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FDA's Emerging Internet Policy: Themes and Recommendations From Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools

Following a decade-long hiatus, the Food and Drug Administration ("FDA") appears ready to finally address industry Internet communications. FDA's Center for Drug Evaluation and Research ("CDER"), in collaboration with other divisions within FDA,¹ held a two-day hearing Nov. 12 and 13 to help the Agency determine how the statutory provisions, regulations, and policies concerning advertising and promotional labeling should be applied to product-related information on the Internet and newer technologies.

Much has changed since 1996, the last time FDA held a public hearing on this topic. The Internet is now widely used as a medium for companies to disseminate information about their products, and the Internet's ability to facilitate communication and collaboration has substantially evolved over the past few years as a result of a second (Web 2.0) and now third (Web 3.0) generation of Internet development and website design. Web 2.0 focuses on information-sharing between Internet users, whereas Web 3.0 combines information-sharing with other Internet technology to create an Internet that understands and helps a user interpret the meaning of data.

Web 2.0: The term Web 2.0 is commonly associated with Internet applications that facilitate interactive information sharing, interoperability, and collaboration between users. Web 2.0 incorporates emerging technologies such as blogs, microblogs, podcasts, social networks, online communities, video sharing, widgets, and wikis (collectively, "social media") (see definitions below). These social media tools enable people to communicate easily via the Internet to share information, and participate in the creation or development of website content. Social media on Web 2.0 expedites conversation, as opposed to non-interactive websites where users are limited to the passive viewing of information provided to them.

Web 3.0: The term Web 3.0 is commonly associated with a semantic Internet – that is, an Internet that understands the meaning of data. Web 3.0 is an Internet where information is monitored, categorized, stored, and interpreted by the Internet for a user.

The inherent flexibility and intelligence of Web 2.0 and 3.0 is great for society, but also fraught with risk for an FDA-regulated industry that must carefully control its interaction with consumers and health care practitioners. The industry has largely avoided using Web 2.0 out of fear that any social media use may result in FDA enforcement action.

Given the above, it is not surprising that the social media hearing was a welcome relief to many. Even though the hearing technically was only an information-gathering exercise for FDA, it was an important opportunity for industry leaders and stakeholders to contribute to FDA's emerging policy on Internet advertising and promotional labeling.² Below is a brief summary of the major themes and recommendations from the presenters at the hearing. The comments range from general reports about Internet usage and control, to the intersection between social media and industry compliance with FDA rules and regulations. FDA is accepting public comments on specific questions it posed to the public until February 28, 2010 (FDA Docket No. FDA-2009-N-0441) (see questions at end of this article).³

I. THEMES

- **Internet Growth and Control is Problematic:** Even though the Internet is becoming an increasingly important tool for consumers and health care professionals, agreement was nearly universal that the Internet is growing exponentially and the industry cannot monitor every Internet website or communication. Moreover, there is an increasing problem with sifting through Internet "fog" (i.e., massive amounts of data and misinformation posted on the Internet), such

as computer-generated mass advertising website postings that create fictitious postings or disseminate multiple versions of a single consumer adverse event report.

- **The Industry Has Largely Avoided Using Social Media:** The industry has been largely avoiding Web 2.0 out of fear that the use of this technology, including monitoring social media communications, is risky and may trigger FDA enforcement action. The industry is likely to continue this trend until FDA provides guidance.
- **Data-Mining Technology Exists:** Data mining is a technique using modern computing and statistical algorithms to extract meaningful, organized information from large, complex databases, such as web monitoring systems that track social media interactions on the web. Data mining can be used to collect adverse events involving FDA-regulated products, and could aid the FDA in identifying signals of adverse events and the patterns by which they occur. As discussed below, however, there were diverse views about whether the industry should be responsible for monitoring social media through data-mining technology.
- **The Industry and FDA Must Encourage Internet Transparency:** There was universal agreement that the FDA and industry must work together to ensure consumers have access to accurate and truthful information about FDA-regulated products. This includes making it easier for consumers to distinguish between third-party and manufacturer owned/controlled website content.

