FDA Seeks Ways to Regulate Health Web Content

BY ALICIA AULT

At a meeting convened by the Food and Drug Administration, pharmaceutical and medical device manufacturers, advertisers, medical Web site owners, search engine companies, and consumer advocates all argued for greater regulation of health-specific content on the Internet, including social media sites.

The agency was seeking opinions on how it could guide health-related communications and promotions for YouTube, Twitter, blogging, and social networking sites. Notably, there were no speakers from any medical society or health care provider organization.

The FDA has not said when it might issue guidance, but it will continue to accept comments until Feb. 28, 2010, said Thomas W. Abrams, director of the FDA Center for Drug Evaluation and Research's division of drug marketing, advertising, and communications.

All speakers agreed that consumers and health care providers increasingly rely on the Internet for information about drugs, devices, and specific conditions, and also to forge communities to share everything from caregiving recommendations to tips on how to perform a knee replacement.

All also agreed that there is a huge amount of inaccurate and misleading information and that it has a great potential for harm—to patients and their families, to health care providers, and to industries seeking credibility. Even as they seek to be the go-to place for accurate, scientific information, drug and device makers said they are wary—of social media in particular—because of the lack of FDA guidance.

Consumer groups raised the specter of pharmaceutical or device companies putting out purely promotional information that glosses over FDA rules requiring a fair balance of a product's risks and benefits.

Michele Sharp, senior director of United States Regulatory Affairs at Eli Lilly, said the company "had avoided significant interactions with providers and patients online" because of FDA's lack of clarity.

"We're looking to the FDA to provide leadership," Ms. Sharp said.

Jeffrey K. Francer, assistant general counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), said that "the FDA should facilitate manufacturers' communication of important medical information about their products in a responsible way, taking advantage of the same technologies that the FDA and the White House use, including blogs, video, search, and social networking sites such as Twitter."

PhRMA has proposed that posts on Twitter or blogs or other social media sites be accompanied by an official logo that would signify that the information was officially sanctioned by the FDA. Tweets, which are limited to 140 characters, could provide a hyperlink to the full risk and benefit information, Mr. Francer said.

He and other industry representatives said they wanted FDA to review information and promotional materials before they were posted on the Web. This would be a departure from current policy where only a small fraction of print or broadcast materials are reviewed in advance.

Some groups are trying to establish rules before FDA does. The Interactive Advertising Bureau said it was developing standards to provide "safe harbors" for the drug and device industry. IAB members provide 85% of online ads in the United States, said IAB representative David Wright. The Social Media Working Group has also been discussing what drug companies can do to self-police, said Mark Gaydos, chairman of the group and a regulatory affairs director at sanofi-aventis U.S. The group is made up of representatives from five pharmaceutical manufacturers who meet on a voluntary basis.

Google also proposed its own standards for "sponsored" searches. The search result would include a link to the official drug site and a link at the end, "more info," which would take users directly to the risk information, said Amy Cowan, head of industry for Google's health division. All results would also include a short warning statement. ■