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A Few Things I Learned at FDA's Social Media Hearing

What's Next is What Counts

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Unless you have been living under a rock—and not reading this newsletter—you probably know that the FDA convened a public hearing on November 12 and 13, 2009, to hear comments from dozens of speakers about FDA regulation of social media and the Internet.

You can access a boatload of presentations, summary articles, podcasts, tweets, and practically everything you will ever want to know relating to this hearing at www.fdasm.com, a Website set up by Ignite Health. Currently, there are more than 160 articles related to the public hearing now available online: http://tr.im/FnQL

This article presents what I consider key takeaways, a synopsis of the presentations I made at the hearing, a review of Ignite Health's study regarding effectiveness of sponsored links, and what I believe should be the next steps.

Some Key Takeaways

In his closing remarks, Tom Abrams, DDMAC Director, said "what we have heard is [the Internet is] a different medium." This is the first time that anyone at the FDA has has acknowledged the Internet as "different." Usually, FDA says it is "media-agnostic"; ie, its regulations apply to all media and do not have to be modified for any particular medium.

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

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..."

Of course, we all hope that the FDA will not repeat its 1996 performance, which was to convene a very informative 2-day public hearing and then not issue any new guidance.

This time, Abrams informed us, the FDA is "determined to do this work. It's important and we will do it."

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.

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 excus-ed 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 #3: THE DRUG INDUSTRY IS MORE AFRAID OF BEING LEFT OUT OF THE CONVERSATION THAN HAVING NEW FDA GUIDELINES THAT RESTRICTS HOW IT CAN ENGAGE IN THE CONVERSATION

I got a sense of urgency from the pharmaceutical company presenters. The industry is worried about the vast amount of user-generated and other competing 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 diminished. Marketers worry about that and they see a need to get into the conversation. Guidelines, even somewhat restrictive ones, will help them do that.

Google suggested a new way to present Rx branded paid search ads (see "Search Advertising Options for Pharma: What to Do While Waiting for Those Guidelines"; PMN#810-02; http://bit.ly/8leV8s).

Google, however, did not mention sidewiki. Let me repeat/paraphrase what I said in my presentation:

"Mr Googlechev, tear down this sidewiki!"

PMN Survey Results Presented

I made two presentations at the FDA hearing:

1. Part 1, covering FDA issues 1 (Accountability) & 2 (Fulfilling Regulatory Requirements); http://bit.ly/4KXzXl
2. Part 2, covering FDA issues 3 (Posting Corrective Information) & 5 (Adverse Event Reporting); http://bit.ly/5GwcPm

These presentations summarize most of the results to date of the ongoing survey that PMN has been running since 20 September 2009 (find the survey here: http://bit.ly/7MRIG4).The survey includes all 19 questions for which FDA seeks answers. Currently, there are over 400 responses. The complete set of survey data (de-identified)—including comments—will be posted to the public comment docket.

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Some key points I made include:

- Media agnostic regulations are not popular among industry experts.
- The "One-Click Rule" is desired by the industry. However, most often it takes two clicks to reach the approved labeling (package insert; PI). *Since the PI is virtually unreadable, there needs to be a better way to provide the fair balance regardless of the number of clicks!*
- There are some ideas for dealing with space limitations imposed by certain social media apps.
- DISCLOSURE of involvement with or influence over 3rd-party social media content should be *prominently displayed alongside relevant content when possible*.
- Each company should have a *public* Social Media Policy (SMP) that includes a notice of its transparency/disclosure and other policies relating to social media. [Just like every pharma company has a public privacy policy that applies to all its product Web sites, each pharma company should have a public SMP that applies to all its social media activities, whether owned or sponsored by the company.]
- 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 be REQUIRED to do so *only for sites owned or directly sponsored by them*.
- Vast majority of "adverse experiences" reported on social media sites do NOT meet the requirements for Adverse Event (AE) reporting.
- Although there are monitoring tools available, the *resources required to monitor all social media sites for AEs are not justifiable*.
- Consequently, *few companies have standard operating procedures for processing AE 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 (see "Social Media Adverse Event Reporting Safe Harbors"; PMN Reprint #89-01; http://bit.ly/o4gAx).
- Some innovative ideas for fulfilling regulatory requirements to submit social media promotional materials to FDA were suggested, including:
  - Register sites with FDA for agency
  - Submit "templates" (designs and/or sample content) of social media sites to FDA for pre-approval/approval
- But there was *no consensus opinion about satisfying regulations* regarding submission of social media promotional materials.
- Too stringent regulations will prevent companies from carrying on two-way social media conversations with consumers and healthcare providers. *Such conversations can have a beneficial impact on public health*, especially when clarifying or correcting misinformation.