II. RECOMMENDATIONS

- **The Industry Cannot Monitor/Control Everything:** There was a nearly universal sentiment expressed that the industry cannot be held responsible for content that it does not generate or encourage. However, a few consumer groups advocated for requiring manufacturers to actively monitor the Internet through data-mining techniques for adverse event reports (see adverse events discussion below).
- **FDA Should Establish a Multi-Disciplinary Internet Advisory Board and Hold Public Workshops:** Acknowledging that the Internet will continue to emerge at a faster pace than can be regulated by FDA's current regulatory process, the industry, consumer groups, and social media companies called for a standing FDA advisory board that would work closely with industry through meetings and workshops to address emerging Internet technologies. One participant called for workshops to "collectively generate ideas, leverage the knowledge, expertise and experiences of the participants and work toward viable solutions" to problems posed by emerging technology.
- **FDA Should Consider Using Website Symbols:** An industry representative asserted that FDA should adopt a prominent universal safety symbol – the FDA logo or other FDA-approved symbol – to indicate that a linked page contains the manufacturer's FDA-regulated risk information. The symbol would help health care professionals and patients identify official websites of FDA-approved medical products containing reliable and comprehensive information about benefits and risks. Other participants proposed a similar symbol that would link to an FDA website page containing FDA certified information about the product, or an FDA website explaining that FDA holds industry-sponsored websites to a high standard (e.g., fair balance), whereas unaffiliated websites are not subject to this standard and may be false or misleading.
- **FDA Should Facilitate and Encourage the Use of Emerging Technologies By Acknowledging Space Limitations in Some Media and Creating New Fair Balance Standards:** The industry and social media companies called on FDA to provide guidance and allow manufacturers to present brief introductions to health information, including brief but accurate indication descriptions and warnings based on the space constraints of some social media, provided there is easy access to longer, comprehensive warnings through a prominently labeled hyperlink. Some participants called for the industry to catalog all social media communications (e.g., blog entries, Twitters) and periodically submit these catalogs to FDA as advertising and promotional materials, similar to traditional FDA-2253 submissions. Others called for FDA to sponsor grants to encourage innovative solutions to help the industry and FDA resolve new problems.
- **Industry Should Be Responsible for Correcting Some Internet Information, But Not All:** Consumer groups called for FDA to hold the industry responsible for "correcting" information identified through data-mining technologies. The industry called for a much narrower approach and warned of the danger of encouraging the industry to enter into social media dialogues to issue corrections. The industry also called for guidance on how the industry should handle off-label references made through social media. For example, some social media can be posted and become part of a website without the permission or knowledge of the website owner (e.g., Google Sidewiki, a browser sidebar allows the public to contribute and read information alongside

any web page). It also may be inappropriate for industry to correct off-label use discussions on a physician blog or physician discussion board. Some in the industry and some social media companies called for guidance based on the role a manufacturer plays on a website, such as hosting, participating, monitoring, or sponsoring before determining whether and to what extent corrective action is necessary. Still others called for an entirely new vocabulary beyond traditional labeling, such as “owned” media, “paid” media, “earned” media, and “hosted” media that could then be used by industry to determine whether and to what extent corrective action is necessary.

