FDA Seeks Ways to Guide Health Info on the Web

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.

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All of the participants 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 the 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 the 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 the 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 working 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, who is head of industry for Google's health division. All results would also include a short warning statement.

Consumer advocate Diana Zuckerman, Ph.D., said she believed that the FDA has historically done a poor job of monitoring direct-to-consumer promotions and going after violators.

The agency will be even more challenged in an environment where information can be changed hourly, said Dr. Zuckerman, president of the Washington-based National Research Center for Women and Families.

But, she said, the FDA must monitor the Internet and social media.

"Realistically the FDA would need a lot more resources to do that," Dr. Zuckerman acknowledged.

The center, along with Consumers Union, will push for higher users fees to fund policing of the Web, Ms. Zuckerman said. ■

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Adverse Event Reports Go Unused

The Food and Drug Administration's Center for Devices and Radiological Health fails to use adverse event reports in a systematic manner to detect and address medical device safety problems, a report from the HHS Office of the Inspector General found. The center has no documentation of following up on deaths, serious injuries, and device malfunctions reported by manufacturers and medical facilities, and most reports are not read in a timely fashion, according to the report. The Inspector General's office found that the FDA center received about 73,000 adverse event reports in 2003, and more than 150,000 in 2007. The Inspector General recommended that the center develop better protocols for reviewing and tracking the reports.

Preventive Services Underused

Only about one in four Americans aged 50-64 years regularly gets recommended preventive services such as screenings and immunizations, according to a report from the Centers for Disease Control and Prevention. The CDC, which compiled the data in collaboration with AARP and the American Medical Association, noted that preventive services often missed by older adults include influenza vaccination, cholesterol screening, breast and cervical cancer screening, and physician screenings for unhealthy behaviors such as binge drinking. The report, which identifies ways to make these services more accessible and convenient, is available at www.cdc.gov/aging.

Electronic Tools Effective: AHRQ

Consumer health informatics—electronic tools designed to provide tailored health advice to patients—could save money by eliminating the need for some health education now provided by clinicians, said a report from the Agency for Healthcare Research and Quality. Health informatics also could improve clinician-patient interactions, the AHRQ said. The agency reviewed more than 100 studies of consumers getting health information via the Web, computer programs, and other electronic avenues such as texting and chat groups. The analysis found that the most effective tools tailor messages using a patients' own health information and provide feedback on progress. Feedback provided by a clinician doesn't seem to be any more effective—the key is timeliness, not the human touch, the study concluded.

AMA Weighs In on Chemicals

The American Medical Association has called for more effective government oversight of endocrine-disrupting chemicals. At its midwinter meeting, the organization adopted a resolution, introduced by the Endocrine Society, calling for most regulations on the chemicals to be handled by a single office. The exception: Endocrine disruptors used as pharmaceuticals would continue to be regulated by the FDA. The resolution also calls for policies on the chemicals to be developed jointly by endocrinologists, toxicologists, occupational- and environmental-medicine specialists, epidemiologists, and policy makers. "This new resolution marks an important step in engaging policy makers to enact policies that decrease public exposure to these potentially harmful chemicals," said Dr. Robert Vigersky, Endocrine Society president.

CDC Eliminates HIV Exclusion

People seeking to immigrate to the United States will no longer be required to undergo HIV testing, under a final rule issued by the CDC. "While HIV infection is a serious health condition, it is not a communicable disease that is a significant public health risk for introduction, transmission, and spread to the U.S. population through casual contact," CDC officials wrote in the Federal Register. The rule goes into effect on Jan. 4. Until now, CDC policy has been that individuals with HIV who are living outside the United States are not eligible to receive a visa for admission to the country. The CDC received more than 20,000 public comments on the proposed change, of which about 19,500 supported removing HIV from the list of communicable diseases of public health significance, agency officials said.

New Surgeon General Confirmed

Dr. Regina Benjamin has been unanimously confirmed by the Senate as the U.S. Surgeon General. Dr. Benjamin, a family physician who is founder and CEO of the Bayou La Batre (Ala.) Rural Health Clinic, will start her work by responding to pandemic influenza A(H1N1), Health and Human Services Secretary Kathleen Sebelius said in a statement. The American Academy of Family Physicians praised the confirmation. "All Americans will benefit from Dr. Benjamin's medical expertise, clinical experience, and advocacy for all patients," the academy's president, Dr. Lori Heim, said in a statement. "She is committed to ensuring that everyone has access to health care, regardless of economic status." Dr. Heim also praised Dr. Benjamin's perseverance in providing care to the underserved. Since the late 1990s, her clinic was destroyed by two hurricanes, Georges and Katrina, as well as a fire.

—Jane Anderson