

Insights and Recommendations in the Wake of the FDA Social Media Hearings

On November 12 and 13, 2009, the FDA held a public hearing on the promotion of FDA-regulated medical products (prescription drugs, prescription biologics, and medical devices) using the Internet and social media tools. The goal was to guide the agency in creating regulations for the ever-changing Internet landscape. With current promotional guidance addressing only print and broadcast, most manufacturers* have shied away from fully engaging with consumers online—resulting in the absence of an industry voice in online health discussions.

Before the hearings, the FDA announced [five topics](#) that represent the challenges most frequently associated with the online promotion of medicines. While the FDA invited general comment, it was particularly interested in data or research that would help formulate future guidelines.

A panel of FDA officials heard about 80 testimonies, mainly from [advertising agencies, research companies, Web sites, search engine companies, consumer groups, and manufacturers](#) with a vested interest in health. The hearings were well-attended by the public and covered at length in mainstream and social media. Edelman reported extensively on the testimony ([see recaps on our blog](#)).

Health engagement is here to stay—but will industry have a seat at the table?

Nearly everyone testified that the Internet has become—and will continue to be—a major source of health information for the general public. It's also a breeding ground for *misinformation*, which is why most speakers agreed we need regulated players (that is, manufacturers) to be engaged. As several speakers noted, conversations about health are taking place already—and without the appropriately regulated voice of the manufacturer, consumers and health care professionals are missing valuable, accurate information.

Unfortunately, the number of testimonies that expounded on the Internet and its challenges far outweighed the number of concrete recommendations to address them. And despite the subject matter being all about “engagement,” interaction between the FDA panel and the speakers was limited. The good news is that the FDA seems to recognize its shortcomings and is eager for suggestions from those who are better-versed. The agency will continue to [accept written testimony](#) on this topic until February 28, 2010. We urge all companies with a stake in health to express their opinions about the recommendations provided at the hearings and to give additional suggestions or data for the FDA to consider.

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We probably won't see guidelines for about a year. We also hope to see the formation of an FDA social media “task force,” a solution suggested by several speakers to help the agency stay current on new media. In the interim, we must continue to rely on past experience, existing [DDMAC guidance](#), and what we heard from those who testified.

Challenges and solutions to effective, responsible engagement

Edelman has long counseled companies that health is a business imperative and that they must engage proactively, transparently, and in real time with all stakeholders about health and wellness. We recognize the challenges manufacturers have faced in the past decade in engaging online because of the lack of regulatory guidance. And we believe this hearing will ultimately—though perhaps not immediately—make

* For purposes of this report, “manufacturer” refers to manufacturers, packers, and distributors of prescription drugs and biologics

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a significant difference in the way manufacturers communicate online.

Following is our perspective on the specific topics discussed and recommendations put forth.

1. For what online communications are manufacturers accountable?

The general consensus was that manufacturers can be responsible only for content (static and user-generated) on sites they own, sponsor, or influence. Most agreed that manufacturers should be able to engage with users on these sites to address comments or questions about their products. On the flip side, most said that manufacturers should not be held responsible for content and comments on unaffiliated third-party sites or sites on which they advertise but do not have editorial influence. Most everyone agreed that manufacturers must disclose their involvement in a site if they created the content, collaborated on the content, or paid for someone else to create the content. (See Question 3 for related discussion on manufacturer responsibility for correcting misinformation.)

Edelman POV: We agree that manufacturers cannot be held responsible for third-party content, but the manufacturer's voice *must* be heard in forums that it owns or influences. This benefits not only the company but also the consumers who are looking for an authoritative voice. We recommend that the FDA allow manufacturers to enable user comments on sites and blogs. Bridge Worldwide provided sound guidance for responding to comments: 1) engage only if your product is specifically mentioned, 2) use short, consistent safety disclaimers, 3) use prescribing information as the script, 4) communicate that the answers provided are legitimate, and 5) catalog and periodically share this engagement with the FDA. Manufacturers should train communications and marketing staff to respond to user-generated content in

much the same way call center operators are trained to answer patient questions and sales reps are trained to talk to physicians. When it's not possible to give a simple answer, these responders should encourage patients to speak to their doctor.

