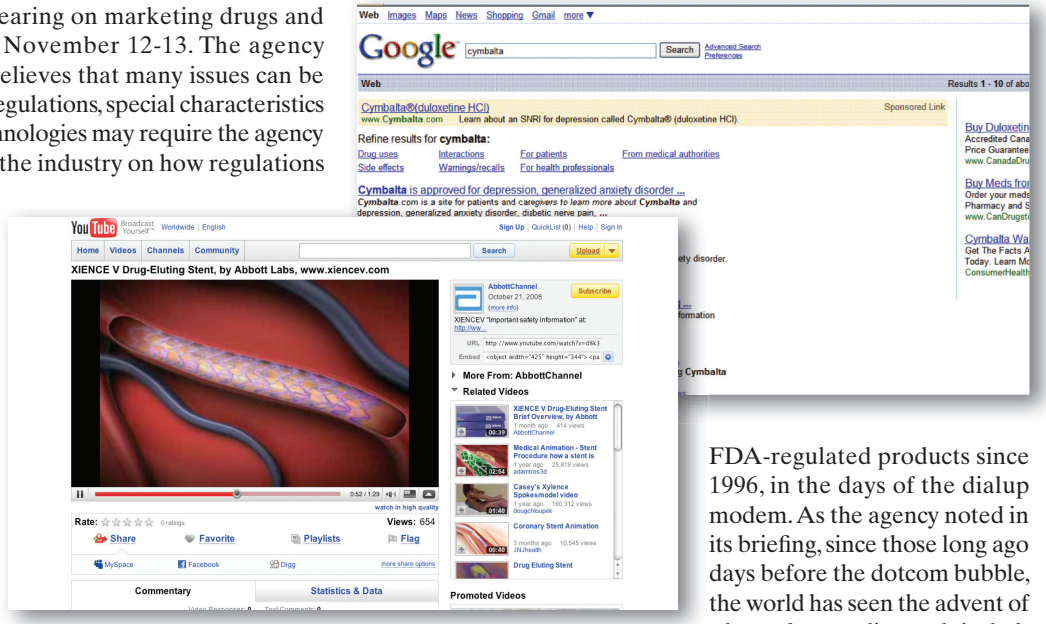
SOCIAL STANDARDS

With FDA set to hold its first public hearings on Internet promotion in 13 years, **Matthew Arnold** looks at the key questions and what might come out of it

The FDA will hold a public hearing on marketing drugs and devices using social media November 12-13. The agency conceded that although it "believes that many issues can be addressed through existing FDA regulations, special characteristics of Web 2.0 and other emerging technologies may require the agency to provide additional guidance to the industry on how regulations should be applied."

In a notice printed in the September 21 Federal Register, FDA said: "There are no regulations that specifically address Internet promotion separately from the other types of promotion discussed above, nor are there any regulations that prohibit the use of certain types of media to promote drugs and medical devices. Although no rule has specifically addressed Internet promotion, it is fairly clear that some promotional efforts are substantially similar in presentation and content to promotional materials in other media or publications. At the same time, FDA recognizes that the Internet possesses certain unique technological features and that some online tools that may be used for promotion offer novel presentation and content features."



Sponsored links for Lilly's Cymbalta (top right) and VNRs for Abbott's Xience V (above) fell afoul of hazy fair balance rules for online ads

It's a remarkable gesture for an agency often criticized as hidebound and unwilling to adapt to its rules to suit new technologies—in fact, it's the first public hearing on Internet promotion of FDA-regulated products since 1996, in the days of the dialup modem. As the agency noted in its briefing, since those long ago days before the dotcom bubble, the world has seen the advent of a host of new online tools including blogs, microblogs like Twitter, podcasts, social networks and online communities, video sharing sites, widgets, Wikis and more.

Whether it will fill in any of the vast gray areas around new media remains to be seen. The FDA cautioned "that although a question may raise a particular issue, that does not necessarily mean that the agency will issue guidance or regulation on that issue." Nonetheless, it opens a window of promise—and some peril—for drug and device marketers desperate for clarity. "It's a

long overdue and tremendous opportunity to get some guidance on how to act in this arena, lessening fear of unpredictable enforcement," says Jack Barrette, chairman of WEGO Health. "We would prefer restrictive guidelines over our own best guesses, which leads to hyper-conservative over-caution."

