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Transcript

Presentation #2 Made at 2009 FDA Hearing on Use of Social Media for Rx Drug Promotion

Social Media and Adverse Event Reporting

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Find the accompanying PowerPoint presentation here:
http://www.virsci.com/JMack-FDASM-Slides_Part2.pdf

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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 more of what I learned from a survey of my readers regarding the questions FDA posed in its September 21, 2009, public notice.

SLIDE 2:
I presented information about the survey yesterday, so I won't go over that again today.

SLIDE 3:
Today I will cover adverse event reporting and social media.

SLIDE 4:
What I learned from my survey was this:

- The vast majority of "Adverse Experiences" reported on social media sites **do NOT meet the requirements for AE reporting**
- Although there are monitoring tools available, the **resources required** to monitor all social media sites for adverse events are not justifiable
- Consequently, **few companies have standard operating procedures** for processing adverse event information from social media sites
- However, **pharma companies can help consumers report adverse events directly to the FDA using social media tools** such as widgets placed on drug.com Web sites.

The following slides present some details.

Continues on next page…

SLIDE 5:
FDA and my survey asked "What challenges are presented in handling adverse event information from these sources?" Respondents to my survey could choose one or more of the answers shown in this slide and/or submit additional comments:

[REFER TO SLIDE]

- The amount of information from these sources is potentially too vast to be processed economically (ie, **lack of resources**)
- Finding adverse event information from these sources is like finding a needle in a haystack (ie, **too daunting**)
- The information is usually incomplete and does not meet the requirements for submitting a meaningful AER (ie, **not actionable**)
- There are many potential issues that won't fully be known until the practice of monitoring social media for AEs is more prevalent (ie, **unknown issues**)

As usual, 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. Again, these are not scientifically significant results, but interesting nevertheless.

As you can see, practically ALL pharma respondents believe that the information is **not actionable**; that is, does not meet the requirements for submission of adverse event reports to the FDA. Details are shown in the next slide.

SLIDE 6:
What can I say? Practically the only certainty about adverse experiences posted on social media sites is that the drug is identifiable. Most people use some kind of alias to mask their identities on social media sites. Therefore, **neither the reporter nor the patient** (often one and the same) is identifiable, according to my survey respondents.

SLIDE 7:
FDA wants to know if there are any tools that drug companies can use to help them monitor social media sites for adverse information about their products. Survey respondents were offered several choices, which you can see here:

[REFER TO SLIDE]

- Use of automated keyword searches of selected social media sites by specialized agencies and/or professionals
- Intermittent searches of selected social media sites performed by company personnel or agents
- Intermittent searches of SEARCH ENGINES performed by company personnel or agents
- Routine and automated keyword searches of TWITTER (eg, performed by SocialOomph or other services)
- Use of social media monitoring tools that do not include keywords

While the tools are out there, I get a sense from respondents that pharma is not using them, especially if they believe that only 1 in 500 adverse experiences reported online are actionable. In other words, **active monitoring is just a waste of time and resources**.

SLIDE 8:
Many of respondents believe their companies do not have standard operating procedures for processing adverse event information or they are not aware of such procedures.

If there are procedures, they do not specifically address adverse information found on social media sites.

My survey has revealed many problems the drug industry would face if required to monitor and process all “adverse experiences” it came across on social media sites.

To protect themselves, many pharma companies intentionally block employee access to social media sites. As one respondent said, “I suspect the ostrich approach is dominant.” This “hear no evil, see no evil” approach also prevents pharma marketers from engaging with consumers online to offer them relevant, FDA-approved information.

SLIDE 9:
Many survey respondents thought that consumers should report AEs to their physicians who then should file AE reports. In other words, **pharma companies should be taken out of the AE reporting loop altogether**.

I am not in favor of that either in the online world or in the real world.

Speaking of the online world, however, what if pharmaceutical companies did some kind of extraordinary public service that would qualify them for a safe harbor that relieved from acting as the "middle man" in the AE reporting process?

The drug industry, for example, could collaborate with the FDA to develop an **AE reporting widget** to be prominently displayed on drug.com home pages as shown in this slide. This mockup was created by Fabio Gratton, Co-founder and Chief Innovation Officer at Ignite Health.

Such a widget can perform several functions, including:

1. **Educate consumers** about the known side effects of drugs,
2. **provide guidance to consumers** for discussing their adverse experience with their doctor, and
3. give consumers an **easy, direct method for reporting AEs online**, by phone, or by fax.

Under such an "AE Reporting Widget" safe harbor program, pharmaceutical companies who post approved widgets on their drug.com Web sites will be allowed to monitor and engage in conversations of 3rd-party social media sites without the need to process or report any potential adverse events they may come across in the process. They can merely direct consumers to the widgets on product pages.

It may even be possible to include such widgets on pharma-sponsored Facebook and YouTube pages so that these can be opened up for comments from viewers. If comments are received that contain adverse experiences, the "safe harbor" could allow the company to advise the commentater to use the widget to report the event in a structured manner.

Precedent
The idea of a safe harbor allowing companies to bypass certain government regulations is not new. In 1997, for example, the FDA allowed direct-to-consumer (DTC) Rx ads on TV that did not include the complete approved physician labeling (package insert) as long as "adequate provision" was made to reference a toll-free phone number, a Web site or a current issue of a magazine that contains a print ad where the full safety information could be found.

SLIDE 10:
I would like to end with my presentation with a blatant promotion of a T-shirt to commemorate this hearing. It's the "I WENT TO FDA'S SOCIAL MEDIA HEARING & ALL I GOT WAS THIS LOUSY T-SHIRT"™

Have no fear, I did not actually invest any money to create a stockpile of these shirts. I believe that things will be different this time. The FDA will come out with some kind of guidance before the end of 2010 on the use of social media for drug promotion.

I am hopeful, therefore, that a new grassroots organization will not be necessary to fill the void this time!

SLIDE 11:
Once again, 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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