



November 17, 2009

Promotion of Medical Products Using the Internet and Social Media

FDA Public Hearing Offers Forum for Industry Stakeholders to Share Comments and Suggestions Regarding Promotion Using Unique Media

The Food and Drug Administration (FDA) held a public hearing on November 12 - 13, 2009 to discuss the application of existing regulations to the promotion of medical products on the Internet, given the medium's "continually evolving nature." In September, FDA published a *Federal Register* notice announcing the hearing and requesting written comments through February 28, 2010. Through the public hearing and written comment process, FDA seeks general and specific comments on Internet and social media promotion and other communications, including (but not limited to) the following issues:

- The scope of responsibility/accountability of manufacturers, packers or distributors;
- The manner of fulfilling regulatory requirements;
- Parameters for linking between sites; and
- Adverse event reporting.

The at-capacity hearing room was filled with industry stakeholders including product manufacturers, industry trade associations PhRMA and AdvaMed, Internet search providers, patient advocacy groups, interactive media consultants, and individual consumers who provided thought-provoking presentations and suggestions to an FDA panel chaired by Division of Drug Marketing, Advertising and Communications (DDMAC) Director Tom Abrams and comprised of representatives from DDMAC, other divisions of the Center for Drug Evaluation and Research, the Office of the Commissioner, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine and the Office of the Chief Counsel.

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The two day hearing included 77 presentations by 69 different speakers addressing the following key themes:

- **Unique nature of Internet** – Speakers provided compelling statistics regarding the explosive use of the Internet by patients and caregivers to seek and share information, chronicle their health experiences and create support communities. Presenters noted the unique nature of the Internet compared to traditional media such as newspapers, magazines and television, pointing out that the Internet is interactive, immediate and allows more voices to be represented because there often are no financial costs to participate online. Other presenters noted that the seemingly limitless space and access afforded by the Internet compared to TV and print media warrants additional regulatory oversight.
- **Importance of product manufacturers engaging in the conversation online** – Presenters also stressed the importance of allowing medical product manufacturers to engage with patients and caregivers online. Speakers noted that manufacturer-created content is actually the only content online that is regulated by FDA and that manufacturers are the experts about their own products. Other speakers agreed that manufacturers should engage online, but indicated that certain Web-based applications such as email, Twitter and comment boards are not appropriate venues for product promotion.
- **Guidance is needed** – Speakers overwhelmingly cited the need for FDA guidance regarding the application of existing regulations to the Internet and its applications including blogs, microblogs, podcasts, social network sites, widgets and wikis, among others. The current lack of specific guidance from FDA leaves product manufacturers often on the sidelines, unwilling to engage in important discourse about products and correct product misinformation. Speakers further suggested that, given the ever-evolving nature of the Internet, traditional guidance would be immediately obsolete and that FDA should establish public workshops or a working group to address new technologies and develop solutions with stakeholders.
- **Manufacturer accountability** – A majority of speakers suggested that pharmaceutical manufacturers should be held responsible only for content that they create, encourage or sponsor financially; they should not be responsible for information created by third parties. However, a patient advocacy group suggested that companies must be responsible for all promotional information because it is not always clear who is financially responsible for content.
- **Correcting information** – Speakers noted the logistical challenge of monitoring the Internet, especially considering the multitude of conversations occurring in chat rooms and on social networking sites each day. Some presenters suggested that manufacturers should not be held responsible for policing information online, but noted that it might be in a company's best interest to correct false information about products. Another speaker suggested that companies are obligated to correct misinformation about their products, especially when patient health is at risk. Other speakers noted that manufacturers should be required to make a "best" or "reasonable" effort to correct misinformation, and suggested that FDA develop standards for what would constitute a "best" or "reasonable" effort.



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- **Creation of a universal symbol** – PhRMA proposed (and other speakers supported) the creation of a universal symbol that could be included on manufacturer webpages to signal that the information on the webpage was FDA-regulated information. The symbol would include standard language such as: “All drugs have risks—see the manufacturer for more information about this product’s specific risks.” Manufacturers would be required to adhere to guidelines and standards created by FDA in order to post the symbol. Other advocates of the use of a universal symbol or logo emphasized that it would elevate risk information, reduce confusion about risks by providing consistency, and become immediately recognizable to consumers. However, other speakers expressed concern that content could be altered after the “seal of approval” was granted, misleading consumers about the accuracy of the information.
- **Appropriate use of links** – Speakers explained that links are an inherent part of the Internet experience and are easily understood by Internet users. Rather than hiding information, speakers asserted that links are a superior way to connect users to important, comprehensive risk information instantly. Presenters did note that links must be comprehensive and descriptive so that users know precisely to what information they are linking. Others noted, however, that one click away is “one click too far” and emphasized that evenly-balanced risk and benefit information should be included throughout a product website.

Additionally, Google introduced two new proposed formats for sponsored link advertisements—one format for traditional branded advertisements and one format for products with boxed warnings. The branded sponsored links would include (1) benefit and risk information prominently within the sponsored link; (2) room for both the generic and brand names of the drug; (3) a brief description of the indicated use or benefits statement; (4) a brief description of the major risks within a standardized “Warning” line; and (5) two links to more information, one which would take users directly to important risk information.

The sponsored link for boxed warning products would not include an indication but would include a fixed safety and prescribing statement, including information about the boxed warning. The boxed warning format would include room for the brand and generic names and also contain two links to more information, one which would take users directly to important risk information.

- **Adverse events** – Speakers noted that, while adverse experiences with medical products sometimes are discussed in chat rooms or on comment boards, it is rare that such discussions include sufficient information for a product manufacturer to determine whether the experience constitutes a reportable adverse event. Other speakers noted adverse experience information provided via social media can provide useful information, but also can be biased, inaccurate or misleading. Presenters cited the anonymous nature of the Internet and noted that many online commenters use a screen name or post anonymously. These presenters worried that attempting to contact an Internet commenter to obtain additional information about an adverse experience would be an unwelcome invasion of privacy. However, other speakers suggested that FDA should require manufacturers to monitor social media sites that discuss company products and report adverse events accordingly.



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Speakers generally seemed more comfortable with requiring manufacturers to provide links to MedWatch or embedding a MedWatch widget to allow Internet users to directly report Adverse Events directly to FDA. Other speakers also cited the MedWatch system, noting that FDA should work to simplify MedWatch and undertake an education campaign to encourage consumer reporting.

DDMAC's Tom Abrams provided concluding remarks, noting that the Internet is "rich in the information it can provide" but "presents challenges." Director Abrams further noted that FDA "wants to give this much thought" and emphasized that the agency has "much work to do in this area," but did not provide a timeline for the issuance of guidance. Director Abrams emphasized that FDA seeks the involvement of stakeholders and reminded all stakeholders, particularly those with data to share, to submit comments to the FDA docket.

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Please contact us if you have questions concerning FDA's current requirements affecting the use of Internet, social media, or other communication technologies, or if we can assist with the monitoring, analysis or preparation of written comments to the agency.

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