■ **Adverse Event Reporting**

- **MedWatch Icon:** All parties, including industry and consumer groups, agreed that FDA’s MedWatch icon or a new icon should be posted throughout the web to facilitate adverse event reporting. Some proposed requiring the icon on all industry-sponsored sites, including educational/disease websites. Others proposed allowing the icon to provide a safe harbor to companies participating in certain social media technologies (e.g., blogs, chat rooms). This would allow and may even encourage the industry to contribute to important product-related dialogues currently held by consumers and professionals in social media contexts.
- **Adverse Event Monitoring:** Some consumer groups advocated for FDA to require the industry to actively monitor all Internet social media for adverse events. Private public relations and social media companies admitted that a large majority of Internet social media could be monitored through current data-mining technology. The industry and others took a narrower stance and proposed requiring the industry to actively monitor only websites under complete or substantial control or support an FDA-regulated entity.
- **Pursuing Incomplete Adverse Event Reports:** There were diverse views on whether incomplete adverse event reports (e.g., anonymous website postings) should be pursued, and even whether certain social media is an appropriate context for the industry to investigate potential adverse events. Although some proposed that the industry investigate all adverse events communicated through social media, including incomplete adverse event reports posted on third-party websites, others felt this was inherently problematic. For example, if a consumer posts a response on a discussion board about a non-specific drug treatment for a certain condition – setting aside the fact that the consumer may not be asking for assistance or reporting anything – FDA may not want to encourage the industry to post responses that could interfere with the purpose of the chat room or dialogue (a post on a third-party discussion board that does not reference a product name could generate 50 responses from manufacturers and significantly interfere with the discussion).
- **New Internet Trend Reporting of Adverse Events:** A social media representative proposed transitioning from an individual based adverse event report to one that reports trends and patterns in patient communications. Data-mining technologies could help the industry identify trends that would trigger further analysis.

III. CONCLUSION

This is the first step in what will likely be a long process within FDA to establish a framework for regulating the Internet, provide guidance to the industry, and find a way to adapt to emerging technologies. Even though the hearing was a listening exercise for FDA, there were some encouraging signs that the Agency may adjust its current practice of attempting to apply the same standard to print and Internet communications and advertising. In his closing remarks, Tom Abrams, Director of FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”), said “what we have heard is it’s [the Internet] a different medium.” He also acknowledged that FDA “must get this right” and the Agency had “much work to do” in this area. We can only hope the Agency is sincere continuing to address this issue throughout 2010, and continues to engage the industry as it did during the recent public hearing. As one presenter noted, the industry is not asking FDA for a comprehensive Internet guidance document “wrapped in a bow” and ready for dissemination by December 2010; the industry simply wants to see that the Agency is sincere in addressing the industry’s concerns and is making progress.

Social Media Technology Definitions

- **Blogs (e.g., Blogger, WordPress, TypePad):** Blogs are websites with regular updates (in reverse chronological order—newest update at the top) that typically combine text, images (graphics or video), and links to other web pages. Blogs are usually informal and take on the tone of a diary or journal entry. Some blogs are very personal, while others provide mainstream news updates. Most blogs encourage dialogue by allowing their readers to leave comments.

- **Microblogs (e.g., Twitter):** Microblogs are comprised of extremely short written blog posts, similar to text messages, and provide real-time updates. Twitter is an example of a popular microblog service that lets users broadcast short messages up to 140 characters long (“tweets”) using computers or mobile phones.
- **Podcasts (e.g., audio sharing):** Podcasts (a blend of the terms “iPod” and “broadcast”) are audio or video files that users can listen to or watch on computers or on a variety of portable media devices (like an iPod, Zune, and certain cell phones). Podcasts are usually short and are often free, and users can arrange via subscription to receive new podcasts automatically via their computers or other media devices.
- **Social networks and online communities (e.g., Facebook, MySpace, LinkedIn, Friendster, Sermo):** Social networks and online communities give users opportunities to connect with or provide resources to clients, colleagues, family, and friends who share common interests. In many social networks, users create profiles and then invite people to join as “friends.” There are a variety of different social networks and online communities, many of which are free, and they range from general to those tailored for a specific demographic or interest area.
- **Video sharing (e.g., YouTube, Blip.tv, Vimeo):** Also called a “video hosting service,” video sharing allows individuals to upload video clips to an Internet website. The video host will then store the video on its server and show the individual different types of code to allow others to view or comment on the video.
- **Widgets:** Supposedly short for “window gadget,” a widget is a graphic control on a web page that allows the user to interact with it in some way. Widgets can also be easily posted on multiple websites, can have the added benefit of hosting “live” content, and often take the form of on-screen tools (clocks, event countdowns, auction-tickers, stock market tickers, flight arrival information, daily weather, etc.).
- **Wikis (e.g., Wikipedia, SideWiki, Medpedia):** The term “wiki” comes from the Hawaiian word for “fast.” Wiki technology creates a web page that anyone with access can modify—quickly and easily. A wiki can be either open or closed, depending on the preferences of the community using it. An open wiki allows anybody to make changes and view content. A closed wiki allows only community members to make changes and view its content. Some wikis allow anyone to view content but only members to edit the content. Google Sidewiki is a browser sidebar that lets you contribute and read information alongside any web page.

