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Transcript

Presentation #1 Made at 2009 FDA Hearing on Use of Social Media for Rx Drug Promotion

Accountability, Fulfilling Regulatory Requirements, and Posting Corrective Information

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SLIDE 1:
Good morning. I am John Mack, Publisher of Pharma Marketing News and Pharma Marketing Blog. Today I will present what I learned from a survey of my readers regarding the questions FDA posed in its September 21, 2009, public notice.

SLIDE 2:
I was a panel member at the 1996 public hearing. That meeting inspired me to co-found the Internet Healthcare Coalition, a non-profit group that developed the eHealth Code of Ethics, which addresses the problem of misleading health information on the Internet. In other words, I am more than just another blogger with an axe to grind.

But I DO have an axe to grind! On my blog I often criticize the FDA and PhRMA for not aggressively correcting violations of regulations and voluntary guidelines regarding direct-to-consumer communications via the Internet. I was the first and only person, for example, to suggest in late 2006 that the so-called "one-click rule" violated FDA regulations.

SLIDE 3:
Via the Internet, I reach a large audience of professionals, the majority of whom are pharmaceutical marketing and sales professionals who are employed at drug companies or at agencies and outside vendors working for the drug industry. This is also a community that I often engage in conversation. Sometimes, the best conversation occurs when I ask opinions in surveys, such as the one I will talk about today.

SLIDE 4:
The survey I present today asked my readers to respond to FDA's 19 questions. As of November 1, 2009, 354 responses have been collected. The vast majority – 80% – of respondents support the pharmaceutical industry. Twenty-three percent work for pharmaceutical companies and 47% for service providers, agencies, consultancies, etc.

Although FDA asked open-ended questions, my survey included possible answers to the questions. I developed these choices based on my experience with the issues and from comments submitted as the survey progressed. The results are by no means scientific, but interesting nevertheless.

The hundreds of comments received are even more valuable than the votes for specific solutions. While not many pharma company representatives are speaking here today, their employees have spoken through my survey and you should hear what the "rank-and-file" have to say.

SLIDE 5:
Today, I cover Accountability, Fulfilling Regulatory Requirements, and Posting Corrective Information. Because of time limitations, I will present only a few main takeaways and support them with data from the survey. The complete results of the survey, which will continue to be hosted online through January, 2010, will be submitted to the public docket.

SLIDE 6:
With regard to accountability, results from the survey suggested several best practices, namely:

- DISCLOSURE of involvement with or influence over 3rd-party social media content should be prominently displayed **alongside** relevant content when possible.
    - Half of survey respondents agree [DATA IN NEXT SLIDE]

- Each company should have a **Public Social Media Policy** that includes a notice of its disclosure and other policies relating to social media.
    - About two-thirds of survey respondents agree [DATA IN NEXT SLIDE]

- Companies should monitor social media sites for unauthorized use or modification of its approved content and make a best effort to remove or correct the content. But they should **only** be REQUIRED to do so **for sites owned or directly sponsored by them**.

SLIDE 7:
FDA asked: "How should companies disclose their involvement or influence over discussions or material, particularly discussions or material on third-party sites?" Respondents to the survey could choose one or more of the answers shown in this slide and/or submit additional comments:

[REFER TO SLIDE]

- Disclosure is necessary only when content is paid for
- Disclosure should be prominently displayed alongside relevant content when possible
- Disclosure and disclaimers should be included prominently on the corporate website near any links to social media outlets
- Each company should have a public SM policy that includes a notice of its transparency policies

I've divided the answers into three categories: (1) all respondents, (2) respondents who say they work within pharma companies, and (3) respondents who say they work for companies that supply services to pharma companies. The numbers in parantheses indicate the number of responses for each group.

Public Social Media Policy
I was surprised that a majority of respondents agreed that each 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. Just a thought.

SLIDE 8:
It's a no-brainer that paying directly for content is a good parameter for determining influence over 3rd-party content. Even ads placed alongside content can be seen to influence that content.

I also believe that **non-monetary gifts** such as "wining and dining" or inviting bloggers to events or hiring bloggers as "consultants" can influence content. Again, that may be of more interest to the FTC than the FDA.

SLIDE 9:
Independence and influence are on opposite sides of the same coin. The vast majority of survey respondents believe that directly paying someone to post discussions on social media sites such as Twitter means that the content is not independent.

Grants vs Ads
Respondents did not feel that there was much difference between sponsoring discussions by paid ads or through independent grants. Patient communities and the public health, however, can benefit from sponsorship. For that, independent grants are preferable to paid ads. As pointed out in the 1996 hearing, however, "independent grants" may be an oxymoron – grants may not be renewed if the grantee does not live up to expectations, even if those expectations are not voiced by the grantor.

