HEALTH ED™

The FDA Social Media Hearings

Clearer Paths—Stronger Burdens

www.HealthEd.com

p: 908•654•4440

f: 732•587•2600

©2010 HealthEd Group, Inc. All rights reserved.

HealthEd Director of Strategic Services Jeff Greene was on hand in Washington, DC, during November 2009 to observe the FDA social media hearings, which were much anticipated by the pharma industry. This document serves as a summary of his observations and provides our collective outlook for HealthEd clients and partners.

Introduction

On November 12 and 13, 2009, the FDA convened a public hearing in Washington to answer the following questions:

1. For what online communications are manufacturers, packers, or distributors accountable?
2. How can manufacturers, packers, or distributors fulfill regulatory requirements in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications?
3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?
4. When is the use of links appropriate?
5. How is adverse event (AE) information from Internet and social media tools being received, reviewed, and processed? What challenges and uncertainties are presented in handling AE information from these sources?

More than 70 presenters over the 2 days provided myriad analyses, opinions, data, and recommendations. Based on these presentations, on responses by the FDA panel, and on an understanding of the current pharma landscape, HealthEd has identified key takeaways that could *potentially* impact digital communications by the pharma industry in 2010 and beyond.

Understandably, until the FDA provides written guidance, no one can accurately predict how the landscape might change. Instead, our key takeaways aim to capture and extrapolate the themes that emerged from Washington, seen through the lenses of:

- The needs and interests of healthcare consumers and care partners
- Prevailing data and digital best practices
- Feasibility for the industry

Because this paper is written especially for marketers and patient educators in the industry, takeaways are divided into "Clearer Paths," which may support more relaxed regulations, and "Stronger Burdens," which may necessitate greater efforts on the part of the industry.

Background: Our View

In our experience working with, listening to, and learning from healthcare consumers across nearly every disease category, it's become clear that consumers have needs that are not being addressed by the current healthcare system. And that is a key reason so many are turning to the Web and social technologies.

For many healthcare consumers, the unmet need is physician access—the chance to ask 1 or 2 more questions and receive a clear answer. Yet in today's landscape, physicians have no incentive to spend the time that would require. For other healthcare consumers, the unmet need is a trusted source of information. Our research continues to show that consumers don't trust the healthcare industry (in light of rising costs, drug safety concerns, confusing medical jargon, and many other factors). They often struggle to trust their family and friends, who may not fully understand their disease or who may have their own biases and fears.

Many healthcare consumers therefore meet their needs online by searching for what the Pew Internet & American Life Project calls a "just-in-time someone-like-me." In "The Social Life of Health Information," Pew, a nonpartisan research center, reported that more than 40 percent of consumers who looked online for health information did so by reading someone else's commentary. We expect this trend to continue, with or without the participation of the pharma industry—making these hearings critical to industry stakeholders and healthcare consumers alike.

First Steps: The Healthcare Consumer View

An underlying theme of many presentations during the hearings was that the historical focal point of healthcare in America—the healthcare provider—appears to be shifting. In contrast, the empowered healthcare consumer is taking form, energized by the free flow of online information and perhaps a sense of frustration with the medical establishment.

Understandably, the establishment is uneasy. When Bill Drummy of Heartbeat Digital finished a thoughtful proposal for an AE reporting system for consumers, panelist Gerald Dal Pan, MD, asked: "What's the role of the physician in all of this?" His question remains to be answered.

Despite the FDA's and the industry's stated goal of improving the healthcare consumer's online experience, patient advocates were few in number at the hearings. Those who did present voiced sobering opinions. Kim Witczak, an advertising executive from outside the healthcare industry, said her husband committed suicide 6 years ago after he was prescribed Zoloft off-label. Having worked as a patient advocate ever since, she implored the FDA to use the Internet as a venue for educating patients and collecting reports about AEs. Steven Findlay of Consumers Union (which publishes *Consumer Reports*) asked the FDA to more closely monitor unbranded pharma Web sites—and, in fact, any Web site receiving funding from pharma.

