



Statement of
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FDA Public Meeting on
Promotion of FDA-Regulated Medical Products
Using the Internet and Social Media Tools

November 12 – 13, 2009

Introduction

Good morning. I am Jeff Francer, Assistant General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies, which are dedicated to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2008 alone, PhRMA members invested over \$50 billion in the research and development of new medicines.

PhRMA is committed to helping assure that promotion of medicines is truthful, scientifically accurate, and non-misleading. To help accomplish these goals, PhRMA has created its *Code on Interaction with Healthcare Professionals* and *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines*. Thus, PhRMA is pleased to participate in today's public meeting, and appreciates the efforts of the FDA, especially CDER's Division of Drug Marketing, Advertising, and Communications, in seeking public input on the important issues involving communication about medical products over the Internet.

Introduction: The Unprecedented Demand for Reliable Health Information Online

One issue that is indisputable today is that patients and healthcare professionals are turning to the Internet to gather health information in unprecedented numbers. Internet users have begun to use wikis, social networks, and blogs to gather information on topics of interest and to share experiences with other users. These tools also benefit professionals and medical students by providing a forum to exchange information on medical research and topics of common interest.¹

According to a recent survey by the Pew Research Center, 61% of American adults (83% of Internet users) now look online for health information.² Pew found that online health research has "an impact on decisions or actions and there are clearly more positive experiences than negative ones." 42% of all adults, or 60% of e-patients, say they or someone they know has been helped by following medical advice or health information found on the Internet.³ In addition, one-third of Americans are now looking online for information about medicines.⁴ But according to Pew, "The internet does not replace health professionals." 86% still ask a health professional when they need health information.⁵

Access to truthful, reliable information on the Internet will improve public health, and the FDA should facilitate such communication. Patients increasingly use the Internet as a source of information when caring for themselves or others. According to data from comScore Inc., 78% of patients who are online visit a health-related site to learn more about their own condition (as well as 56% of Caregivers).

¹ See, e.g., American Medical Association Facebook Profile, <http://www.facebook.com/AmericanMedicalAssociation> (last visited Oct. 23, 2009); Reach-MD Facebook Profile, <http://www.facebook.com/pages/ReachMD-the-Channel-for-Medical-Professionals/42225727881#> (last visited Oct. 23, 2009); Open Medicine Wiki, http://wikisr.openmedicine.ca/index.php/Main_Page (last visited Oct. 23, 2009).

² Susannah Fox & Sydney Jones, Pew Internet and American Life Project, *The Social Life of Health Information -- Americans' Pursuit of Health Takes Place Within a Widening Network of Both Online and Offline Sources* 4 (June 2009) ("Pew Survey").

³ *Id.* at 7 (emphasis added).

⁴ Manhattan Research, *Cybercitizen Health Study* (2009).

⁵ See Pew Survey at 15.

In addition, the Department of Health and Human Services Healthy People 2010 report recognizes the power of the Internet to provide patients with health information.⁶ One of the goals of Healthy People 2010 is to increase Internet access, because “access to the Internet and subsequent technologies is likely to become essential to gain access to health information, contact health care organizations and health professionals, receive services at a distance, and participate in efforts to improve local and national health.”

The Appropriate Role of Biopharmaceutical Research Companies

Pharmaceutical manufacturers use the Internet to provide truthful, scientifically accurate, and meaningful information to healthcare professionals and patients about the products they discover, develop, and produce. Already, they provide the only FDA-regulated promotional information online.

America’s research-based pharmaceutical companies already provide FDA-regulated information to patients and healthcare professionals in print and broadcast media. Given the extraordinary growth of the Internet as a source of health information, the FDA should facilitate manufacturers’ communication of important medical information about their products in a responsible way, taking advantage of the same technologies that the FDA and the White House use, including blogs, video, search, and social networking sites such as Twitter™. As demonstrated by the FDA’s own use of Twitter, it is clear that information about medicines can be provided in a truthful, non-misleading manner.

