

Social Media and the Internet: Regulating an Earthquake

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Bill Drummy, one of the multitude of thought leaders to speak at the US Food and Drug Administration hearing on using the internet and social media to promote medical products, gives his take on the proceedings.

On two wet and chilly days in November 2009, several hundred determined souls gathered in the US in a subterranean auditorium near the Washington, DC, mall. The attraction? The opportunity to witness a parade of testimony to the Food and Drug Administration about how the agency should regulate internet and social media promotion of medical products¹⁻³.

The auditorium, on loan from the National Transportation Safety Board – the people who investigate plane crashes and other disasters – reminded attendees of a concrete bunker, complete with what seemed to be a lead-lined ceiling, the better to keep out any unruly wireless telecommunication signal.

The irony of holding hearings about the internet in an internet-proof facility was not lost in the speakers' room tucked wisely behind sound-proof glass in the back of the auditorium. Yet the snickering was not entirely fair, since the FDA very effectively broadcast the event via webcast to many, many hundreds more gathered in conference rooms and desktops across the US and beyond.

In fact, the FDA hearings, long overdue, represented perhaps a watershed event in the rapidly evolving world of healthcare in the digital age. At issue: whether and how pharmaceutical companies should engage in online communications and conversation and what rules should the FDA apply to regulate the burgeoning digital channel.

Given the growth of healthcare content online (now a top three category, according to Google), virtually everyone in the industry agreed that receiving clear guidance from the FDA may well usher in a new era of more effective involvement for pharma, particularly on the remote frontier of social media. While the hearings are only a first step, at least the topic had risen high enough on the agency's radar to warrant serious attention. And the FDA took an admirably broad-minded approach to the subject. Although it asked for responses to a set of specific questions, the topics were so far-reaching that virtually any point of view could be comfortably folded into a response.

The FDA also adopted a generous attitude toward speaker selection; apparently giving a slot to anyone who applied by the deadline. This led to an occasionally amusing rumba-line of presenters, with some visiting the podium for as little as five minutes. Yet the sheer number of voices gave the hearings something of the quality of a chorus. And while there was a numbing amount of repetition – why did so many speakers find it necessary to intone that the internet was really, really important? – one walked away from the hearings sensing that it was, well, a democratic process.

Three broad emerging themes

I did not hear all the presentations – I was occasionally scampering up two flights of stairs to make a phone call or check emails, and I was preoccupied at times with preparing for my own speeches that I was to deliver to the FDA. But I perceived three broad themes emerging from the hearings:

- the need for “radical simplification”;
- the potential of technology to improve the dialogue; and
- the limits of pharma responsibility.

The FDA panel members offered no opinions of their own, so listeners could only infer their opinions from the questions they asked. Yet from reading these faint signals, it did appear these themes struck a chord.

Radical simplification

The argument presented in a number of the more engaging presentations was that when it comes to communicating risk and benefit information about medical products, less is indeed more.

In what was perhaps the most newsworthy presentation of the hearings, Mary Ann Belliveau and Amy Cowan from Google unveiled a new ad format for Google search ads that included a spare few words of safety information included in the ad, with a prominent link to the complete safety information.

In one of the mock-ups that Google presented, an ad for a fictional product included the following text: “Warning: Avoid if you have liver problems. Not indicated for children under 18. [More info.](#)”

In a second example, Google proposed a model for search ads promoting products with boxed warnings (see Figure 1). Below a line including the product’s brand name, the sample copy read: “Click to see full safety and prescribing information, including boxed warning. [More info.](#)”

Google was suggesting that by making the major risks of the product clear, branded drug ads could be used effectively within the strict character limit, while actually increasing the effectiveness of the safety messaging to patients.

Rumour had it that Google has had a series of meetings with the FDA to present its new sponsored ad concepts. While no-one would say whether it had received the FDA’s “blessing”, just one week after the hearings healthcare products manufacturer Bayer began running Google search ads for its black box contraceptive product Yaz that looked remarkably similar to the format proposed by Ms Belliveau and Ms Cowan (see Figure 2).

