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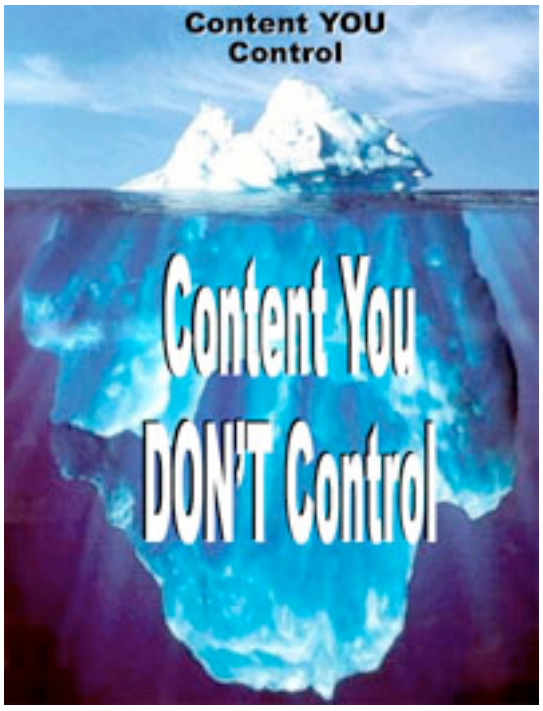
Accountability for Pharma Content on Social Media Sites

Who Owns and Controls the Content?



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The FDA asked ths public for comments regarding how pharmaceutical companies should be held accountable for communications about Rx product(s) and how much control they exert over activities on the Inter-net, regardless of whether the promotional activity occurs on company-sponsored venues or on third-party venues. Related to this, FDA also asked whether or not pharmaceutical companies should correct misconceptions or misinformation about their products, including unapproved uses of their products that are being conveyed on a Web site outside their control, such as on a blog, social networking site, or a wiki Web site (i.e., Wikipedia).

A substantial portion of the comments submitted to the FDA by the drug industry was devoted to the accountability issue and the related issue of correcting misinformation on social media sites.

Who Controls the Content?

When addressing the issue of pharma accountability for published drug information, it is natural to define the level of control that pharma companies have over the content. FDA specifically asked for com-ments in answer to this question: "When should third-party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?"

The *Pharma Marketing News* Survey, "WANTED: Answers to FDA's Questions Regarding Pharma's Use of Social Media" (PMN Survey), results of which were submitted to the FDA, asked respondents to choose one of the following responses to the above question:

- When marketer or agent sponsors the discussion (eg, provides a specific grant to independent 3rd-party host such as a patient advocacy group to sponsor the discussion)
- When marketer or agent paid for the content (eg, paid patients for testimonials or otherwise provided compensation)
- When marketer or agent paid for display ads to be run on specific discussion pages (eg, only discussions related to the product advertised)
- None of the above

The results are shown in Figure 1, below. Although a near majority of respondents felt that 3rd party content is not independent if sponsored by pharmaceutical company grants, none of the companies that submitted comments to the FDA agreed.

Abbott cited FTC's "Guides Concerning the Use of Endorsements and Testimonials in Advertising," which became effective in December, 2009. "The

