

An Edelman Report:

# Day Two of the FDA Social Media Hearing

The FDA's [social media hearing](#) concluded today with a second round of testimony on the challenges surrounding online promotion of health information. The morning session focused on adverse event (AE) reporting, while the afternoon session supplemented yesterday's discussion of manufacturer accountability, real-time information, corrective information, and use of links. ([Read our Day 1 summary.](#)) Yesterday's hearing received significant media coverage and we expect the same for today's panels.

Following is a top-line overview of common themes from today's testimony and some of the recommendations put forth.

## Challenges and Solutions in Online Adverse Event Reporting

### *Common Themes and Consensus*

Several presenters noted that because of unclear guidance around AEs, companies are turning their heads and not engaging. David Saggio of LehmanMillet said industry is "paralyzed," while John Mack of *Pharma Marketing News* referred to a "see no evil, hear no evil" approach.

Echoing yesterday's discussion of responsibility, most speakers said it is impossible for the pharmaceutical industry to police the entire Internet for potential AE reports due to the sheer volume of information. PhRMA's Jeffrey Francer reminded us that current industry guidelines say manufacturers should monitor their own Web sites but not external ones, and that if companies become aware of AEs on any site, they must address them.

HealthCentral's Chris Schroeder called for greater clarity around the definitions of ownership and sponsorship and posited that advertising on a site does not make a company responsible for reviewing it for AEs. Steven Findlay of Consumers Union held that while companies can't be accountable for the entire Web, they should take on some degree of voluntary monitoring. And Heartbeat Digital's Bill Drummy said once companies begin monitoring, they have a responsibility to correct misinformation and report AEs.

Nearly everyone agreed that a major challenge in online AE reporting is that only a small 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.](#)) Several speakers quoted Nielsen Online's figure that only 1 in 500 online AEs is reportable. So the question is: How far are companies expected to go to obtain the information that would make AEs reportable? And would this search violate patient privacy—the very thing that attracts so many people to the Internet? According to WEGO Health's testimony, about half of health activists say companies should respect people's privacy and not probe for AE information, but about half also say that every effort should be made to track down this information.

### *AE Reporting Recommendations*

To make AE reporting more feasible, several presenters 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.

Findlay added that such an icon should appear on all Web sites and forums that discuss health information, not just those supported by manufacturers. A number of speakers, including consumer Kim Witczak (one of several people today to use a personal story as a backdrop to her testimony) recommended that MedWatch be overhauled to make it easier to understand and use.

On a similar note, Wion, Mack, and others recommended an AE widget that could educate consumers about AE reporting and allow for reporting directly on the widget. This widget would act as a “safe harbor” to allow companies to engage with patients without worrying about how to collect and report AEs.

In terms of mining AE information, Francer recommended that in forums where AEs are being discussed, companies publicly announce where and how patients can direct their AEs and encourage them to do so privately. James Heywood of PatientsLikeMe described a system his site has developed to track people’s experiences with medicines, including AEs, and said that if this system could be overlaid with company AE data, it would be more robust. And Tara Churik of WCI Consulting called for a public-private sector collaboration to create an international standard for mining data.

Food and drug lawyer Arnold Friede was the only presenter to directly call into question the usefulness of the current AE collection system. At best, he said, it captures only 10% of AEs and that the FDA has made an enormous financial investment to analyze the system’s usefulness and determine how it can be modified.

Finally, Zen Chu of Accelerated Medical Ventures (citing the FDA’s “anachronistic methods”) recommended that the agency assemble a new media and technology advisory board and hire more people well-versed in interactive media. Chu suggested pharmaceutical companies could help pay for these additional staff.

### **Additional Testimony on First Four Topics**

This afternoon’s testimony largely mirrored yesterday’s themes. Speakers continued to note that the pharmaceutical industry needs adaptable Internet-specific guidelines as soon as possible. Schroeder said that the magnitude and permanence of the shift to online health information cannot be overstated. He cited 100,000 Facebook members in diabetes groups and 200 Twitter posts on Ambien in just 24 hours.

Many presenters (including Drummy, W2 Group’s Larry Webber, and Jonathan Richman of Bridge Worldwide) discussed the importance of transparency and agreed that companies should plainly disclose their involvement in a Web site or forum. Several speakers, such as Cadiant Group’s Jim Walker, addressed the problem of low health literacy and the Internet’s potential to improve it.

Additional highlights from the afternoon session include:

- James Heywood was one of few speakers to address the downside of manufacturers correcting inaccurate information online; he said this would put industry in the role of health care professional and could actually interfere with the patient-doctor relationship.
- Hensley Evans of imc2 reiterated that companies should be able—but not required—to correct inaccuracies on third-party, unaffiliated sites. She recommended responding to inaccuracies with a simple statement such as “This information about brand X is inaccurate. Accurate info can be found on [www.brandX.com](http://www.brandX.com).”
- Donna Wray from TGaS Advisors noted that most user-generated content has no mechanism for correction and spoke about the challenges of Wikipedia. She suggested (as echoed by other presenters) that manufacturers should not be responsible for activities on Wikipedia.

- Richman provided five recommendations for how manufacturers could engage in social media: 1) engage only if your product is specifically mentioned, 2) use short, consistent safety disclaimers, 3) use prescribing information as the script, 4) validate that the answers provided are legitimate, and 5) catalog and periodically share this engagement with the FDA.
- Fabio Gratton from Ignite Health shared retrospective data from 10 brand Web sites that looked at how people came to the sites (mostly through search, especially paid search advertising). Gratton's data proved that product claim ads resulted in more people going to the site and viewing the safety information.
- Bruce Grant from Digitas Health shared data from a survey that showed consumers had the most recall of balanced information when there was a clear designation to "click here for risk information." Similarly, Wendy Blackburn from Intouch Solutions recommended the use of an "RxRisk" visual icon that would link to safety information. This standard icon would work in limited-space mediums. Blackburn also recommended an educational campaign so consumers would understand the icon.
- Clifford Thumma from Pfizer presented data from a study Pfizer conducted to determine how best to present safety information for consumers' understanding. While the study showed that people learn and navigate the Internet in different ways, the safety information was best understood and received by consumers when it followed the traditional customs of Internet use.
- Dr. Freda Lewis-Hall said Pfizer learned to engage with physicians in a way that is personal, relevant, and controlled through Sermo's AskRx application, which allows physicians to ask questions of Pfizer experts and receive – within 24 hours – a concise and scientific answer that can be shared with the community at large. Daniel Palestrant, founder of Sermo, echoed this point from a physician perspective, noting that information that is passive and unidirectional is largely ignored, but engagement-driven messages are highly valued.

## What Happens Now?

Unlike other FDA hearings, this one was not meant to end with an immediate vote or decision. In his closing statement, the FDA's Thomas Abrams admitted that the agency has "much work to do" to understand the interactive medium. He also noted that the FDA will accept written testimony on these topics through February 2010. The agency will then reflect on the considerations and recommendations it received and begin to develop guidelines based on this testimony. Several sources have predicted that guidance will not be available until at least late next year.

In the next few days, Edelman will assess the extensive testimony we heard this week as well as the social and traditional media coverage surrounding it. We will provide an in-depth report next week that both summarizes and provides perspective on key topics. We hope you will continue to follow our Digital Health team on Twitter ([@EmilyDownward](#), [@EngageInHealth](#), and [@RickMurray](#)) and visit our blog at [www.engageinhealth.com](http://www.engageinhealth.com).