Of course, the critical dialogue between patients and their health care professionals necessarily supplements the general information provided by manufacturers, whether information is provided through the Internet or more traditional media. According to the Pew survey, 53% of respondents who stated that an Internet search had improved their own health, or their care for someone else, stated that the information they found online led them to ask a doctor new questions, or to get a second opinion from another doctor.⁷

As Internet media evolve, the FDA should facilitate manufacturers’ use of new technologies and means to communicate risks and benefits. Consumers on the Internet are accustomed to viewing pop-ups, rollover text, links, and other communication mechanisms. FDA should recognize, as the FTC has, that space limitations in certain formats warrant allowing certain long warnings to be accessed using a prominently labeled hyperlink.

An FTC staff paper states that web sites “are interactive and have a certain depth—with multiple pages linked together and pop-up screens, for example—that may affect how proximity [of disclosures] is evaluated.”⁸ Significantly, the FTC’s staff paper concludes that “[h]yperlinked disclosures may be particularly useful if the disclosure is lengthy.”

Certain technologies, such as microblogs, emphasize brevity, but they may provide more information by hyperlink. FDA should facilitate the use of such technology and not apply paradigms created originally for brochures and other physical media.

⁶ HHS, Healthy People 2010 vol. 1, ch. 11, “Health Communication,” available at <http://www.healthypeople.gov/document/HTML/Volume1/11HealthCom.htm>.

⁷ Pew Survey at 7.

⁸ FTC, Dot Com Disclosures: Information About Online Advertising 6 (2000), available at <http://www.ftc.gov/bcp/edu/pubs/business/e-commerce/bus41.pdf>.

Maintaining Responsible Online Communications By Manufacturers: A Proposal

PhRMA's members are proud of their role as the most knowledgeable and reliable source of information about the lifesaving medicines they research, develop, and manufacture. To that end, PhRMA looks forward to working with FDA and stakeholders to identify ways in which biopharmaceutical manufacturers may communicate about their medicines online in a truthful, scientifically accurate, and non-misleading way.

One possible solution might involve FDA approving prominent use of the FDA's own logo or a new universal FDA-approved graphic symbol, along with a standard universal warning that would be approved by FDA (e.g., "All drugs have risks. Click here for more information from the manufacturer") in places throughout the Web where there is not enough room for complete disclosure of all warnings, indications, and contraindications (e.g., search results and microblog posts.) The prominent graphic and link could take users directly to pages displaying the FDA-approved Prescribing Information (PI) and/or Medication Guides. The use of the FDA's own logo, or some other FDA-approved symbol, would increase the prominence of the link and also help patients and healthcare professionals identify the official manufacturer sites containing FDA-regulated benefit and risk information. While use of such a universal graphic symbol would require the cooperation of many parties, including Internet companies, PhRMA hopes that our proposal is one way to advance the conversation about how best to communicate the risks and benefits of medical products in new online media.

PhRMA believes that FDA should allow for manufacturers to present brief "introductions" to health information, including brief but accurate indication descriptions, just as FDA now does in its Twitter postings, based on the space constraints of some new media (e.g., search results, blog entry, twitters). Of course, such an introduction should also contain an affirmative statement about the risks of a medicine, even if abbreviated. A condition of providing more comprehensive benefit and risk information in an abbreviated format could be that such entries contain prominent and clearly marked links indicating that users should view more information such as full indication, full risk information, and more complete fair balance. The link label itself – perhaps with a universal graphic as we propose – should balance a truthful abbreviated indication statement, if the link: (i) is prominently marked, (ii) contains a definitive statement that use of the drug entails risk, and (iii) moves the user directly to a page containing a full statement of the indication and risk information.

Public Health Dangers Posed By Illegal Internet Drug Sellers

Given the real public health dangers and lack of accountability posed by illegal Internet drug sellers, FDA should encourage manufacturers' legitimate, FDA-regulated communication on the Internet as a source of reliable information. FDA and other government agencies should redouble enforcement efforts against Internet drug sellers that could be sources of counterfeit medicines, and could also be selling medicines to consumers without either a prescription or an adequate description of drug risks.