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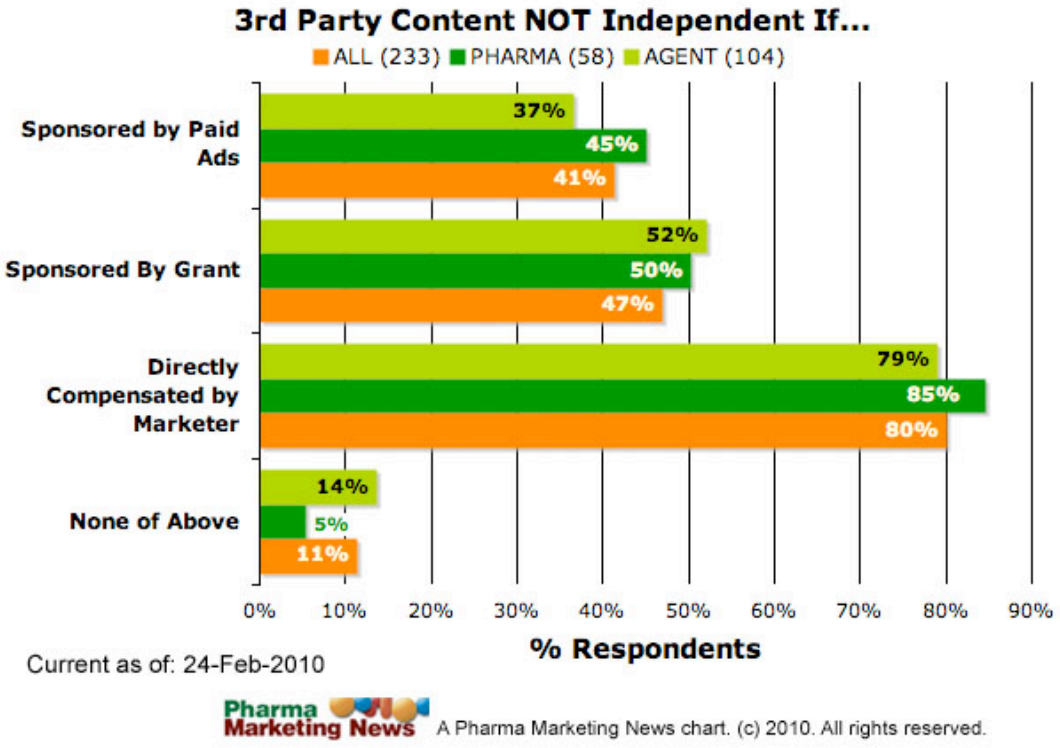

Figure 1. Data from PMN Survey

FTC Guide," said Abbott, "focuses on whether 'viewed objectively' the relationship between advertiser and speaker is such that the speaker's statement can be considered 'sponsored' by the advertiser, and thus an 'advertising message.' When this same concept is applied to IN/SM [Internet and Social Media] 'content' ownership, clear levels of accountability can be established in guidance."

Some Communications Are of No Concern to FDA

Pfizer pointed out that "not all product-related communications by or on behalf of a manufacturer are within FDA's regulatory authority." Sanofi-Aventis (S-A) agreed. "Accountability does not mean that all manufacturer communications should be regulated as promotional labeling (or advertising), as the internet may prove itself a good medium for appropriate scientific exchange," S-A said. For company-created community focused solely on a disease, not specific treatments, S-A said "where company has made no overt attempt to solicit product comments, FDA should not hold the company accountable."

Owned, Earned, Shared Media

Many comments included schema for categorizing media according to how much control pharma has over published content. Abbott defined 3 types of media:

1. **Earned Media** – where the manufacturer provides information (eg, "to a reporter"), but does not control the resulting message;
2. **Paid Advertising and Shared Social Media** – where the manufacturer controls the original message, but may not be able to protect the message from being later manipulated independent of the company;
3. **Owned Media** – where the manufacturer controls the content and distribution (eg, e-mail, brochures, websites) exclusively.

"Manufacturers should be held accountable for content that appears on owned media at all times," said Abbott. "As well, manufacturers should be held accountable for content appearing on paid advertising or shared social media, but only when the content is within manufacturer control initially, not if the content is modified independent of the company at a later date." Manufacturers should not be held accountable for content in earned media.

Alternative Schemas

While Abbott defined three types of communications, Astrazeneca (AZ) defined four types:

1. Company-controlled, hosted online communications. Such communications would be defined as communications placed on web sites and other online properties that are under the control of a product sponsor. Controlled sites and properties would be defined as those that the sponsor owns, operates, or where the sponsor retains editorial control. Such communications would include company-owned product information web sites, company controlled disease information sites, company sponsored and controlled content areas on third party web sites such as Facebook.
2. Company-controlled communications. Such communications would be defined as communications that a product sponsor places or provides for use by web sites and other online properties that the sponsor does not control and where such communications are used in the form, manner, and context for which the sponsor provides it. Such commun-ications include company sponsored and created advertisements or banners on third party web sites. They can also include company provided content such as videos, online tools, or articles.
3. Real-time, social media participation communications. Such communications would be defined to include company real-time, social media interactions on web sites and online forums that are not company –controlled. Such communications typically occur in chat areas, comment areas or as an integral part of the operation of the web site (for example in pop up or pop over windows created by the web site creator).
4. Independent Communications. content that a product sponsor does not provide or post or material that was originally provided but that has been altered by others outside the control of the product sponsor. An example of such communication would be Google Sidewiki.

