g., Facebook), and information on any other third-party sites sponsored by the manufacturer or over which the manufacturer exerts any influence or control, financial or otherwise.
- Manufacturers should not be responsible for content on independent third-party sites over which the manufacturer has no influence or control.
- Manufacturers should not be responsible for content posted by users and consumers. If, however, such posts appear on a manufacturer-owned or sponsored website, the manufacturer may have a responsibility to remove any information that presents inaccurate or off-label product information. If the posts ask questions regarding off-label indications, manufacturers may direct the consumer and the on-line community to contact the company's medical information department.

Speakers also acknowledged that, given the amount of information available on the Internet, it is important to be able to identify reputable information. PhRMA, among others, suggested use of an FDA-approved logo or seal of approval that could be affixed to a sponsored link, webpage, or particular information on a webpage, indicating that FDA had reviewed and approved that information. FDA panel members questioned several speakers on this suggestion, seeming to express concern about how the agency could effectively ensure that the logo would be applied only to FDA-approved material.

Industry representatives also stated that FDA's approach to regulating Internet and social media content should not hinder or discourage the free exchange of information. Speakers encouraged FDA to examine its application of fair-balance requirements with regard to Internet and social media content in light of the fact that such media are not strictly promotional, but also facilitate the exchange of vital health and disease management information and encourage discourse between and among patients, caregivers, physicians, and others. Numerous speakers repeated the concern that manufacturers are currently wary of participating in social media because of the lack of guidance and the potential for being cited for noncompliance.

Several online marketing and search companies, such as Google and Yahoo!, noted the practical challenges of holding regulated industry responsible for the content of product-related links. Some of the speakers stated that the

summaries that accompany links are critical to effective searching and Internet navigation, and the extent to which FDA limits or prescribes the specific content of sponsored links has a direct impact on the effectiveness of traditional Internet search tools. They noted, for example, that when consumers conduct a general search on the Internet, they rely on summary information accompanying the links in the search results to determine whether they have located the information or website they are seeking.

Google noted that, before the issuance of 14 Untitled Letters by FDA in late March 2009,[2] sponsored links about prescription drug products informed the users that information contained therein was prescription drug information, and consumers were able to access the relevant risk information. Since the issuance of the letters, however, the click-through rate has dramatically decreased because many prescription drug manufacturers now limit the content of summaries to include little more than the product name, thereby reducing the effectiveness of user queries and the utility of search results. Some Internet providers stated that, as a result of the letters, it has become more difficult for the public to differentiate between various links and to determine those that most appropriately address their inquiries. The Internet companies expressed the view that the so-called "one-click" rule, in which required risk information about a product is no more than "one-click" away from general product information or promotional messages, is a useful regulatory solution to these issues.

Consumer and nonprofit groups expressed contrasting views from those of industry and online marketing agencies. For instance, Consumers Union noted that pharmaceutical companies should not be engaged in promotion through blast emails or chat rooms, and that the regulations that exist for monitoring promotion through traditional media should also apply online, and perhaps even more stringently. Its representative stated that the limited space provided in blog or chat room formats is not a valid reason to not comply with the relevant regulations. He also stated that search engine use should be reviewed by FDA.

Similarly, the representative from the National Research Center for Women and Families noted that risk information should be readily accessible, and that "one click away is one click too many." She also said that companies should be held responsible for all information about their products that appears to be promotional, regardless of the ostensible source of the information. She said this is particularly important because of the amount of information on blogs and the number of advertisements bought and paid for on third-party websites. She said that if a company says it is not responsible for the content of a website or blog that discusses its products, it should be responsible for requesting any necessary corrections (e.g., any inaccurate or off-label information), and should have to demonstrate to FDA that the company was not initially responsible for the placement of such information.

## ADVERSE EVENT REPORTING

Several speakers highlighted the regulatory challenges associated with identifying and evaluating potential adverse events (AE) in the form of statements or consumer complaints on third-party websites, blogs, chat rooms, or other forms of social media such as Twitter. Under FDA regulations, drug manufacturers are required to submit information to FDA regarding serious and unexpected AEs within 15 days of receipt of such information. As explained by FDA in the Federal Register notice announcing the hearing, AE information "that is submitted via the Internet to an entity with postmarketing reporting obligations…should be reported to FDA if there is knowledge of the four basic elements for submission of an individual case safety report," specifically: (i) an identifiable patient; (ii) an identifiable reporter; (iii) a specific drug involved in the event; and (iv) an adverse event. FDA also explained in the Federal Register notice that "entities should review any Internet sites sponsored by them

2 On March 26, 2009, DDMAC sent Untitled Letters to 14 pharmaceutical companies addressing their use of "sponsored links" on Internet search engines (i.e., links (with product-related content) from which a user can access the official product websites). FDA's position, as explained in the Untitled Letters, is that a sponsored link violates the Federal Food, Drug, and Cosmetic Act's (FDCA's) misbranding provisions where the product-related content associated with the link contains inadequate or misleading information related to a drug product's risks or indications.

for [AE] information, but are not responsible for reviewing any Internet sites that they do not sponsor; however, if they become aware of an [AE] on an Internet site that they do not sponsor, they should review the adverse experience and determine if it should be reported to FDA."[3]

Speakers acknowledged uniformly that the Internet presents difficulties with respect to postmarketing reporting of AEs. Numerous speakers stated that drug manufacturers are hesitant to fully engage in online social media specifically because they want to avoid learning about potential AEs and the resulting reporting obligations, particularly because the guidance in this area is unclear. Several speakers noted that AE information reported online typically does not contain the four elements necessary to be reportable to FDA, and the extent to which manufacturers are required to seek additional information regarding the potential AE is unclear. Several speakers recommended that FDA shift its focus on AE reporting from manufacturers to patients or consumers, who are currently able to report AE information on the FDA website. Some speakers suggested that product-specific Internet sites could include links that would direct readers to FDA's AE reporting website. Speakers noted, however, that the current reporting form for patients and consumers is very technical and not user-friendly, and recommended that FDA revise the reporting form for patients and consumers.

The broad take-away from the hearing is that there is consensus among regulated industry, Internet providers, and public interest groups on the need for FDA guidance and regulation of Internet promotion and postmarket AE reporting issues. There are, however, divergent opinions on how far-reaching these regulations should be and how they can be most effectively implemented. DDMAC Director Abrams concluded the hearing by noting that FDA has much work to do on the issue of Internet and social networking. He said that FDA understands that the Internet is different from traditional promotional media, but that online communications cannot be misleading, and must be balanced.

Pending further guidance, companies should prepare for further FDA scrutiny of this area by developing compliance policies to address the challenges of involvement in Internet and social media tools, including but not limited to:

- policies relating to employee involvement in social media, and in particular statements regarding company products;
- company involvement in physician and patient-focused social media, including both company-sponsored sites and third-party sites run by third-party organizations (and particularly those receiving manufacturer support through grants or other funding);
- addressing the challenge of Sidewiki and similar functions that make third-party generated information directly available in conjunction with company websites;
- updating promotional review policies to ensure consistency with developing FDA approaches to risk communication on the Internet, including sponsored links;
- policies regarding statements that company-affiliated parties (e.g., investigators, patients) may make on the Internet, which may constitute endorsements or testimonials requiring both review and specific disclosures; and
- ensuring a consistent and compliant approach to pharmacovigilance with respect to Internet-reported adverse events.

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*We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:*

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3 74 Fed. Reg. at 48087.