How Consumers Find Brand.com Websites

Fabio Gratton, founder and chief innovation officer at Ignite Health, presented data about how people are exposed to safety-related information within the context visiting branded drug.com Web sites.

More specifically, IgniteHealth provided insights concerning the frequency with which users actually click on different categories of links (e.g., banner ads, links within Web sites, sponsored links, organic search result links, etc.) to get additional information about products, and how in turn those links impact a user's content consumption behavior on a manufacturer's product Web site ("Brand.com").

IgniteHealth's study included ten Brand.com Web sites representing 8 different therapeutic categories and yielded a collective 4.3 million unique visitors worth of data collected over the course of 5 years.

"There is indeed a direct and positive relationship between people clicking on specifically sponsored search listings and even more specifically on product claim ads – the kind of ads we can't currently do any more," said Gratton. "And that relationship is that people coming from those types of ads are three times more likely to look at safety-related information on brand.com Web sites than if they came from organic search links or simply typing in the URL" (see Figure 1, below).

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Product Claim Ads	Reminder Ads	Help-Seeking Ads
13.85% Average CTR	5.45% Average CTR	1.05% Average CTR

Figure 1. Impact of Ad "Type" on Click-Through Rates. An analysis of 50 pay-per-click campaigns was conducted to understand how ad-types affect click-through-rate (CTR). Historic data was pulled from 2005-2009. Source: Ignite Health

Summary of Ignite Health's Findings

- Search engines (organic and sponsored listings) are the most significant traffic driver to Brand.com Web sites, accounting for 58% of all traffic
  - Paid search, when active, drives 38% of all traffic
- 27% of all visitors to Brand.com Web sites will look at safety-related information
- Visitors driven from paid search ads are more likely to look at safety-related information (32%) versus those driven by either direct URL (19%) or organic search listings (10%)
- "Branded" sponsored listings ("Product Claim" ads) garner significantly higher click-through rates (13.85%) when compared to "Helping Seeking" ads (1.05%) and
- "Reminder" ads (5.45%), resulting in a higher volume of users getting to Brand.com Web sites and consuming safety-related information

If being exposed to safety information is a worthwhile goal as far as public health is concerned, then FDA's 14 letters restricting product claim search ads has had a negative impact. However, as many presenters pointed out at the hearing, there is a need to improve the readability of package inserts and drug safety information. Merely being exposed to incomprehensible information may not be enough.

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, public 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.

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. FTC, for example, can go after companies that violate public policies, FDA can't.

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

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.

One Small Step for FDA, One Giant Leap for Pharma!
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 over 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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Other Stakeholders Must be Brought Into the Process

In the UpFront OpEd piece "What's Next from FDA" (http://bit.ly/65IFMs), I listed a dozen or so questions pharmaceutical marketing professionals wanted answered by the FDA regarding what the next steps in the process will be. A short poll revealed the relative importance of the major questions (see Figure 2, below).

At the top of the list was the question: *Does the FDA plan to proactively reach out to more stakeholders—patients, public, and physicians in particular—during the comment period?* If so, how will it do that? What can we do to help?

