Presentation Notes

Social Media Regulation Fear & Loathing in Washington, DC
What's Next is What Counts

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Healthcare Social Communications Leadership Forum Breakfast
Business Development Institute

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In my presentation before the FDA at last week's public hearing, I made some specific suggestions based on a survey of my readers. After my presentation, Thomas Abrams, director of FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC), thanked me for presenting specific solutions that the FDA could consider when it creates new guidelines for the promotion of FDA-regulated products on the Internet and social media sites.

In his closing remarks, Abrams said "what we have heard is [the Internet is] a different medium." As far as I know, this is the first time that anyone at the FDA has said that. Usually, the FDA says it is "media-agnostic." In other words, its regulations apply to all media and do not have to be modified for any particular medium.

Abrams went on to say "FDA wants to give this much thought as we determine the best approach to the Internet and social media tools. FDA has much work to do in this area..." Sounds like Abrams is setting us up for a long wait before FDA issues any social media guidelines. But, he also said the FDA is "determined to do this work. It's important and we will do it."

TAKEAWAY #1: THIS IS NOT YOUR FATHER’S FDA

In contrast to the first Internet FDA public hearing in 1996, this one hammered into the FDA's head how important the Internet is for health information seekers. Speaker after speaker made the point: the Internet can no longer be ignored if you are serious about protecting the public health. This time, pharmaceutical companies also made the same point.

In 1996 only visionaries could imagine how important the Internet would be in the health arena. FDA’s job is not to be a visionary, so the agency can be excused for not acting in 1996. This time, they have seen the light and have even used the Internet themselves to help improve public health.

TAKEAWAY #2: YOU DON’T HAVE TO BE A VISIONARY TO SEE THE POSITIVE AND/OR NEGATIVE IMPACT THE INTERNET, ESPECIALLY THE SOCIAL MEDIA PART OF THE INTERNET, CAN HAVE ON PUBLIC HEALTH, WHICH IS THE MAJOR CONCERN OF THE FDA.

I got a sense of urgency from the pharmaceutical company presenters. The industry is worried about the vast amount of user-generated health information and resources on the Internet. The industry's share of voice on the Internet—especially the social media part of the Internet—is rapidly being dwarfed. Drug companies worry about that and they see a need to get into the conversation. Guidelines will help them do that.

TAKEAWAY #3: THE DRUG INDUSTRY IS MORE AFRAID OF BEING LEFT OUT OF THE CONVERSATION THAN HAVING NEW FDA GUIDELINES ON HOW IT CAN ENGAGE IN THE CONVERSATION
WHAT’S NEXT?
As Bob Dylan said “You don’t need a weatherman to know which way the wind blows.” This line is said to have inspired the name the American radical left group the Weathermen, which blew up Department of Defense weapons labs and brownstone bomb factories in the West Village of NYC. Weathermen radicals were “visionaries” whose solutions were worse than the problems they were protesting. Still, everyone felt a need for a change.

What shouldn’t be next are FDA “Weatherman” style guidelines that are too restrictive and worse than the problems they are designed to solve. In my humble opinion, FDA Internet/social media guidelines should establish the FLOOR upon which more consumer-friendly social media policies are built.

WHAT’S NEXT #1: DON’T WAIT FOR FDA GUIDELINES TO START BUILDING YOUR OWN PUBLIC POLICIES GOVERNING YOUR USE OF SOCIAL MEDIA

A majority of respondents to my survey agreed that each pharma/medical device company should have a public social media policy. Whereas FDA regulates labeling and promotion, FTC regulates unfair and deceptive trade practices. FTC, for example, can go after companies that violate public policies, FDA can’t. PhRMA suggested that FDA and FTC "redouble their enforcement efforts against fraudulent activities on the Internet.” A public social media policy is a good example of how FTC can get involved.

WHAT’S NEXT #2: URGE THE FDA TO WORK ON ONE PIECE OF THE PUZZLE AT A TIME AND NOT ISSUE ONE GUIDANCE COVERING ALL THE ISSUES RAISED

One Small Step for FDA, One Giant Leap for Pharma!
If FDA decides to bite off more than it can chew, it will take a long time to issue any guidance and whatever it comes up with will be out of date as soon as it is published.

A much better approach would be to tackle a few issues at a time. FDA could, for example, issue guidance regarding space limitations imposed by certain tools such as Twitter (and other SMS, text-based apps) and services such as search engine ads. FDA could officially sanction the "one-click rule" in these cases as long as certain criteria were met, such as proposed by Google and PhRMA.

Just as the industry has been advised to take "baby steps" when getting involved in new media, the FDA should also take baby steps when regulating the Internet. It should—as many suggested—set up a task force composed of different stakeholders to advise them on which issues to tackle at any given time.

If the FDA adopts the "baby step approach" to regulating the Internet, I am hopeful that the first "step" will occur before the end of 2010.
WHAT’S NEXT #3: CONTRIBUTE TO THE DEBATE

The comment docket will be open until the end of February, 2010. All stakeholders should submit comments.

My survey, which now has close to 400 responses, can be found online at http://bit.ly/zPR1f. It will continue to accept responses through January, 2010. I plan to submit the complete results of that survey—not including any identification of respondents—to the FDA docket. This survey includes some specific solutions that you can comment on. Those comments will be the basis of further dialogue I will carry on in *Pharma Marketing News*, Pharma Marketing Blog, and via Twitter!

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**WANTED: Answers to FDA’s Q’s Regarding Pharma’s Use of Social Media**

*Pharma Marketing News Questionnaire & Survey*

*Say what’s on your mind!* Anonymous comments welcome! Results will be submitted to the FDA.

http://bit.ly/zPR1f