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February 28, 2010  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

RE: PROMOTION OF FOOD AND DRUG ADMINISTRATION-REGULATED MEDICAL PRODUCTS USING THE INTERNET AND SOCIAL MEDIA TOOLS (DOCKET NO. FDA-2009-N-0441)

The Word of Mouth Marketing Association (“WOMMA”) respectfully submits these Comments in response to the request by the Food and Drug Administration (“FDA”) for public comments pursuant to 74 Fed. Reg. 48,083 (Sept. 21, 2009).

## **I. Overview of WOMMA**

### **A. Background of WOMMA**

WOMMA is the leading trade association in the marketing and advertising industries that focuses on word of mouth, consumer-generated, and social media platforms -- or marketing techniques that include buzz, viral, community, and influencer marketing as well as brand blogging and enhancement.

WOMMA is committed to developing and maintaining appropriate ethical standards for marketers, advertisers, and brands engaging in such marketing practices, identifying meaningful measurement standards for such marketing practices, and defining “best practices” for the industry.

Founded in 2005, WOMMA has approximately 450 members, which include: (i) marketers and brands that use word of mouth marketing to reinforce their core customers and to reach out to new consumers; (ii) agencies that deliver word of mouth services and

technologies; (iii) researchers that track the word of mouth experience; and (iv) offline and online practitioners.

Members of WOMMA abide by mandatory Standards of Conduct and a Code of Ethics that establishes “best practices” guidelines designed to assist in the development of compliance procedures to evaluate and execute marketing campaigns. This Code, in fact, was favorably recognized by the Federal Trade Commission (“FTC”) in the agency’s recent release of its Guides Concerning the Use of Endorsements and Testimonials in Advertising.

As part of its educational mission as a self-regulatory body, WOMMA just released Disclosure Guidelines for its member companies participating in social media marketing. Developed with extensive industry input, these Guidelines are designed to provide marketers with clear and practical direction when engaging social media participants (“bloggers”) in brand marketing initiatives.

#### **B. WOMMA’s Interest in these Proceedings**

The experience of many WOMMA members involved with social networking and online communities clearly shows that social media plays a very strong usage around healthcare. The reasons are simple:

- Patients - - and their family and friends - - need emotional support regarding almost any illness or disease, from simply colds to terminal cancer, and they believe that they can best receive this support from people like themselves with similar experiences.
- The matters surrounding health care are complex, deep, and changing every moment, thus requiring constant and instantaneous education - - which advances the needs of all stakeholders.

Furthermore, WOMMA members have overwhelmingly found that consumers have developed skills to navigate, engage in, and filter information, opinion, and relationships in social network environments. They have also found that consumers or citizens with health care concerns first go to the Internet to educate themselves and frame their thinking; and *then* they go to doctors or health care providers to focus their decisions and actions. Finally, WOMMA members have found that proactive participation by pharmaceutical and other health care companies assists the consumer in their education and decision-making, and that meaningful participation is desired by them.

Accordingly, WOMMA submits that the FDA should articulate standards or criteria that acknowledge these realities by providing health care and pharmaceutical companies with an appropriate roadmap to provide meaningful, non-deceptive communications on social media platforms. Through these Comments, WOMMA respectfully provides initial, but fundamental, core principles and standards that are designed to assist the staff in articulating such criteria; and WOMMA looks forward to being an active and valuable voice in this dialogue.

## **II. History of Proceedings and Overview of FDA Request for Comments**

### **A. Warning Letters to Pharmaceutical Companies Last Year Concerning Sponsored Links, and Their Impact**

The FDA is responsible for regulating labels and advertising of prescription drugs and certain other products. This authority was granted to the FDA by Congress in the 1962 Amendment to the Food, Drug, and Cosmetic Act (the “Act”). Regulating drug advertising falls within the purview of responsibilities of the Division of Drug Marketing,

Advertising, and Communications (“DDMAC”) of the FDA’s Center for Drug Evaluation and Research (“CDER”). Neither the Act nor the regulations promulgated by the FDA thereunder have been updated with respect to labeling and advertising in several decades, and thus pharmaceutical companies have had no clear-cut rules to follow when developing the content and format of their electronic ads.