Pro-Industry Speakers Dominated the Agenda

The list of speakers at the mid-November 2009 FDA public hearing can be divided into the following seven categories (the number in parantheses represents the number of speakers in each category):

1. Search Engine (2)
2. Trade Media (2)
3. Pharma Company (4)
4. Consumer Advocate (5)
5. Industry Advocate (6)
6. Health Website (8)
7. Industry Service Provider (28)

Obviously, there's quite a skew towards industry groups, which can best be seen in the pie chart in Figure 3, next page.

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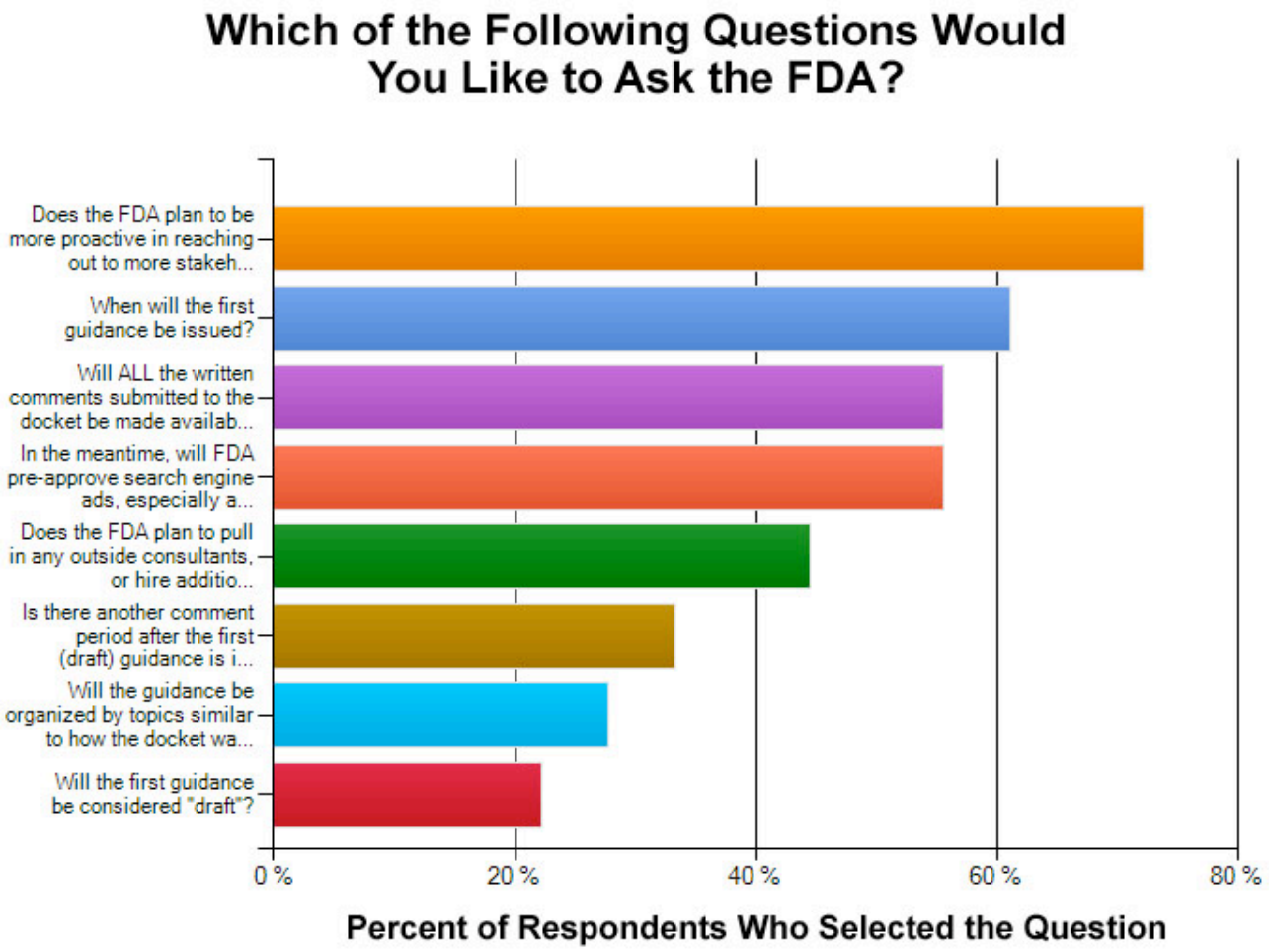