Until we receive FDA guidance, we urge manufacturers to create their own social media policies for internal and external communications by their employees. We recommend engaging with consumers through moderated means; that is, screening comments before posting them. Moderated boards or comments should have a clear disclaimer about the nature of comments that will be posted and an estimated time in which they will be posted. Responses to individual consumers should follow the existing guidelines and be within the approved indication, be fair and balanced, and not interfere with the patient-physician relationship.

Transparency is essential. We always recommend including a clear disclosure statement if site content is authored, paid for, or otherwise influenced by the manufacturer.

TRADITIONAL MEDIA COVERAGE ADDRESSES MAJOR ISSUES, THEN DROPS OFF SHARPLY

Traditional media coverage of the hearing began several days in advance, with a focus on PhRMA's proposed "universal safety symbol." Coverage peaked on Day 1, with a pre-hearing AP article on the PhRMA proposal receiving extensive pick-up by local news outlets. A second AP article, specifically concerning Yahoo! and Google's contributions to the hearing, was posted later in the day and ran in local and national news outlets, including *Forbes*, NPR.org, CBS News, ABC News, and *USA Today*.

In addition, a Reuters article appeared on ABCNews.go.com, MSNBC, *The New York Times*, *Forbes*, and local outlets. Overall, most coverage addressed the problem of limited space, and noted a "lack of clarity" and "need for guidance" on how to display risk information.

Coverage dropped off significantly on the second day of the hearings. Although Day 2 presentations focused heavily on AE reporting, media coverage continued to focus on limited-space issues. Most articles this day were from smaller online outlets, although a short HealthDay article was picked up online and in local news outlets. Coverage has petered out since the hearings ended.

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2. How can manufacturers fulfill regulatory requirements when using Internet tools that are associated with space limitations or allow for real-time communications?

Most speakers agreed that space limitations and real-time format shouldn't keep manufacturers from engaging, and that there needs to be a short and unmistakable way of communicating important information in these formats. Google recommended that in the paid search space, branded ads have two links—one to promotional information and one directly to risk information. PhRMA recommended a universal icon that would let users know they are viewing information from a manufacturer about an FDA-approved product and would link to risk information. Similarly, Intouch Solutions recommended an "RxRisk" icon that would link to safety information and would work in limited-space mediums.

There needs to be a short and unmistakable way of communicating important information to consumers in space-limited formats.

A major topic of discussion here was the "one-click rule"—a loose guidance most manufacturers adopted (in the absence of formal guidance) to run online ads in small spaces with a medication's full safety information one click away. This "rule" was deemed unacceptable in April when the FDA sent violation letters to manufacturers for using it. Most presenters argued that the one-click rule is necessary to address space limitations, and that it should be reinstated with new FDA guidance. This discussion also raised questions of health literacy, as several speakers argued that no matter where risk information is found, it must be made easier for consumers to understand.

Edelman POV: We support a brief risk statement or visual icon that indicates risk, as long as consumers are educated about what this icon means. We also support an FDA "seal of approval," though the agency will need to create a safeguard to protect the icon from being replicated. We expect that the forthcoming FDA guidance will allow the one-click rule, but until then, because of the recent violation letters, we do not recommend posting branded search ads. At this time, the best paid search solution is to use unbranded URLs to drive to branded sites. While this is not optimal for several reasons, including consumer confusion, it is the only solution right now that lets manufacturers give consumers the information they are seeking without incurring a violation.

We support the simplification of risk information so consumers can understand the potential risks of medicines. However, few recommendations were put forth as to how this can be done and would be welcome by the FDA.

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

Most speakers agreed that manufacturers should be responsible for correcting inaccurate information on sites they own or sponsor, but not on third-party, unaffiliated sites. (See Question 1.) Several added that companies should attempt to correct third-party misinformation even if they are not obligated to. One presenter recommended responding to inaccuracies with this simple statement: "This information about brand X is inaccurate. Accurate info can be found on brandX.com." Others questioned whether manufacturers should have to correct information on third-party sites that are "highly trafficked"—but did not recommend how this category would be defined.

Edelman POV: Companies should be able, but not required, to correct inaccuracies on third-party,

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unaffiliated sites. We recommend that companies monitor the Web extensively to see what consumers are saying about their products and, when appropriate, correct misinformation with a simple statement directing users to the related brand Web site. On their own Web sites, manufacturers should take full responsibility for all content and correct misinformation as soon as possible.