Though the FDA has yet to publish specific guidelines regarding disclosures in electronic Web 2.0 drug ads, last year DDMAC issued a series of Notice of Violation Letters (each, a “Letter”) that hold Internet ads to the same standards generally applied to traditional print ads.<sup>1</sup> For example, DDMAC sent one such Letter on March 26, 2009 to Biogen Idec that charged the company with distributing electronic advertising that misbrands its drug product TYSABRI, a treatment for Multiple Sclerosis.<sup>2</sup> Biogen funded sponsored links on Internet search engines that stated “Multiple Sclerosis – MS: A Multiple Sclerosis Treatment That’s Different from the Others. [www.Tysabri.com](http://www.Tysabri.com).” Though the small ad provided a link to full product information that included the requisite risk information about the drug, DDMAC asserted that linking to complete information “does not mitigate the misleading omission of risk information from these promotional materials.” DDMAC necessarily concluded that regardless of the inevitable space limitations on ads in an electronic context, the advertiser was obligated to provide all required risk information, the established name of the product, and an adequate brief summary that includes an accurate statement of the drug’s indication.

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<sup>1</sup> While the Letters were addressed to specific drug manufacturers, they are considered instructional tools for the industry as a whole.

<sup>2</sup> Letter to Nadine D. Cohen, Biogen Idec, from Sharon Watson, DDMAC (March 26, 2009). The Notice of Violation Letter and copies of the TYSBARI promotional materials are available at <http://www.fda.gov/cder/warn/warn2009.htm> (last visited February 25, 2010).

The Letters had a rather immediate chilling effect on pharmaceutical companies' online promotional efforts. After the Letters were issued, many companies decided revise their sponsored search results so that product names would no longer appear in URLs.

Yet, such a decision had the effect of decreasing transparency for consumers.<sup>3</sup> Without product names in the URLs, consumers are robbed of important information about the landing pages, and may have difficulty drawing the connection between the medical condition about which they are searching and the medication indicated for its treatment.

#### **B. Federal Register Notice Concerning FDA's Hearings and Request for Comments**

Subsequent to the industry's negative reaction to the Letters, coupled with the common knowledge that the Letters may have actually resulted in decreased transparency for consumers, the FDA invited interested parties to present their views at a public hearing in November and to submit comments in response to the FDA Notice published in the Federal Register.<sup>4</sup> This Notice crystallized the FDA's realization that "special characteristics of Web 2.0 and other emerging technologies may require the [FDA] to provide additional guidance to the industry on how the regulations should be applied."<sup>5</sup>

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<sup>3</sup> During Google's presentation at the FDA public hearing in November 2009, Amy Cowan noted that "users find the sponsored links now less transparent and relevant to the queries" as evidenced by the drastic decrease in click-through rates. In defense of using links, Cowan stated that "[t]he ads prior to the notice of violation letters clearly let consumers know that they were a prescription drug advertisement, and, in fact, users were more likely to visit these sites and get access to the important risk information." See presentation by Mary Ann Belliveau, Director, Health; and Amy Cowan, Head of Industry, Health; Google, November 12, 2009 FDA Public Hearing, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm184250.htm> (last visited February 24, 2010).

<sup>4</sup> Notice on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, 74 Fed. Reg. 48,083 (Sept. 21, 2009).

<sup>5</sup> *Id.*

### **C. November Hearings**

On November 12 and 13, 2009, the FDA held formal hearings into the application of social media platforms to drug and medical device advertising. Over fifty presentations were made to the FDA panel,<sup>6</sup> and several key themes emerged that are central to the development of appropriate standards and criteria.

First, there are abundant benefits in using the Internet, Web. 2.0, social media platforms, and user-generated content for gaining information about health care issues. In particular, these platforms:

- Provide valuable information to consumers that aid in their decisions and actions;
- Provide valuable information for professional-only communities (with social media serving like conferences and journals to professionals); and
- Enhance the doctor-patient relationship, as the consumer is more engaged and empowered in the process.

Second, the Internet and social media environment have no limits on time (as is the case with television) or space (as is the case with print). As a result, communications through the Internet and social media channels are better equipped to provide consumers with more meaningful risk/balanced information.

Third, consumers are reasonably savvy about their ability to navigate on-line to obtain health care information. Accordingly,

- Links and hyper-links are very useful; and

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<sup>6</sup> WOMMA provided two presentations during the hearings. One involved the realities of adverse event reporting in social media; and the other one involved the finding of best practices for social media health advertising.

- Clicking is the functional equivalent of turning a page; and thus, clicking to obtain risk information in limited environments is not only appropriate but normal navigational behavior.

Fourth, social media will expand as will emerging technologies.

Fifth, severe and profound consequences can result if the FDA fails to act or, in contrast, overreacts in providing guidance on the role of social media in communicating to consumers. Such a failure or overreaction can constitute a “chilling effect” on brands, pharmaceutical companies, and other care providers, as these stakeholders would likely decide to avoid social platforms for education and promotion all together; and, if that were the case, consumers would obtain inaccurate or incomplete information. As one commentator pointedly noted during the hearings, “snake oil salesmen” could take over.