Figure 2. How respondents to a PMN survey voted on questions they would like to ask the FDA. For details on questions, see "What's Next from FDA" (http://bit.ly/65IFMs)

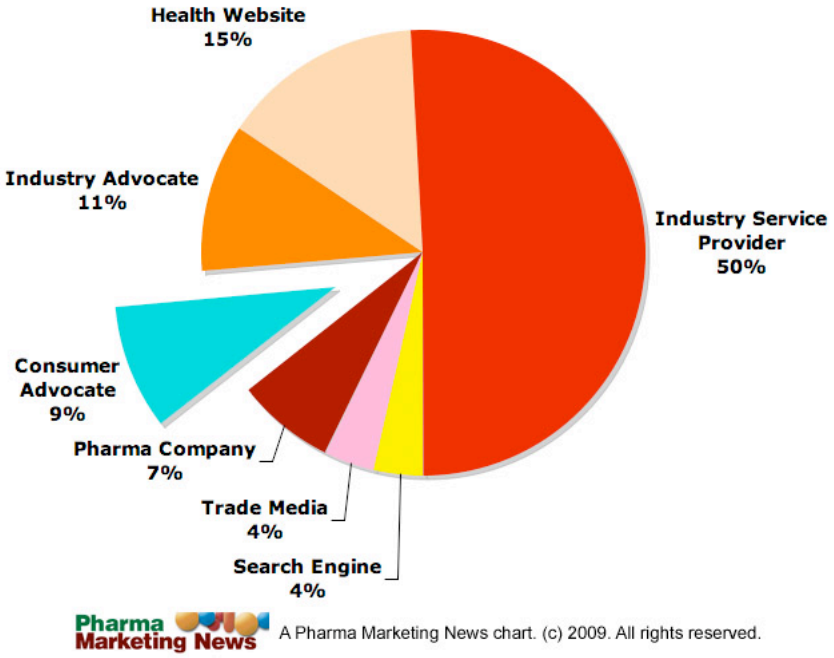

Figure 3: Presenters at the 2009 FDA Public Hearing on the Internet and Social Media by Category. Note: a few presenters in the "Health Websites" category may also represent the consumer and/or patient point of view. These include PatientsLikeMe and WEGO. Putting those two sites into the "Consumer Advocate" category would increase the consumer slice of the pie to 13% vs. 9%.

This distribution of speakers may be typical of FDA public hearings. After all, the FDA did not pay for speakers' expenses. Money talks because nobody walks to these things. Unfortunately, that means that consumers were under-represented.

Consumers, however, can submit written comments to the docket. At first, however, no comments were available to the public. In my Pharma Marketing Blog post on October 30, 2009, I wrote: "I have yet to see ANY submitted comments and I don't know if this is because there are none, or the FDA is keeping comments hidden from public view even though they promised otherwise. It would be a travesty if consumers do not have a voice in this process" (see "Industry Groups will Eat Consumer Advocates' Lunch at FDA Social Media Public Hearing"; http://bit.ly/2y2arq).

Not Everyone Wants FDA Guidelines

After I complained to Jean-Ah Kang, Special Assistant to the Director, DDMAC, comments started to appear on the www.regulations.gov site, which is collecting the comments here: http://bit.ly/17ijQb

Below, I include a selection of the more juicy ones. These comments were submitted by individuals, most of whom are critical of pharmaceutical marketing and advertising. Hopefully, there will be more comments from consumers who were notably ABSENT during the "public" hearing in mid-November.