According to the Department of Homeland Security, "the Internet has become the primary tool for criminal organizations to advertise, communicate and conduct sales of

counterfeit pharmaceuticals. The Internet has also become the primary mechanism for consumers to find, order and make payments for counterfeit pharmaceuticals.”⁹

Warning the public against fake H1N1 treatments just a few weeks ago, Commissioner of Food and Drugs Margaret A. Hamburg, M.D. stated recently, “Medicines purchased from Web sites operating outside the law put consumers at increased risk due to a higher potential that the products will be counterfeit, impure, contaminated, or have too little or too much of the active ingredient.”¹⁰ FDA stated that it purchased and analyzed several products represented online as Tamiflu® (oseltamivir), which may pose risks to patients. According to FDA, “[o]ne of the orders, which arrived in an unmarked envelope with a postmark from India, consisted of unlabeled, white tablets taped between two pieces of paper. When analyzed by the FDA, the tablets were found to contain talc and acetaminophen, but none of the active ingredient oseltamivir.”¹¹

Given the dangers posed by illegal Internet drug sellers, it is even more important that FDA facilitate manufacturers’ ability to provide truthful, scientifically accurate — and FDA-regulated — health information to healthcare professionals and patients.

Accountability of Manufacturers

FDA has posed a critical question during a time when all users may now ‘comment’ on or contribute content to almost any web page in numerous formats. Social media tools offer an unprecedented opportunity for third parties to speak about a sponsor’s products without the knowledge or control of the product sponsor. For instance, Wikipedia, an online encyclopedia featuring user-generated entries, includes pages describing many marketed drugs with information on the history of the drug, FDA-approved uses, lay media coverage, and investigational research. While some of the entry’s content may repeat the sponsor’s own labeling or advertising, Wikipedia users can alter this content and post additional information. As a result, the final Wikipedia page may – through no fault of the sponsor – fail to comply with FDA advertising and labeling rules were the page attributed to the sponsor.

A biopharmaceutical manufacturer can only be accountable for a web site that it controls, which should be defined as: a site — (i) whose content 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) which is funded entirely by the manufacturer or its agents. For purposes of enforcement, once FDA determines that a site is controlled by a manufacturer, it must then determine whether the material may be regulated as promotional labeling or advertising under FDA’s statutes and regulations. Importantly, not all manufacturer communications online constitute promotional labeling or advertising about their products.

PhRMA’s member companies recognize that they have an obligation to patients and healthcare professionals to provide meaningful and scientifically accurate information about their medicines online. Thus, PhRMA proposes that employees or agents of a manufacturer who post content on the manufacturer’s site, or other sites, as part of their employment should

⁹ Department of Homeland Security, U.S. Immigration and Customs Enforcement, ICE Efforts to Combat Counterfeit Pharmaceuticals (2006), *available at* http://www.ice.gov/doclib/pi/news/factsheets/counterfeit_pharms.pdf.

¹⁰ FDA, FDA Warns of Unapproved and Illegal H1N1 Drug Products Purchased Over the Internet (2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186861.htm>.

¹¹ *Id.*

be required to disclose their relationship with the manufacturer in any posted content and make sure that content is truthful, scientifically accurate, and contains an appropriate balance between benefits and risks.

Attributing statements to a manufacturer that the manufacturer did not cause or control would, however, be untenable. Such third party statements simply do not fall within the definition of either labeling or advertising under the Federal Food, Drug, and Cosmetic Act (FDCA), one of which would be necessary to support a violation of law by the sponsor. Labeling is defined by the FDCA to include “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”¹² A third-party statement cannot reasonably be considered to accompany a drug merely because the statement refers to the drug. Rather, to be labeling, the statement must be intended to be part of an integrated commercial transaction.¹³ Likewise, advertising, which is not defined by the FDCA, cannot reasonably be understood to encompass third-party statements simply because those statements reference a drug. The common meaning of the term envisions promotion for commercial sale, a motivation held only by the drug’s sponsor or its agents.¹⁴ In sum, the statutory language of the FDCA provides no sensible basis to find that an unaffiliated third party may misbrand a drug with no involvement by the drug’s manufacturer, and we are unaware of any previous FDA enforcement action seeking to hold a manufacturer responsible for statements outside its control.¹⁵

Like other types of companies, manufacturers of biopharmaceutical products are not able to monitor the entire Internet for references to their products. Moreover, companies often will be unable to correct inaccuracies on sites that they find but whose content they do not control. Even when sponsors take corrective measures, there is no guarantee that the sponsor’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.