Figure 1. Model proposed by Google for search ads promoting black box products

The screenshot shows a Google search for 'zinaxa'. The search results include a sponsored link for 'ZINAXA® (azioglitazone)' with a 'More Info' link. Below the sponsored link are several organic search results related to depression. Three red arrows point from text boxes to specific elements in the search results:

- Arrow 1: Points from the text box 'Headline will link to designated landing page, such as the homepage' to the 'ZINAXA® (azioglitazone)' headline.
- Arrow 2: Points from the text box 'The "safety & prescribing" statement is fixed & cannot be modified' to the text 'Click to see full safety and prescribing information, including boxed warning, [More Info](#)'.
- Arrow 3: Points from the text box 'This additional "More Info" link will direct to risk information' to the 'More Info' link.

Google Proprietary

Figure 2. Actual Google search ad promoting Bayer's Yaz contraceptive, appearing one week after hearings

The screenshot shows a sponsored link for 'YAZ® Official Site' with the text: 'www.YAZ-US.com (drospirenone & ethinyl estradiol) Read important product info here. Click to see full safety and prescribing information, including boxed warning. [More info](#)'.

Other presentations – mine especially – further advanced the idea of radical simplification. Although developed independently, my recommendation for display ads was remarkably similar to Google's for search ads: the most common side effects of the product would be displayed prominently within the ad, with a clear link to complete safety information (see Figure 3).

Figure 3. Model proposed by Heartbeat Digital for display ads

The model for a display ad is shown in a rectangular frame. It consists of three sections:

- DRUG X IS FDA APPROVED FOR RHEUMATOID ARTHRITIS** (in a blue header bar)
- COMMON SIDE EFFECTS ARE NAUSEA AND DIZZINESS.**
- GET SAFETY PROFILE HERE.**

Alternative technology

Not to be out-done by Google, Yahoo! presented some innovative ideas for tackling the safety issue. As far as anyone can tell, the current “standard” for presenting important safety information (ISI) in a display ad seems to be the “scrolling ISI” – ie paragraphs of legalese rendered in tiny type. Why is this considered the “standard”? Because in the absence of any clear guidance from the FDA, pharma legal and regulatory personnel have reasonably concluded that the only defensible approach is to include as much information as possible. But of course doing so in a static format makes ads almost completely useless, or certainly less useful than the clever use of internet technology could make them.

Yahoo! approached the problem by urging the FDA to allow pharma ads to use techniques that befit the “unique characteristics” of the internet. These techniques included pop-up windows that include safety information, and even video solutions playable directly from search ads. According to Yahoo! vice president David Zinman, these formats would “give users an unlimited amount of time to see as much safety information as they want”. And that can only help improve consumer comprehension.

Mr. Zinman also urged the FDA to allow more flexibility regarding the use of video in general. In particular, he recommended that pharma companies be allowed to create “shorter duration” videos, with the ISI presented simultaneously in a separate window.

The limits of responsibility?

Perhaps the richest trove of data and thoughtful opinion centered on the freedom and responsibility of the pharmaceutical industry to participate in ongoing social media conversations about its products.

Several presenters attempted to bring the “voice of the patient” into the room with original research prepared for the hearings. Jack Barrette, Bob Brooks and Marie Connelly from WEGO Health, a US company that identifies and assembles consumer health “activists”, conducted a survey of 162 of its members about the appropriate role for pharma in the social media dialogue. Among the findings, 73% of the advocates agreed that “healthcare companies’ use of social media tools brings accurate information into conversations about drugs or devices”. Some 63% agreed that healthcare companies “should get involved in monitoring and correcting misconceptions or misinformation about their products anywhere on the Internet”.

Similarly, according to Mark Bard of pharmaceutical and healthcare market research firm Manhattan Research, among consumers who have an opinion about pharma’s involvement, a strong majority agree that pharma should be involved in social media (38% agreed, while 23% disagreed). And 70% of doctors also want pharma to participate in these discussions.

Opposition & Contradictions

Certainly, not all the opinions about pharma’s involvement in online communications were so sanguine. Diana Zuckerman, head of Washington, DC-based independent, nonprofit think tank National Research Center for Women and Families, took an adversarial view, arguing that the industry’s participation should be viewed with suspicion and must be strictly constrained. Dr Zuckerman even argued that pharma should be held responsible for monitoring Wikipedia, the multi-million-page internet encyclopedia run by volunteers. She complained about misleading entries about drugs – entries that she suspected had been planted by pharma marketers.