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4. When is the use of links appropriate?

As noted by several presenters and addressed in Question 2, links can be a useful way to direct consumers to information that isn't available in limited space. By using links, we can provide consumers with an accurate aggregate impression of a product's risks and benefits, rather than trying fruitlessly to present all information in one place. Once again, this raises the question of ownership and responsibility, as a branded product site might provide a link to an unaffiliated patient resource site that falls outside the manufacturer's control.

Edelman POV: When linking from a manufacturer-owned site to a third-party site, include a clear disclaimer that the user is leaving the site and the company is not responsible for the content on the third-party site. As noted in Question 2, while we generally would not recommend linking from an unbranded search ad to a branded site, this is currently the best paid search solution given the recent warning letters related to the one-click rule. We hope this problem will be addressed when the FDA issues its guidance and we encourage all stakeholders to ask the FDA for clarification on this issue in their written testimonies.

5. Questions specific to Internet adverse event (AE) reporting.

A full quarter of the hearing was devoted to AE reporting in the online space. While most speakers said it is impossible for manufacturers to police the entire Internet for potential AE reports, others argued that sufficient monitoring tools do exist.

Nearly everyone agreed that a major challenge in online AE reporting is that only a fraction of events discussed online qualify as reportable. (A reportable AE must have an identifiable patient, reporter, event, and drug. [Learn more from our blog.](#)) This raises questions about how far companies should go to obtain the information that would make the event reportable.

Several speakers recommended adding an icon to brand-owned and -sponsored pages that would drive people to [MedWatch](#), the FDA's Web site for collecting AE information. Others recommended a widget that could collect AE information directly. Most argued that the current MedWatch system is difficult for consumers

SOCIAL MEDIA CHATTER DOMINATES COVERAGE AND GIVES AN "INSIDE TRACK"

Considering the nature of the hearings, extensive social media coverage was a given. While the hearing was only two days long, nearly 8,000 tweets on the matter were shared between November 1 and 17. About 70 percent were tweeted during the two days of hearings—the rest were before or after.

These conversations told a different story than traditional media coverage. For example, while testimony from Diana Zuckerman (National Research Center for Women & Families) received little mainstream coverage, the online community reacted vocally to her presentations. As one Twitter user [said](#), "This scares me. Just hoping FDA has a better sense of what's REALLY going on with the web tha[n] Zuckerman."

In addition, communities seem to agree that the patient perspective went unheard. As one patient blogger [commented after the hearing](#), "FDA needs [to] do a better job of explaining its relevancy [to] patient's lives. It has such an important role, but most [parts don't] connect."

Social media discussion has continued since the hearings ended and is bound to shape the ongoing debate. In the coming months, there will be no more relevant place to tap into opinions on the FDA's guidance than the very platforms in question.

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to understand and navigate, and that it needs to be simplified.

Edelman POV: Manufacturers should voluntarily monitor third-party sites for AEs but should not be mandated to do so. Broad monitoring of the Web has benefits not only for collecting AEs but also for knowing what consumers are saying about specific products and diseases. Of course, if a company becomes aware of an AE on any site, it must be addressed.

When a company comes across a potential AE that is not reportable because of missing criteria, the company should attempt to make it reportable by publicly announcing in the forum how and where AEs can be reported. We do not recommend contacting the person privately or trying to gather information by any means that might violate patient privacy.

We do not recommend contacting consumers privately in an attempt to make an AE reportable.

We support the addition of a clear, simple link to MedWatch on company-owned and -sponsored pages. We also agree that MedWatch should be simplified from its current format. We expect the FDA will welcome specific recommendations on how to do so.

As we await guidelines, companies must continue to engage

A major theme we heard was the need to *simplify*. Consumers must have clear, unmistakable ways of identifying sources of content, reporting adverse events, and linking to critical information. And the information they read, especially about medication risks, must be on a level they can understand and digest. This theme will be a key part of the eventual guidelines.

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In the meantime, consumers are going to continue to talk about health—both online and off—and manufacturers need to be there as a credible resource and an active part of the dialogue. If you'd like to learn more about Edelman's recommendations and better understand how they relate to your company and brand, contact Emily Downward (emily.downward@edelman.com) or Kevin King (kevin.king@edelman.com).