Sixth, presenters proactively provided frameworks to determine situations when brands or pharmaceutical companies should be accountable. It was made clear that the industry desires not only to participate in social media platforms, but that they are willing to do so responsibly.

Seventh, the recently-released Guides on the Uses of Endorsements and Testimonials in Advertising by the Federal Trade Commission recognize the role of social media platforms in promotional activity and reveal rather compellingly that appropriate guidance is possible. As a practical matter, these Guides are useful to determine:

- (i) whether a communication constitutes a “promotional message” or “sponsored advertising,” thereby creating responsibilities for the advertiser, brand, and speaker;

- (ii) the circumstances under which disclosures are needed to prevent communications from being deceptive or misleading; and
- (iii) the determination of what constitutes a “material connection” requiring disclosures for sponsored communications.

Finally, the consumer seeking health care information on-line is fundamentally different from other on-line consumers who evaluate advertising. With respect to drugs and devices, consumers make “considered” purchases. In contrast, for retail objects or other consumer goods, consumers may make “impulse” purchases.

### **III. Emergence of Social Media, and Benefits to Consumers and the Public Health and Welfare**

The November 2009 public hearings made it clear that the Internet and social media have emerged as an important option for consumers to seek, exchange and discuss information about pharmaceutical products used for the prevention and treatment of diseases and other health-related issues. Through thoughtful guidance, the FDA can ensure that online social media and other emerging technologies will continue to promote widespread health literacy.

Both patients and healthcare professionals are turning to the Internet to gather health information. According to Google, 4.6 billion health-related searches, across all major search engines, took place in the U.S. during just *the last three months* of 2007.<sup>7</sup> In addition, 36% of people who gathered information about a health condition online

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<sup>7</sup> These searches were conducted by 111 million unique searchers. See Google’s presentation at the FDA public hearing in November 2009, n.2 *supra*.

subsequently spoke to their doctors as a result, and 21% made a change to their lifestyle because of the information they found.<sup>8</sup>

Social networks, blogs, and other emerging technologies have compounded the opportunities for consumers to gather information on topics of interest and share experiences with other consumers online. These tools also benefit healthcare professionals and students by providing a forum to exchange patient care and medical research information.

Social networking sites such as Facebook<sup>9</sup> and Myspace<sup>10</sup>, and microblogs such as Twitter<sup>11</sup>, allow consumers to create profiles through which they exchange pictures and videos, chat with friends, send links to other websites and content, and even publish and maintain personal blogs. Such sites also provide businesses with the opportunity to create unique, branded profiles that consumers can interact with, link to and draw information from.

However, these megasites only represent a portion of the social media in which consumers engage. For instance, there is a clear upsurge in the amount of mission-driven sites involving social components. On these sites, consumers with similar interests, concerns or queries can interact with one another, and many such mission-driven sites involve health-related themes. Consumers who suffer from a chronic illness or who are undergoing medical treatment can connect with an online community of members who

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<sup>8</sup> *Id.*

<sup>9</sup> See <http://www.facebook.com> (last visited February 24, 2010).

<sup>10</sup> See <http://www.myspace.com> (last visited February 24, 2010).

<sup>11</sup> See <http://www.twitter.com> (last visited February 24, 2010).

are experiencing the same thing. This sense of connection fosters levels of trust and interaction that are unprecedented with respect to the exchange of health care information.

For instance, one such mission-driven site is a social network called “Patients Like Me,” which offers a forum for people suffering from particular health conditions to commiserate about their symptoms and collaborate toward better treatment options.<sup>12</sup> According to Patients Like Me, “when patients share real-world data, collaboration on a global scale becomes possible. New treatments become possible.”<sup>13</sup>

A parallel trend is the increasing use of the Internet and social media by physicians and other healthcare practitioners. According to data presented by Manhattan Research at the November FDA hearing, 70% of physicians believe that pharmaceutical companies should be involved in social media, including through the ability to request samples electronically and order free medical journal reprints. Manhattan Research has also reported that the average physician spends eight hours a week on the Internet for professional purposes, and that 87% of physicians interact with pharmaceutical companies online.<sup>14</sup> Moreover, provider-driven healthcare platforms are being quickly

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<sup>12</sup> See <http://www.patientslikeme.com> (last visited February 24, 2010).

<sup>13</sup> See <http://www.patientslikeme.com/about/openness> (last visited February 24, 2010).