AZ proposed that accountability vary by these categories.

Accountability

Of course, AZ believes pharma companies should be "fully accountable" for content published on drug.com sites and other company-controlled, hosted online communication sites. For example, a product sponsor of a social media site that is company-controlled "could control such content through the enforcement of terms of use imposed as a condition of participation and that allow for the review of social media content prior to its appearance on the web site."

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Abbott also mentioned how it might correct content on such social media sites: "However, we also believe that, in the interests of permitting the free flow of information, product sponsors should have the ability to allow real-time, unedited conversations if they promptly (within perhaps 48 hours) remove any information that does not comply with the established terms of use."

When it comes to content a company supplies to third-party sites its does not control, Abbott "believe[s] that the FDA should hold the product sponsor accountable for these communications but not for other communications that may appear with it or be linked to it." This position is based on Abbott's view that the FDA should not hold a product sponsors accountable for things that "it cannot and, in some cases, should not control or attempt to control. The guidance could condition such treatment on the company not intentionally directing the placement of its company-controlled communications with or near content that the company is aware provides information on its product or diseases for which a product is not indicated. For example, directing placement of otherwise balanced company-controlled communications near communications on off-label uses of its product would trigger product sponsor accountability for such content."

The Pharmaceutical Research and Manufacturer's Association (PhRMA) cited a more stringent definition of a site controlled by a manufacturer. "A biopharmaceutical manufacturer," said PhRMA, "can only be accountable for a web site or other content that it controls, which should be defined as content — (i) that is controlled entirely by the manufacturer or its agents; (ii) where the manufacturer or its agents has authority to add or delete all content; and (iii) that is funded entirely by the manufacturer or its agents."

Conversation Is Not Advertising Says Lilly

Eli Lilly took a different approach in defining different kinds of communications for which pharma companies may or may not be held accountable. It defined the following three types:

1. **Advertising**: a stand-alone, creative unit designed to influence, inform, or motivate a target audience that is portable between various communication environments.
2. **Content**: promotional information provided in written, visual, or audio format that is not "Advertising", exists separate and apart from an Advertising unit, and is tailored for a specific communication environment.
3. **Conversation**: an actual or attempted spontaneous exchange of thoughts and ideas by individuals via Internet-enabled technology/ capabilities like blogs, social media sites.

"As is currently the case, " said Lilly, "Manufacturers should continue to be accountable for Advertising, Content and Conversation that the Manufacturer directly or indirectly creates, controls or intentionally influences. The Manufacturer should NOT be accountable for Advertising, Content or Conversation that it neither directly nor indirectly creates or controls or influences. For example, on 3rd party sites where the only involvement with that site is placement of Advertising, the Manufacturer would only be accountable for the Advertising unit, not other surrounding Content or Conversation (to the

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"Earned" News Media

The *New York Times* (NYT) may have "earned" the everlasting favor of Novartis and Merck when it published the story "Study Adds Evidence That Bone Drugs Work, Are Safe." The story reported the results of a study published in the *New England Journal of Medicine* (NEJM).

The study—a meta-analysis of several other studies—intended to dispel the claims put forward by critics such as Gordon Strewler, MD in NEJM and Susan M. Ott, MD, in the *Annals of Internal Medicine* who warned that bones remineralized by "bone drugs" could become brittle and fracture-prone and that these drugs may actually cause what they are supposed to prevent.

The NEJM article's own lead author confesses that "The study was underpowered for definitive conclusions." Of the 12 study authors listed in the NEJM article, at least three are full-time employees of Merck or Novartis. As noted by Carolyn Thomas—author of Ethical Nag (http://ethicalnag.org/)—in a comment to a Pharma Marketing Blog post (see http://bit.ly/9aHDh5), "every single one of the remaining 'researchers' admit owning equity interests in or receiving cash, travel expenses, or 'consulting and lecture fees' from dozens of drug companies. It's like a 'Who's Who' of the industry. Big Pharma can and must do whatever they can to bury the bad news and pump up the good, however they can, including buying a few doctors and a medical journal or two."

extent the manufacturer did not create or control such Content or Conversation). Similarly, when Manufacturer employees engage in personal communications on the Internet, Manufacturers should NOT be held accountable even when such communications involve personal experiences with the Manufacturer's products."