SLIDE 10:
Are there different considerations that should be weighed depending on the specific social media platform that is used or based on the intended audience? Respondents frequently mentioned **space limitations**. I think PhRMA and other presenters have solutions that address this issue and I will have more to say on that shortly.

Other special considerations from respondents frequently mentioned in comments:

- Patients vs Healthcare Providers
- Marketing vs Disease awareness
- User-generated-content vs Pharma-generated content
- Children vs Adults

SLIDE 11:
Respondents most often have seen unauthorized content on sites such as the following:

- YouTube
- Wikipedia
- Twitter accounts
- Blogs
- discussion boards
- Google Sidewiki comments on drug.com sites

Sidewiki
Sidewiki is a good example of how quickly technology can change and how difficult it is for regulatory authorities to adapt to that change.

Sidewiki allows anyone to attach comments to any Web page. Recently, I posted a sidewiki comment about a possible adverse event on Viagra.com. I haven't yet heard from Pfizer and do not know if it was reported to the FDA. By the way, I shared my sidewiki comments with my Twitter and Facebook friends and it quickly spread throughout the Internet. Search Google for "sidewiki Viagra" and you'll find it at the top of the page, just under a paid ad for Viagra.com

Some people think sidewiki is a "game changer"; I think it is a public health nuisance if not worse. Pharma companies should demand that Google provide them and other healthcare companies with an option to **block sidewiki on an entire site with one simple registration of a URL**.

Let's move on to fulfilling regulatory requirements

SLIDE 12:
Key learnings from my survey regarding fair balance include:

- Media agnostic regulations are not popular among industry experts, as I will show in the next slide.
- **The "One-Click Rule" is desired by the industry.** However, most often it takes two clicks to reach the approved labeling (PI).
- There are some **ideas for dealing with space limitations** imposed by certain social media apps. The second slide after this gets into specifics, such as:
    - Use of hash tags in Tweets

SLIDE 13:
As I mentioned, pharma people want the one-click rule. If not that, they would prefer two clicks.

Problem with PI
The problem is not the number of clicks, but what the click leads to.
FDA may say it's OK to link to the approved labeling, ie, the package insert. But almost everyone agrees that most PIs are not readable by the average consumer. It seems to me that the Internet allows for a much more user-friendly presentation of fair balance.

SLIDE 14:
Several ideas were offered about how to present fair balance information when space is limited. Some people believe that linking to the package insert is sufficient.

Hash Tags and Other Symbols
Survey respondent offered a few creative ways to get around the space limitation problem, such as a special hash tag to be used in all branded tweets. If each product was assigned a unique hash tag by the FDA and all product tweets were required to include that hash tag, then the FDA, consumers, and healthcare professionals could easily review all the product tweets and ensure they obey regulations regarding fair balance presentation.

PhRMA has suggested a universal, graphical FDA-authorized safety symbol. A good idea, but it does not allow easy monitoring, in my opinion.

SLIDE 15:
It doesn't seem that there is much data to support conclusions about whether different types or formats of presentations have a positive or negative impact on the public health. Some survey respondents, however, cited a few cases that support a **positive impact** such smoking cessation social media programs.

SLIDE 16:
Some innovative ideas for submission of social media promotional materials to FDA were suggested, including:

- **Registering sites with FDA** for the agency to monitor
- Submitting a **"template";** that is, a design and sample content from the social media site

But there was no consensus opinion. Regulations that are too stringent will prevent companies from carrying on two-way conversations with consumers and healthcare providers. Such conversations can have a beneficial impact on public health, **especially when clarifying or correcting misinformation**.

SLIDE 17:
Survey respondents suggested several specific ideas for submitting social media content for FDA approval, which I already mentioned. The details are in the comments, which I won't get into here.

The main takeaway is that **only a small minority believe it cannot be done**.

SLIDE 18:
Correcting misinformation about regulated products on the Internet is a major issue. The consensus among survey respondents is that correcting misinformation on social media sites not controlled by the company **should not be mandated**.

Correcting Misinformation Should Be Handled Like AE Reporting
Survey respondents offered some support for requiring pharma companies to make an effort to **correct misinformation that is a real danger to public health**. This kind of misinformation should be treated **exactly like adverse event information**. That is

- Sponsors should not be expected to screen for misinformation on third-party Websites not under their control.
- However, if a Sponsor becomes aware of misinformation on such sites that is a threat to public health, the Sponsor should review the information and determine whether it should be corrected.

The only option for correcting misinformation on third-party sites may be to post correct, FDA-approved information as long as the source is also disclosed.

SLIDE 19:
In conclusion, I appreciate the opportunity to present my thoughts in this public hearing. I look forward to collecting even more responses to my survey and plan to submit a full set of results as part of the public comments. Thank you.

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