<sup>14</sup> See presentation by Mark Bard, President, Manhattan Research, November 12, 2009 FDA Public Hearing, available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm184250.htm> (last visited February 24, 2010).

developed with social components to streamline interactions between doctors, patients and insurers.<sup>15</sup>

The benefits of social media for patients, healthcare professionals and the pharmaceutical industry are clear. All of the social networking platforms discussed above will inevitably continue to convey pharmaceutical information to patients through consumer-driven conversations. It is therefore not only appropriate, but necessary, for pharmaceutical companies to be encouraged to host and join such discussions to improve the accuracy of the shared information and to add to the richness and depth of the consumer experience.<sup>16</sup>

Finally, the FDA should note that many technological innovations are made possible through pharmaceutical advertising or promotional sponsorship. As a result, either silence/inaction or placing a regulatory chill on the ability for pharmaceutical companies to use online social media as a promotional tool would likely have the consequence of stifling technological innovation.

#### **IV. Core Fundamental Principles for Governmental Regulation of Social Media**

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<sup>15</sup> Provider-driven healthcare platforms such as Myca Health and its primary care platform “Hello Health” use social networking tools and interfaces to allow communication between healthcare providers and patients in efficient and user-friendly manners “to simplify the engagement between a provider and the patient, and let the physician concentrate on care.” See <http://myca.com/en/mycahub-technology/how-it-works> (last visited February 24, 2010) and <http://hellohealth.com/> (last visited February 25, 2010).

<sup>16</sup> Of course, while a pharmaceutical advertiser may have certain responsibilities to monitor third party user-generated content posted on their websites, the FDA should not take the position that it is in any way a pharmaceutical advertiser’s obligation to troll the Internet for all third-party mentions of their products. It would be patently unreasonable to require this of any company. However, the FDA should empower pharmaceutical companies, at their discretion, to correct inaccurate information about their products posted on third party sites as mere participants in the global discussion.

**Principle No. 1:** Companies have a fundamental interest in participating in social media platforms concerning the medicines or products they provide, and the conditions these medicines and products address.

**Principle No. 2:** Governmental regulation concerning such participation must only relate to those communications that constitute commercial promotional activities sponsored by the companies.

**Principle No. 3:** Any governmental regulation concerning such commercial promotional activity must be narrowly and appropriately tailored to ensure that those communications are (i) truthful; (ii) balanced and not deceptive; and (iii) transparent.

**Principle No. 4:** Any such governmental regulation must account for the nature and navigational realities of various social media platforms, such as the ability to use links and space constraints in certain environments or platforms.

## **V. Regulatory Standards for Promotional Communications**

**Standard 1:** Companies are responsible only for those activities that (a) constitute promotional communications directed to consumers and (b) are intentionally sponsored by the company. In other words, FDA regulatory guidelines concerning advertising by pharma and other health care companies are to apply only to those communications that (i) are sponsored and (ii) constitute promotional messages designed to influence consumer purchasing decisions.

**Example:** Non-branded disease awareness communications do not constitute promotional communications.

**Standard 2:** Companies are responsible for content provided in social media communications that is only under the company’s control, ownership, or operation; or for that content they specifically provide to third-parties, such as WebMD.

**Standard 3:** Companies are responsible for monitoring only those platforms or communications that are under their “sphere of influence.” In other words, companies are responsible for monitoring the discussion only when they have been actively engaged in the promotional messaging within that community.

**Example:** Companies should be responsible for monitoring discussion in a community that they have created or posted content. If a brand representative goes into WebMD discussion boards and posts information, the brand should monitor the follow-up discussions for questions, misinformation, adverse event reporting, and the like.

**Standard 4:** Companies are responsible for reporting adverse events only in those circumstances arising from their monitoring activities (as described in Standards 3. above). Yet, in monitoring and evaluating such adverse event incidents, the privacy interests of consumers must be respected.

**Standard 5:** Any content for which companies are responsible must be transparent, disclosing all material connections between the company and the speaker.

**Note:** The Guides for the Use of Testimonials and Endorsements in Advertising recently provided by the Federal Trade Commission provide an appropriate framework.

**Standard 6:** For content that requires disclosures that are needed to prevent deceptive or misleading information, companies are responsible to ensure that such disclosures be

made clearly and conspicuously given the practical constraints of the particular platform used.

**Note:** The “clear and conspicuous” standard by the Federal Trade Commission provides an appropriate and flexible approach.

### **Conclusion**

WOMMA hopes that these Comments are beneficial and useful, and looks forward to being an active and meaningful participant in this process.

DATED: Washington, D.C.  
February 28, 2010

Respectfully Submitted,

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