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Pharma's Social Media Working Group

Who It Consists of, How It Formed, and Its Role in Driving FDA Guidance

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On November 12-13, 2009, the FDA hosted a public hearing on the "Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools." Over 60 speakers, mostly representing the interests of agencies and service providers, made presentations. FDA will continue to receive written comments from the public on the issues it raised through February 28, 2010, after which it is expected to issue draft guidance.

While a few individuals and agencies have submitted comments, to date only one adhoc group of pharmaceutical industry representatives have done so. That group is the Social Media Working Group (SMWG), which has come together to "facilitate discussions with the Division of Drug Marketing, Advertising and Communications (DDMAC), industry associations, and other pharmaceutical manufactur-ers on social media issues."

The SMWG includes representatives from the following companies: Amgen, Inc.; AstraZeneca LP; Bristol-Myers Squibb; Millennium Pharmaceuticals, Inc.; and sanofi-aventis U.S.

Cynthia Phillips

Each of the participating companies, notes the SMWG, is free to have independent opinions on the issues discussed in SMWG's comments to the FDA. Although the recommendations put forth by the SMWG were "run by" the powers that be at each company, the recommendations do not "come from" these companies. At least that's how Cynthia Phillips, who is currently Senior Director of Regulatory Labeling and Promotional Compliance at Millennium Pharmaceuticals, Inc., a member of the SMWG, put it during a Pharma Marketing Talk interview on 23 February 2010 (listen to the podcast here: http://bit.ly/9fTPCq).

Appropriate for Pharma to Participate in SM

"Healthcare professionals, patients, caregivers and other consumers are increasingly interacting within online communities in which health-related topics are discussed," said the SMWG in its comments to the FDA. "However, this on-line health information is accompanied by serious concerns regarding source, quality, and credibility (Kunst, H., Groot, D., Latthe, P.M., Latthe, M., & Khan, K.S. (2002). Accuracy of information on apparently credible websites: Survey of five common health topics. 8MJ, 324, 581-582). Engaging in these online communities allows pharmaceutical manufacturers to interact with those healthcare professionals, caregivers, and consumers seeking health and product information when and where they are looking for it," said the SMWG. "As authoritative sources of medical product information and the conditions and diseases for which the products are used, it is appropriate that pharmaceutical manufacturers contribute to, and participate in, these communities in order to help ensure the accuracy and completeness of the information presented and discussed."

It's Déjà Vu All Over Again

The SMWG may have played a significant role in getting the FDA to call for a public hearing and the comments it submitted to the docket (see http://bit.ly/9R8s6f) may very well form the basis of FDA's social media guidelines.

The group met with the FDA in October, 2009 and presented the agency with draft guidance on regulating social media. This draft guidance may be similar to the comments SMWG submitted subsequently to the public docket.

According to Phillips this series of events was similar to what happened in the late 1990s when an industry group approached the FDA and proposed guidelines for promotion of prescription drugs via broadcast media (ie, TV and radio). Therefore, if history repeats itself, FDA's draft guidance on "Promotion of Prescription Drug Products Using Social Media Tools," which it intends to release before the end of 2010 (see http://bit.ly/agvOoT), may look very much like the guidelines the SMWG presented to the agency in October, 2009, and submitted to the docket in January, 2010.

The SMWG Creation Story

Here's the SMWG creation story as told by Phillips during the February 23, 2010, Pharma Marketing Talk interview:

"A number of us were doing speaking engagements at industry conferences focused on social media around the country," said Phillips. "Social media was a very hot topic. During those meetings we were asked to bring forth recommendations and [describe] the guidelines under which we were working. We were all very constrained to talking about what we could do, which was not different than what we were doing previously.

"We started talking together and reminded ourselves of an instance when direct-to-consumer broadcast advertising issues were first surfacing in the 1990s. At that time, an industry group went to DDMAC at the FDA and proposed a new way of presenting risk information in a very constrained timeframe [of a 60-second TV commercial]. That, of course, is what we

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see right now in broadcast advertising. After talking with [the industry] and listening to the recommendations, DDMAC formed guidelines very similar to what [the industry] had recommended and that's what we are living with today.

"So we asked ourselves if we as a group could agree on some recommendations to try and help the FDA get comfortable with the idea of coming out with [social media] guidance," said Phillips. "We started meeting over a year ago and came up with a draft guidance. We requested a meeting DDMAC and saw them in October [2009]. Shortly thereafter they announced the public meeting at which we participated. We have since submitted our recommendations to the public docket."

FDA Can't Be Media Agnostic When It Comes to Social Media

The SMWG believes that the current guidelines as they exist today are "difficult to interpret [for use] in any type of space-confined media," which is how Phillips described the situation. "Also, with social media, information is changing instantly and it's very difficult to follow the current regulations on getting the information to DDMAC on time as we are required to do [via Form 2253]. There are interpretative issues that affect social media even more than the Internet. FDA has recognized the Internet only as a very similar form of media to both print and broadcast." Hopefully, that attitude will change. However, there is some fear that the guidance will not address search engine ads, general websites, and display/banner ads.

Terms of Use

In its comments to the FDA, the SMWG focused on how to handle off-label comments (ie, comments about product information or use that is not consistent with the FDA approved full prescribing information), how to submit promotional posts to FDA, and how to deal with adverse event reports on social media sites that are either owned by them or by independent third parties.