The manufacturers of medications and their representatives must be held accountable for each claim they put on any online media concerning their products because the public health and safety demands it. There maybe some online media that are not suited for drug advertising because of the space limitations involved. There may not be enough space for the important risk information that needs to come with the claims. It is too risky and dangerous to allow the drug company claims alone without the risk information. It is not enough to put in a link that you can click on to take you to another site to get the risk information because many people won't do that and will only read the claims of the drug company that it puts up on the social media. But they should always provide a link to the FDA website for people who want an unbiassed and fair assessment of the drug, and so people can report bad reactions to the drug. Thank you and best wishes, Michael E. Bailey. **Michael E. Bailey**/individual

I and many, many others are very much against any further promotion or advertising of Food and Drug Administration-Regulated Medical Products, particularly prescription drugs. I am very much in favor of outlawing the existing practice of advertising prescription drugs. Billions of dollars are spent by pharmaceutical companies to advertise drugs, confusing and misleading the public, most of whom do not have the expertise needed to make proper judgments where these drugs are concerned. This massive amount of money should, instead, be used to reduce the cost of these drugs. **Bruce Overman Jr**/Individual

The last thing this country needs is MORE advertising by drug companies. Prescription drugs need to be administered by doctors acting in the best interest of their patients. Patients need to talk to their doctor about a medical "problem", and let the doctor determine the best treatment. Drug ads serve only to feed hypochondria in

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the public. Marketing of drugs and the costs of advertising serve only to drive up prescription drug costs in America. Our capitalist system is out of control, driving Americans to spent money frivolously. Let's not expand advertising opportunities, let rein them in and recind the rules which allow drug companies to advertise anywhere except medical journals intended for doctors. How many more erectile dysfunction ads do we need to be subjected to? **Randall Pecsek**/Individual

I believe transparency is requested for all of the healthcare industry. Prior to twitter, facebook etc. the public was posting comments on drugs (pros and cons). I have googled drugs by their marketed and generic names to read about other peoples' experiences. I had some reactions to a steroid medication I was prescribed and wanted to find others who might have experienced the same. Doing a search and finding the right forum was extremely difficult and time consuming. A drug makers facebook page or a separate page for each drug was available, it would have made life much easier. A Facebook etc with non-censored updates, stories and comments etc. would have helped me and been faster. If the drug companies and insurance companies (although this is not the topic for the FDA)agree not to censor comments and stories, this is e a great avenue for information exchange. The pros and cons of a drug are more easily assessed through other peoples experiences and comments. Regulations and laws have forced the drug industry to use very complex wording in the packaging (in good faith of full disclosure) however this not helpful to the consumer but overwhelming. I would much rather go to a social media site and view what the possible tangible experiences are so that I may weigh my options and assess the risk. If the FDA chooses to regulate social media I do not see how this is a move toward transparency. The more the FDA represses communication avenues the less people feel informed. Regulating the censoring of comments etc. should be enforced but there are too many loopholes in trying to prevent the healthcare industry from engaging in new communication avenues. 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. **Kathryn Rowerdink**/Individual

Medical products must always state side effects. I recommend that the FDA increase regulation to include that Internet users must always be presented with an easily readable screen describing side effects and an acknowledgement button before users can proceed onto any "features" or "benefits" of medical products. **Patrick Rockhill**/Individual

Each week I will take a look at the docket and see what new comments have been made public and post a selection to the Pharma Marketing Regulatory Issues Forum (see http://bit.ly/7CzsY). This should be recommended reading for all pharma marketers interested in getting a point of view they may not often hear from their usual sources of information.

Pharma Marketing News

You may submit comments to FDA directly at www.regulations.gov. Or you can use this online form, which allows you to submit comments about specific issues raised by the FDA AND vote on proposed solutions. You can remain anonymous and be assured that your comments will be submitted to the public docket before the February 28, 2010 deadline. Also, after completing the survey you will be able to see how other respondents voted on solutions.

TAKE THE SURVEY HERE: http://bit.ly/7MRlG4