Healthcare consumer opinions about regulation are hardly unified, though. In a survey conducted by the patient social network WEGO Health, one member recalled the time an Allergan employee posted a response to her message: "It made it seem like we aren't just yelling into the air." A consumer who added a comment to the FDA docket after the hearings wrote: "The FDA should encourage communication between patients and drug makers. Not only will this help the drug companies to assess needs and fill gaps but consumers are more likely to make their voices heard and feel empowered."

Takeaways—"Clearer Paths"

1. Pharma will not be responsible for sites it doesn't influence or support. This was one of the clearest takeaways from Washington. Speakers both supportive and critical of the pharma industry said basically the same thing: The Web is too large and too diffuse for the FDA to require manufacturers to police the whole of it.

An example that speakers cited again and again is Sidewiki, a new Google tool that lets users who install it attach comments to any Web page as if the comments were part of the page's content. When other Sidewiki users visit the page, *all* the comments appear … even those that are patently false.

To balance negative comments, webmasters are allowed to post a comment in the "first position" on Sidewiki for their pages—say, a Brand.com. However, Lilly's Michele Sharp stated that if a pharma company were to do this, it would imply an endorsement of the Sidewiki content that followed. If a future user came along and posted off-label information, the pharma company would be liable.

It's a good point. We believe it's highly unlikely a manufacturer would be held accountable for content posted by somebody else on a site (or an application) not influenced by the pharma company, such as Sidewiki or Wikipedia. The question that

remains: Where will the FDA draw the line between "influenced" and "noninfluenced" Web sites?

If a pharma company in any way pays for or contributes funding to a Web site, the FDA is going to consider that "influence." However, it's not clear where pharma's compliance liability might begin or end if the FDA allows manufacturers to post on social media Web sites they are neither paying for nor advertising on.

2. Paid search will live. Google's Mary Ann Belliveau and Amy Cowan, who gave the final presentation on the first day of the hearings, unveiled proposed search ads with a new "risk line" they said would address concerns about fair balance. Belliveau and Cowan shared 2 proposed formats: one for black-box drugs and one for other medications. In addition to featuring a link to an advertiser's Web site, both proposed formats included a link to safety information.

While the proposal was well received by the audience—mostly industry members and vendors—the FDA panelists had no questions for Google. It wasn't until the second day of the hearings that the FDA panelists saw a persuasive argument for paid pharma search. Fabio Gratton of Ignite Health shared traffic data from 10 Brand.com sites his company hosts. The data showed a direct correlation between branded product search ads and consumer exposure to safety-related information.

Specifically, Gratton said that over a 5-year period, 32 percent of consumers who clicked on a paid product-claim ad proceeded to view safety information on the studied sites. In contrast, 19 percent who directly typed in a Web address viewed safety information, and only 10 percent who clicked on a link in organic search results viewed safety information.

The data clearly caught the attention of the FDA. Two panelists asked questions about the study methodology, and during the break immediately following Gratton's testimony, several panelists were overheard in conversations about the findings. Combine Gratton's data with the constant stream of testimony about medical inaccuracies and bogus cures commonly found on the Web, and a compelling picture is formed. The FDA knows that Brand.coms are one of the few sources of regulated drug information on the Web. Because these sites typically don't appear high in organic searches for common health terms, paid search is an effective option to promote them.

We believe the FDA will look closely at the Ignite Health data and any similar data provided to the docket and will ultimately conclude that the public would benefit if pharma had some leeway to continue promoting its Web sites through paid search—provided those promotions included statements about risk. Google presented one tactical solution for achieving this end within the spirit of existing guidelines. Ultimately, whatever

specific search guidance the FDA provides to manufacturers, the search engines—hungry for advertiser dollars—will adapt accordingly.

3. MedWatch will evolve. This takeaway could add some burden to the industry if it came to pass, but we believe it would be a welcome burden. Numerous presenters panned the current version of the FDA's MedWatch, which lets healthcare consumers visit a Web site to report AEs. A more effective MedWatch—one that makes use of modern Web technology—would ensure standardization in AE collection. It would help alleviate patient advocacy concerns about the lack of reporting, as well as industry concerns about the perils of reporting.