Much of the “responsibility” conversation – and indeed a full half-day of the hearings – was devoted to the topic of adverse event reporting. And on this topic the views were inconsistent and even contradictory. The pharma-sympathetic representatives argued either that: 1) adverse

events were not actually that significant in the online conversation and, therefore, could be reasonably handled; or 2) the task of monitoring all mentions of their brands on social media sites was well-nigh impossible so pharma should only be responsible for monitoring sites they directly controlled.

According to Melissa Davies of Nielsen Online (whose business includes monitoring social conversations), only a small percentage of social media comments would actually qualify as adverse events, as determined by the FDA's existing criteria. Nielsen manually reviewed 500 randomly selected product-related messages and found only one that fit the FDA definition of a reportable adverse event.

But according to Chris Schroeder of HealthCentral, an online collection of condition and wellness-specific interactive experiences, expecting pharma companies to be accountable for third-party content is unreasonable. He said: "Americans are increasingly having conversations online that used to take place in person. Trying to make pharmaceutical and medical device companies accountable for those conversations will keep those companies from engaging consumers online."

So we have two incompatible viewpoints: Adverse events in social media conversations are rare and easily managed, and social media conversations are so rampant it is unfair to make pharma accountable for monitoring them.

Yet I thought both of these comments really missed the larger point.

Bigger issues at stake

It may be true that few social media entries meet the FDA's technical definition of a reportable adverse event. But we have been through an earthquake; the ground where we used to stand has shifted. Both because of pharma's currently woeful position in the eyes of the American public (the industry is trusted by just 42% of Americans, according to the 2009 trust survey by PR firm Edelman), and because of what social media portends, the traditional view of pharma's responsibility in the public conversation must be rethought. On a social media site, the person posting may be using an alias, and, therefore, is not an "identifiable reporter" and, therefore, does not meet the FDA's existing definition of an adverse event. Does that mean if a pharma company representative reads a posting about someone feeling suicidal after taking one of the company's products it is OK for the manufacturer to ignore it? I trust we all agree that the answer is no.

So the argument from some – that adverse events are not very frequently found in social media – takes too narrow a view. But the contrasting viewpoint – that mentions of brands may be so rampant that pharma could not possibly keep up – seems equally naïve. What technology has wrought, technology can also resolve: software tools can scan the web and uncover any significant mention of a product, and these comments can be further categorised into relevant buckets that can then be scanned by human reviewers. Yes, it does require some effort and some resourcing. And no, it will not be possible to guarantee that every single comment will be captured. But any comment that crosses a definable threshold of attention should be trackable.

And there is something much bigger at stake than resource efficiency.

From the pharma company's point of view, understanding the online public conversation about their products holds enormous potential value. Monitoring will almost certainly uncover great insights about patients' interests, behaviours and concerns. And it may also reveal some problems that a medical product manufacturer should want to know about. In the event there is a possible adverse event mentioned, the pharma company reviewer would then be able to enter the conversation, express the company's concern and ask for a way to discuss the possible problem privately. Is that not the correct way for a responsible company to behave? And, in the court of public opinion, is that not the best way to demonstrate a true commitment to public safety?

The betting line

The multimillion dollar question at the end of the FDA hearings was this one: when, exactly, might the agency issue some guidance for the industry? The smart money seems to be on “in about a year”, and given that the opportunity for public comment extends until mid-February 2010, that seems like a reasonable bet.

Reasonable, but unfortunate. Because particularly in the area of social media, not much is likely to change without explicit FDA direction. The best hope may be that, as with Bayer’s Yaz search ad, enough putative guidance will be leaked to the industry so that pharma companies will understand at least the broad outlines of the FDA’s position.

An entirely unreasonable, outrageous and yet perfectly fond hope remains that, after two days in the bomb shelter, the FDA committee will have emerged with a new appreciation for the transformative power of the internet and social media, and an equally profound understanding of the need to transform their traditional approach to decision-making as well.

Reference

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