The status quo, says FDA law expert Arnold Friede, isn't doing anyone any good. "Whatever the paradigm is commercially, it doesn't do anyone any good for FDA to adopt an approach that makes new media unavailable," says Friede, who has been sharply critical of the agency's March fusillade of untitled letters directed at brands using sponsored links on search engines to promote their products. Friede has characterized the letters as an example of "FDA's approach to regulation of the Internet as simply a different form of print communication."

"These opportunities don't come along very often," he adds, noting, "It took them 10 years or more to adopt a distinct policy that would accommodate TV advertising. Better to do it before another ten years passes." The resulting policy, he says, must be "commercially reasonable, technically feasible, legally supportable and in the public interest."

Searching for trouble?

WEGO's Barrette says the agency's notice of the hearing posed several key questions, the first being that of "how much responsibility do companies have for everything anyone will ever say anywhere?" Is a company responsible for everything published on sites it sponsors that are run by third parties, from content to comments?

"That's been a major roadblock for companies to start even monitoring for adverse events," says Barrette, because their reporting responsibilities under the FDA's new Adverse Events Reporting System remain foggy. Are they required to report every fuzzy comment they find while trawling the web? Would pharmas be better off just blocking search engines on all their office computers?

OK, that's probably an extreme scenario, but don't doubt that drug company legal departments have entertained it.

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—Arnold Friede, Arnold Friede & Associates

"This is FDA's chance to say, 'This is our definition of an adverse event, this is how it's applied online and if there's no identifiable reporter, you are not responsible," says Barrette. "Again, it comes back to the question of what is the limit of a company's responsibility. If users intended anonymity through usernames or avatars, is that company required to dig deeper?"

The present situation, in which companies are afraid to look for fear of what they'll find and uncertainty over what to do with it, does nobody any good, says Barrette. "Would you really want the general public to feel that you felt it was too dangerous or scary to search for adverse events, or would you want to be known as a company that goes to the ends of the earth to find them? Every company wants to do the second but they're all afraid of the limitless nature of the web."

The agency poses several specific scenarios for evaluating when third-party content is effectively company content—when companies encourage users to post their own videos to a company site, when manufacturers send out packets of information to prominent bloggers, or when companies create online communities for patients or healthcare professionals to discuss disease states and the conversation turns to their products. Companies, they noted, have a variety of ways of controlling third-party content on their sites—by disallowing comments or requiring approval before posting, or by setting time limits on when comments are visible.

The agency said it wants to hear views on when third-party communications should be treated as those of the companies themselves, and—intriguingly—whether there are platform-specific considerations that should be factored in when considering communications through a particular social media channel. Also of interest to agency policymakers is the question of unauthorized dissemination of modified product information by non-company users.

Fabio Gratton, chief innovation officer at Ignite Health, says firms looking to impress FDA should bring plenty of data. "They're looking for empirical evidence," says Gratton. "They're looking for people to bring to the table something more substantive than a philosophical or legalistic argument."

Gratton has proposed the development of a simple universal widget for adverse events reporting, incorporating "click to call or click to chat" connecting reporters to doctors or nurses, perhaps funded by FDA user fees.

"Nobody's going to do it until there's guidelines," adds Gratton, who also feels FDA should avail itself of some social media technologies in its dialogue on these topics. "Public hearings are very 1800s," he quips. "Let's be social about social." ■

FDA letters sank sponsored links, spurred rethink

DDMAC's assault last spring on sponsored links upended the "one click rule" that had become accepted best practice in the industry—and pretty much demolished the use of the medium by pharma companies.

ComScore data shows that sponsored link exposures to US internet users fell by 59% within a week of March 26, when the infamous 14 untitled letters on allegedly violative links were issued, and were down 84% by the end of June.

The letters said, in essence, that the sponsored links had failed to communicate appropriate risk information. Where industry marketers had assumed they were safe if they linked to a page containing the full fair balance (hence the "one click"), DDMAC said "this is insufficient to mitigate the misleading omission of risk information from these promotional materials," never mind that Google's sponsored links limit advertisers to 95 characters.

The question of whether "one click" is sufficient to warn viewers of risks was foreshadowed last year, when several firms, including Medtronic, Stryker and Abbott, came under pressure from watchdog Community Catalyst's Prescription Project over online VNRs that the group said constituted ads. Abbott Labs responded by embedding fair balance information directly into its Xience V VNR.

The 14 letters had the effect of rallying industry marketers and leading them to press FDA for a more specific and appropriate set of standards, and led to the formation of an informal industry group aimed at developing, in the words of Arnie Friede, "an alternative paradigm" for the regulation of industry communication through social media.