What's wrong with the current MedWatch? For one thing, the site requires consumers to download a long PDF document and fax it to the FDA rather than submit a report online through a simple Web form. And according to PatientsLikeMe CEO James Allen Heywood, MedWatch collects only a small percentage of total AEs. He had a few more things to say: "MedWatch is hostile … and written in a language that patients don't understand."

Perhaps the greatest weakness of a fax-based MedWatch is its lack of portability—it can't live as an interactive widget accepting submissions directly on a Brand.com, as proposed by John Mack of *Pharma Marketing News*. Clearly the FDA realizes MedWatch must change with technology. Consumers and healthcare providers can now subscribe to alerts via RSS feed or text message. And consumers can download a simple widget that displays links to the MedWatch Web site.

We believe the FDA will add forms technology to a new version of MedWatch, possibly by late summer 2011, enabling healthcare consumers to type AEs directly into the system. If the agency goes that far, it would be only a short additional jump to build syndication into MedWatch, enabling manufacturers to place a standard AE reporting widget on sites they own or next to sponsored content on sites such as WebMD and YouTube. To be sure, such a reporting system would add certain requirements to pharma's Web launches and online sponsorship initiatives. But we believe that inserting a few simple lines of code would be a fair price for the increased certainty pharma companies would enjoy in knowing they were operating within guidelines.

Takeaways—"Stronger Burdens"

1. The FDA may allow—and encourage—pharma companies to correct misinformation they find on the Web. Many in the industry testified for increased pharma presence in the online landscape because of the preponderance of drug misinformation. Peter Pitts of

Porter Novelli stated that without the participation of regulated pharma, "the social media field is left to snake oil salesmen, Internet drug dealers, unscrupulous trial lawyers … Nature abhors a vacuum."

Pitts and others were really arguing for more freedom to promote regulated pharma information—via search, Twitter, and other platforms. But if this "vacuum" is as potentially damaging as some suggested, the FDA might reason that to truly protect healthcare consumers and serve the public interest, it should empower pharma to correct any misinformation it finds. Several speakers provided support for this line of reasoning.

Maureen Miller of Compass Healthcare said, "It is in the best interest of patients and caregivers that we correct inaccurate information in pharma," and recommended that manufacturers be given the option to address false statements through a corrective post by a self-identified company representative. Such a post might contain a link to a Brand.com with accurate information.

RAPP's Robert Gramattica said almost 60 percent of patients in a 300-patient survey conducted by RAPP believed that pharma companies are responsible for reviewing and correcting inaccurate information on non–company-owned Web forums. Perhaps more surprising, 88 percent of patients surveyed said it would be helpful for a manufacturer representative to comment, after an erroneous post, with factual information. Gramattica's testimony was well received, and panel chair Thomas Abrams, director of DDMAC, specifically thanked him for offering to submit full survey data to the docket.

After reviewing the RAPP data—and reading similar data and consumer research verbatims submitted by PatientsLikeMe, WEGO Health, and other healthcare social networks—we believe the FDA will recognize a unique opportunity to enlist industry resources and ingenuity to carry out a core piece of the agency's mission: protecting healthcare consumers from drug misinformation.

2. The FDA may clarify criteria required for reporting a consumer AE, and the new criteria could be stronger. On the Monday after the hearings, the FDA sent 22 warning letters to various online pharmacies, citing them for selling unapproved drugs to American consumers. In looking at these warning letters, the reader will immediately notice that for 2 of the intended recipients, the FDA was able to find only a handle or a generic e-mail address:

- onlinepharmacyy.com@proxy.dreamhost.com
- D Hunter

Now, consider the AE presentations at the hearings. Many speakers noted that the anonymity of the Web would make it hard to report an AE post by "diabetesgirl84," for example. But if the FDA can send a warning letter to "onlinepharmacyy.com," why shouldn't pharma report an AE by "diabetesgirl84"? We believe the FDA could determine that in fact pharma companies should—provided "diabetesgirl84" has a forum profile that lists a means of contact or that links to a blog or other site where private contact can easily be made.