FDA Questions on Social Media

1. For what online communications are manufacturers, packers, or distributors accountable?

- a. What parameters or criteria should be applied to determine when third-party communications occurring on the Internet and through social media technologies are subject to substantive influence by companies that market products related to the communication or discussion?
- b. In particular, when should third-party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?
- c. How should companies disclose their involvement or influence over discussions or material, particularly discussions or material on third-party sites?
- d. Should different considerations be weighed depending on the specific social media platform that is used, or based on the intended audience? If so, what are these considerations?
- e. With regard to the potential for company communications to be altered by third parties, what is the experience to date with respect to the unauthorized dissemination of modified product information (originally created by a company) by noncompany users of the Internet?

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)?

- a. How should product information be presented using various social media tools to ensure that the user has access to a balanced presentation of both risks and benefits of medical products?

b. Is there data to support conclusions about whether different types or formats of presentations have a positive or negative impact on the public health?

c. Are there proposed solutions that may help address regulatory concerns when using social media tools associated with space limitations, or tools that allow for real-time communications to present product information?

d. How should companies address the potential volume of information shared on various social media sites with regard to real-time information that is continuously posted and regulatory requirements to submit promotional materials to FDA as applicable (see, e.g., 21 CFR §§ 314.81(b)(3)(i), 314.550, 314.640, 514.80(b)(5)(ii), 601.12(f)(4), 601.45, and 601.94)?

3. What parameters should apply to the posting of corrective information on websites controlled by third parties?

a. The agency is interested in any data or research on how companies have approached these issues.

b. Are there any parameters or criteria that could be used to determine the appropriateness of correcting misinformation and/or the scope of information a company can provide when trying to correct misinformation on a website outside a company's control?

c. Should the parameters differentiate with regard to the prominence of the third-party site (i.e., readership), its intended audience (e.g., general public, health care professionals, patients), its intended purpose (e.g., personal diary, encyclopedia-type reference), and/or the author of the information on the site?

4. When is the use of links appropriate?

a. The agency is interested in any comments about the appropriateness of various techniques regarding the use of links (including between various social media tools), and data or research about whether or not users find these approaches to be misleading.

b. Should parameters be established for links to and from websites?

c. In addition, the agency is interested in any data or research concerning the frequency with which users actually click on different categories of links (e.g., banner ads, links within websites, sponsored links, organic search result links) to get additional information about products.

5. How should FDA and manufacturers handle adverse event reporting made through social media?

a. 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?

b. How is adverse event information from these sources being received, reviewed, and processed?

c. What challenges are presented in handling adverse event information from these sources?

d. What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?

1 FDA's Center for Biologics Evaluation and Research ("CBER"), Center for Veterinary Medicine ("CVM"), and Center for Devices and Radiological Health ("CDRH").

2 Many industry leaders and stakeholders provided input at the public hearing, including PhRMA, AdvaMed, Eli Lilly, Pfizer, Johnson & Johnson, Sanofi Aventis, and many media groups, including Google and Yahoo!

3 74 Fed. Reg. 48083 (Sept. 21, 2009). In addition to the questions presented in the this Client Alert, FDA seeks data and research on the use of social media tools in promotion, including data from companies on their own experiences, the extent to which health care professionals and consumers are using and are influenced by various social media tools, and the impact of Internet and social media promotion on the public health. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to www.regulations.gov.

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