"If companies choose to monitor the site," says the SMWG, "they should consider establishing guidelines for anticipating, monitoring, and responding to unsolicited off-label comments and questions posted by third-party visitors within company-hosted online communities." These guidelines would be communicated to online community members via a Terms of Use agreement. "FDA could require that companies monitor such sites/communities on a regular basis (each business day, for example) to ensure compliance with the Terms of Use and take appropriate action when the Terms of Use are violated."

For product-related sites, the SMWG recommends the following Term of Use:

> This site is intended as a forum for discussing FDA-approved uses of [product x], which are [insert approved indications]. As such, postings containing product discussions that are not consistent with the FDA-approved prescribing information (include hypertext link to full prescribing information) are subject to removal. Product-related questions should be directed to Customer Service or [other appropriate department for handling] at [toll-free number, fax, email].

Handling Off-Label Posts

With regard to responding to unsolicited request for off-label information, the SMWG recommended that the site "retain the off-label request posting, along with the company acknowledgment, to ensure the community is informed of its off-label nature. This avoids the risk of an off-label question being viewed without clarification" and also avoids, as the SMWG comments say, "undue censorship."

The FDA may have a problem with this. First of all, the cat's out of the bag if you allow unsolicited off-label posts to be retained, even if for a short period of time. Given the viral nature of social media such as Twitter, the post can be replicated throughout the Internet within hours and reach the top of search engine results.

The SMWG is a bit vague on how long off-label posts should be retained and leaves it up to individual companies to decide: "The company would remove the off-label posting/statement within a reasonable time to ensure availability of this information is limited. Companies should also determine criteria for type of information to be addressed/corrected and length of time information would remain online."

To Moderate or Not to Moderate?

Perhaps a better way to handle this on sites owned by pharmaceutical companies is through enlightened moderation; ie, reviewing comments before they are posted. This has become the norm for pharma companies that now have blogs (ie, Johnson and Johnson and GSK, neither of which are part of the SMWG).

When asked about this during the Pharma Marketing Talk interview, Mark Gaydos, Senior Director, U.S. Regulatory Affairs Marketed Products at sanofi-aventis, said "what we are proposing is a way that doesn't slow down the discussion. When you get involved in screening and taking steps to review comments before they are posted, you bring things

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to a halt. We proposed something that will allow the conversation to flow. Since we are talking about a 24/7 proposition here, it doesn't just happen during business hours. [With moderation] you also run the risk of alienating visitors. If we really want to get closer to patients and healthcare professionals, [we can't be] censoring and stifling posts."

Mark Gaydos

"In our discussions," noted Phillips, "certainly moderation came up. A number of us had been speaking about it as an alternative. It is an alternative, but it's a conservative alternative. This was our opportunity to see if we could expand FDA's thinking just a little bit."

"Whether FDA ultimately aligns with [our recommendations] or goes with a more restrictive approach remains to be seen," said Gaydos.

It's not likely that high-volume discussions will ever take place with consumers or patients on branded sites. As has often been said, no one wants a conversation with a drug brand. Gaydos and Phillips were talking primarily about disease related patient-to-patient and patient-to-physician discussions that pharma companies can facilitate on non-branded sites controlled or sponsored by them. One model of such a site would be the UCB sponsored epilepsy community hosted by PatientsLikeMe. This "platform" is designed to collect, analyze and reflect information received from people with epilepsy, regardless of their diagnosis, prognosis or treatment regimen. That information specifically INCLUDES adverse events and off-label comments!

Form FDA 2253 Submission

The SMWG recognizes that FDA's requirement that drug companies submit all promotional materials at the time of initial dissemination is "particularly challenging for social media, which involve real-time dialogue among community members." The group suggests that, for company-owned sites, the following items be submitted on Form 2253 at the time of first use:

- Static elements (graphics, indication, important safety information, package insert link, etc.)
- Proactive promotional company postings such as those intended to introduce a topic for discussion
- The site's URL, which would constitute a submission of the online discussion by reference

"At DDMAC's discretion," said Gaydos, "it could monitor and check in on the conversation to see how companies are interacting with visitors, correcting information, etc."

"An alternative to the time of first use submission is to batch and submit discussion threads occurring within company-hosted discussions," says the SMWG in its comments to the FDA. "These could be captured and submitted on a weekly or monthly basis."

This alternative idea seems to include ALL posts made on the site, not just the "proactive promotional company postings." If the site is a successful social media site, the number of postings can be large and could become a burden for the FDA to review. "We believe that from DDMAC's own perspective [our proposal is] probably preferable to getting bombarded with reams of printed out conversation threads from online discussions."

What About the Future?

Gaydos and Phillips are encouraged by FDA's actions so far. "The fact that they assembled a public hearing and have announced their intention to issue draft guidance [is encouraging]. A valuable component of online conversations about health issues is missing because the pharmaceutical industry is not fully engaged because they feel held back by the lack of guidance. If we are truly going to benefit patients and healthcare professionals, it's important for us to be able to engage on a regular basis in real time as social media was intended to be used. I am hoping that whatever guidance FDA comes out with will facilitate that."

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