The requirement for AE reporting is stated clearly in the Code of Federal Regulations, 21 CFR 314.80 (b). Manufacturers must report postmarketing AEs that are "obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience." If the pharma industry wants to benefit from commercial marketing opportunities on the social Web—and 2 days of testimony made that abundantly clear to the FDA—it makes strong policy sense for pharma to cover its tracks there as well.

Should the FDA move in this direction, it would be hard for the industry to cry foul. A 2008 study on social media AEs, presented by Nielsen's Melissa Davies, found that only 1 of 500 online healthcare messages (.002%) met the FDA's 4 criteria for reporting: an identifiable patient, an identifiable reporter, a specific drug, and an adverse event. To be fair, this percentage might increase if the FDA expanded its definition of "identifiable reporter" to include screen names with associated contact information. Davies also noted that the percentage would increase if she had searched for a specific brand name rather than reviewed a random sample of health postings.

Still, the number of AEs appeared manageable for manufacturers to track, and this may have been on the mind of the FDA's Dal Pan when he asked Davies how long it had taken to review the 500 messages. She answered that Nielsen's human analyzers can typically review 100 messages in a day. We believe the FDA will spend time doing the math using different scenarios and will ultimately recommend some base level of social media reporting for companies that choose to participate in the medium.

As with paid search, we believe vendors of social media "listening" tools—as well as drug-safety-reporting software—would quickly adapt their offerings to meet FDA guidance. Pharma would need to weigh the costs and benefits of adding social media staff and vendors in return for the opportunity to become active players in the social media. We believe if social media reporting did become reality, most manufacturers would make the leap. In light of questionable marketing returns from TV advertising and the rise of niche medications catering to small but active audiences, social media in pharma would become a new educational and marketing frontier.

What's Next?

The FDA did not provide a time frame when it expects to deliver guidance to the industry and did not even indicate whether it would deliver guidance at all. In a note sent to *Pharma Marketing News* and Ignite Health, the FDA's Abrams and several of his copanelists reiterated that the docket closes on February 28, 2010. "We are committed to getting the best information as possible in helping inform our policy," the note stated. "Once the docket closes and we review all the comments, we will be able to determine next steps."

Among those attending the hearings, the consensus was the FDA would definitely respond to the industry and may do so by the end of 2010. Until we hear from the agency itself, pharma marketers will continue exploring opportunities by using digital and social media—some more cautiously than others—aware that clearer paths and stronger burdens likely await them in the coming year.

HEALTHED™

About HealthEd

HealthEd is an agency that uses deep knowledge about patients to unlock the fullest potential of treatments people count on, the fullest potential of relationships between patients and healthcare providers, and the fullest potential of brands committed to improving human health.

Our services are designed to help clients achieve higher returns on marketing resources and become better equipped to realize the fullest potential of educational efforts. We offer a full suite of research, advisory, and program development services to help clients plan, develop, implement, and measure multichannel programs:

• **Audience research** • **Multichannel planning** • **Program analytics** • **Client workshops and training**	• **Instructional design** • **Content development** • **Creative concept development** • **Usability testing** • **Program, vendor, and portfolio management and implementation**	• **Graphic design** • **Video production** • **Web site development** • **Interactive application development**

About The Author

Jeff Greene is director of strategic services, social media, at HealthEd, where his role is to research, create, and collaborate on strategies that educate and empower patients, using social media and digital channels. Previously Greene was executive director of client services at Gold Mobile, a social media consultancy that guided major brands through the emerging digital landscape. He is a dot-com-era veteran with more than 12 years in the marketing field and hands-on experience planning emerging media programs. A sought-after speaker, Greene has trained thousands of marketers in the Unites States and Canada on social media, digital marketing, and integrated communications.

Phone: 908.379.2037 | E-mail: j.greene@TheHealthEdGroup.com | Twitter: @Jeff_Greene