Content Syndication
Lilly also addressed the issue of content syndication. Although Lilly did not mention RSS (ie, Real Simple Syndication), which is a staple of social media content publishing on the Internet, Lilly said "accountability for Content includes the initial implementation and any Manufacturer planned syndication of the content." Whether or not Lilly considers creating a blog RSS feed "planned" or not is unknown. Lilly went on to say "The Manufacturer should NOT be accountable for unapproved syndication of Manufacturer Content by 3rd parties or for alteration of Manufacturer Content by 3rd parties."

User-Generated Content
Johnson and Johnson (JNJ) points out that user-generated content (UGC) "does not constitute promotional labeling or advertising," but a company may "nonetheless have responsibility for UCG in certain circumstances. For example, if a company owned or controlled site includes a chat room, message board or other area designated for online conversation related to a regulated product, then the company should also as a prudential matter be responsible for monitoring and if necessary responding to UCG posted to that site." JNJ does not, however, provide details about situations requiring responses.

JNJ also said "there are different considerations that should be weighed … with sites that are available only to the medical community and for non-product related sites." In the case of a non-product related site, JNJ believes the company has no responsibility to respond to UCG that mentions a specific product. JNJ suggested that the site's intended use should be "prominently indicated" in the Terms of Use and "appropriate actions" taken when those terms are violated.

Pfizer claimed that pharmaceutical companies have no responsibility for UCG published on sites it controls. "Statements by unregulated persons [ie, UCG content submitted by patients] on manufacturer-hosted (or -supported) online forums are not statements by the manufacturers themselves. See FDA, Guidance for Industry: Industry-Supported Scientific and Educational Activities (Nov. 1997) (recognizing that a manufacturer's support of an activity does not necessarily make that activity promotional or otherwise an activity 'by or on behalf of' the manufacturer); see also 47 U.S.C. § 230 (website operation does not cause a person to become a speaker under the Communications Decency Act."

Patient Advocacy Special Case
Novartis argued that not-for-profit/patient advocacy groups are a special case. "Many times,' said Novartis, "manufacturers provide funding to these not-for-profit/patient advocacy groups. Generally, the funding is made through an agreement that specifies that the manufacturer will not have any control over content nor is the funding for the purpose of promoting the company's products. The Agency should not equate 'sponsoring' with control," contends Novartis, "unless a manufacturer owns a site or knowingly exerts control over that site, the manufacturer should not be held accountable for that site's content."

Novartis commented that "a manufacturer (as well as the [patient advocacy] site) should be transparent about any funding provided to the owner of the site. For example, the site may state 'X Manufacturer has provided funding' for this site."

Unfortunately, according to Congressional investigators , some patient advocacy groups may not be revealing their funding sources. In October, 2009, the *New York Times* reported that "a majority of the donations made to the National Alliance on Mental Illness [NAMI], one of the nation's most influential disease advocacy groups, have come from drug makers in recent years" (see "Drug Makers Are Advocacy Group's Biggest Donors"; NYT 10/21/2009). NAMI has refused for years to disclose specifics of its fund-raising, saying details are private. Recently, NAMI's executive director, Michael Fitzpatrick, acknowledges industry donations were excessive and that things would change.

Safe Harbor for Corrections to Misinformation
PhRMA suggests that manufacturers would welcome correcting misinformation about their products posted to sites like wikipedia if these corrections were not subject to FDA regulation. "FDA should confirm formally that, while it is not possible for manufacturers to monitor or correct all inaccurate information about their products on the Internet, such corrections by manufacturers in response to inaccurate postings will not be considered promotional labeling. FDA's adoption of such a policy would thereby allow manufacturers to correct inaccurate information about their medicines on the Internet or social

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media (e.g., Wikipedia, Sidewiki, blogs, or other websites) if they should become aware of such information."

PhRMA acknowledges, however, the futility of correcting misinformation on sites like wikipedia and sidewiki: "Even when manufacturers take corrective measures, there is no guarantee that the company's alterations or posted information will remain in a correct state; users of Wikipedia, for example, may simply edit or delete the sponsor's corrective post. For such independent sites, manufacturers cannot be held responsible for all content. By definition, manufacturers cannot control the content of most independent blogs (including Sidewiki) and therefore cannot be held responsible for them."

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