¹² 21 U.S.C. § 321(m).

¹³ *Kordel v. United States*, 335 U.S. 345, 350 (1948) (“The false and misleading literature in the present case was designed for use in the distribution and sale of the drug, and it was so used. The fact that it went in a different mail was wholly irrelevant whether we judge the transaction by purpose or result. And to say that the prior or subsequent shipment of the literature disproves that it is misbranded when introduced into commerce within the meaning of [section] 301(a), is to overlook the integrated nature of the transactions established in this case.” (internal quotation marks omitted)). Accordingly, FDA regulations and guidance concerning labeling place obligations on the drug’s sponsor and not on independent third parties. *See, e.g.*, 21 C.F.R. § 314.81(b)(3) (requiring sponsors to submit advertisements and promotional labeling to FDA when such materials are made publicly available).

¹⁴ Black’s Law Dictionary 59 (8th ed. 2004) (defining advertising as “[t]he action of drawing the public’s attention to something to promote its sale.”).

¹⁵ FDA may consider a sponsor liable for content presented in an academic journal or at an academic event if the sponsor had the ability to control or dictate what was said in these forums. *See* FDA, Compliance Guide: Drug Product Entries in Periodic Publications (CPG 7132b.17) CPG § 400.700 (1989); FDA, Guidance for Industry-Supported Scientific and Educational Activities 3-5 (1997). Sponsors may also, in some circumstances, be accountable for the content of journal articles if the sponsor distributes reprints of such articles as part of its promotional activity. *See, e.g.*, FDA, Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (2009). Neither of these examples, however, could be characterized as holding a sponsor accountable for the statements of an unaffiliated third party.

Adverse Event Monitoring

America's research-based pharmaceutical companies take extremely seriously their obligation to investigate and report adverse event information to the FDA. Accordingly, PhRMA and its members believe that manufacturers should monitor their own web sites for reportable adverse events, and treat them as they would adverse event information taken from all other media.

PhRMA supports the international standard the Agency has adopted as part of the International Conference on Harmonisation (ICH).¹⁶ Under FDA's existing draft guidance, ICH E2D, states that Sponsors "are not expected to screen external websites for ADR information. However, if [a Sponsor] becomes aware of an adverse reaction on a website that it does not manage, the [Sponsor] should review the adverse reaction and determine whether it should be reported. [Sponsors] should regularly screen their websites for potential ADR case reports."¹⁷

Manufacturers are unable to monitor every web site, blog, or chat room for adverse events, but they can monitor sites that they control. Adverse event reporting should be based on the same criteria required to submit reports found in other media: an identifiable patient, an identifiable reporter, specific use of a drug or biologic, and an adverse event.

Consistent with the ICH standard, "Patient and reporter identifiability is necessary to avoid case duplication, detect fraud, and facilitate follow-up of appropriate cases. The term identifiable in this context refers to the verification of the existence of a patient and a reporter. One or more of the following automatically qualifies a patient as identifiable: age (or age category, e.g., adolescent, adult, elderly), gender, initials, date of birth, name, or patient identification number."¹⁸

In order to help assure reliable adverse event information from online sources, and also to respect patient and reporter privacy, FDA should only require manufacturer reporting of incidents discovered online, if online reporters are privately contactable (*i.e.*, it should be possible to communicate directly with the reporter without the need to post questions to a public forum to obtain more information).

Conclusion

In conclusion, PhRMA appreciates the efforts of FDA in organizing today's meeting. We hope to serve as a constructive partner as the Agency determines how best to regulate online promotional communications by manufacturers of medical products. I'm happy to answer your questions.

¹⁶ FDA's draft guidance was created as an international standard of the International Conference on Harmonisation (ICH), which brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions.

¹⁷ FDA, Post-Approval Safety Data Management: Definitions and Standards For Expedited Reporting -- ICH Harmonised Tripartite Guideline draft at 6 (2003), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm129458.pdf>.

¹⁸ *Id.* at 8.