

An Edelman Report:

# Day One of the FDA Social Media Hearing

In a move many are calling long-overdue, the [FDA's social media hearing](#) (formally: *Public Hearing on Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools*) commenced today. The purpose of this two-day session is for interested parties to comment on Internet and social media promotion of prescription drugs and vaccines. Currently, there is little industry guidance around this topic.

As the FDA's Tom Abrams noted in his opening remarks, "it would be an understatement to say there is much interest in this area." More than 800 people tried to register for the hearing, with only about 300 granted seats on a first-come, first-serve basis. In all, the hearing will accommodate about [80 testimonies](#), primarily from marketing and communications agencies, research companies, health and medical Web sites, major search players, pharmaceutical companies, and consumer groups. Prior to the meetings, the FDA [posed five areas of discussion](#) that represent existing challenges—manufacturer accountability, real-time information, corrective information, use of links, and adverse event reporting. Today's testimonies were devoted to the first four topics.

As expected, nearly every presenter noted that the general public indisputably turns to the Internet for health information, and that the Web is a very different landscape than other media. Many quoted recent Pew research stating that 61% of Americans and 83% of Internet users search online for health information. While the significant need for FDA guidance was made clear, fewer speakers offered tangible solutions. In addition, FDA panel members had the opportunity to ask questions, though participation was relatively limited. Following is a top-line overview of common themes from today's testimony and some of the recommendations put forth.

## General Themes and Consensus

### *Need for Industry Voice*

Most presenters argued that drug manufacturers, as the only regulated players in this space, need to have an online voice. They also argued that a lack of regulations thus far has kept manufacturers largely out of the conversation to the detriment of patients, who could benefit from accurate, regulated, manufacturer-generated information. Many speakers agreed that establishing Internet guidelines is feasible. As food and drug lawyer Arnold Friede noted, the issue we face today is analogous to an issue the FDA faced—and addressed—in 1997, when it created a unique set of guidelines for broadcast advertising.

### *Support for One-Click Rule*

In terms of specific topics, the majority of presenters showed support for the "one-click rule"—a loose guidance most pharmaceutical companies adopted to run online ads with a medication's full indication and safety information one click away. (This "rule" was deemed unacceptable in April when the FDA sent 14 violation letters to pharmaceutical companies related to the method. As Google noted in its testimony, because of the subsequent changes in pharmaceutical search ads, dramatically fewer people are now clicking through to FDA-approved product risk information.) Several presenters pointed out that while we

often think of the Internet as “space-limited” because of applications like Twitter, it’s actually the opposite, providing unlimited access to information through links.

James Sandino, of Integrated Media Solutions, referred to the one-click rule as the “digital law of adjacency,” implying that it is no different than safety information found on the back of a print ad. Only Diana Zuckerman, of the National Research Center for Women & Families, disagreed, stating that “one click away is one click away too many.” And John Mack, of Pharma Marketing News, noted that the problem isn’t the number of clicks but rather the way risk information is presented once users land there, making a plug for clearer, more easily digestible risk information. This sentiment was echoed by Zuckerman and Fard Johnmar of Envision Solutions.

### *Importance of Links*

Speakers including Philomena McArthur of Johnson & Johnson also noted that today’s Internet users understand that relevant information isn’t always right in front of them, but rather available by links, rollovers, or pop-ups. For this reason, as Friede noted, we need to look not only at the information on a single page, but also at the total impression consumers will get by viewing all product-related pages. David Zinman of Yahoo! bolstered this point by noting that people are using search mechanisms especially to find additional information via links.

### *Content Responsibility Debate*

Another notion that was generally supported is that manufacturers can only be responsible for maintaining and correcting content within their control. Several speakers said that this should include content created or sponsored by the company, but not content over which they have no influence, such as consumer-generated conversations on third-party sites. As Elizabeth Forminard from Johnson & Johnson pointed out, there is no regulatory basis for holding a company responsible for user-generated content.

Most other speakers agreed, with several noting that the Internet is simply too big and too fast-moving for manufacturers to police, and that only content “owned” by a company can realistically be controlled. Peter Pitts, of the Center for Medicine in the Public Interest, drew an analogy to traditional PR, noting that when companies disseminate information to the media, they can’t exercise editorial control over what reporters ultimately write. On the flip side, other speakers noted that there are tools available that enable monitoring, and companies should monitor for and amend inaccurate information on some sites—particularly those that are highly trafficked.

## **Specific Recommendations to the FDA**

### *Universal Safety Symbol*

Several speakers offered concrete recommendations for the FDA to consider in the development of Internet and social media guidelines. The most prominently discussed recommendation, which garnered significant media coverage in advance of the hearing, was PhRMA’s idea to establish a universal FDA safety symbol that would signal to users that they are reading information from a manufacturer about an FDA-approved product. This icon, along with standard, universal risk information, would link to a product’s FDA-approved Web site including full indication and risk information. Theoretically, this icon would help consumers and HCPs identify credible information more easily. However, the panel questioned whether the FDA could feasibly review all information that would carry the seal.

### *Standardized Formats*

On a similar note, David Abrams of the Interactive Advertising Bureau recommended standardized Web formats that would provide product information in a way that meets FDA requirements. This way, consumers could easily access risk information, while companies could engage online with the comfort that several regulatory issues are addressed by the format alone. Google also provided its recommended approach for branded search ads, which included a standard link to safety information.

### *Key Partnerships*

Some recommendations focused on relationships. John Kamp, for example, proposed that the FDA work more closely with the FTC to regulate the online space, while Friede called for the FDA to work with the Department of Justice and the Office of the Inspector General. Zuckerman said the FDA needs to develop relationships with Web sites that are used heavily for health queries, such as Wikipedia and Drugs.com.

### *Social Media Committees*

Other proposals focused on the creation of a specific social media committee. Eli Lilly's Michele Sharp called for a series of public workshops to collectively generate ideas and work toward viable solutions. Tiffany Mura from Consensus Interactive recommended an advisory committee comprising an interactive strategist, medical director, consumer advocates, and pharma representatives to meet regularly with and advise the FDA.

## **Looking Ahead to Day Two**

Tomorrow's hearing, which will begin at 8 a.m., will focus primarily on the challenges of adverse event reporting online under current regulations, as well as additional testimony on the topics discussed today. Notable speakers include Francer, Mack, Health Central's Christopher Schroeder, Sermo's Daniel Palestrant, John Bell and Melissa Davies of Word of Mouth Marketing Association, and Pfizer's Freda Lewis-Hall and Clifford Thumma. We will provide another summary at the end of tomorrow's hearing, as well as a comprehensive report early next week.

For updates during the second day of the hearing, we encourage you to follow the conversation live on Twitter through Edelman's Digital Health team (@[EmilyDownward](#), @[EngageInHealth](#), and @[RickMurray](#)). You can also visit us online and share your thoughts at [www.engageinhealth.com](http://www.engageinhealth.com).