

ARE YOUR META TAGS SHOWING?

PROMOTION OF FDA-REGULATED MEDICAL PRODUCTS USING THE INTERNET AND SOCIAL MEDIA TOOLS

EARLIER THIS YEAR, the FDA issued the first enforcement action against a pharmaceutical company for its use of a social media sharing tool in marketing a prescription drug. A notice of violation letter directed Novartis Pharmaceutical Corporation to stop disseminating allegedly misleading promotional content utilizing the “Facebook® Share” social media widget (letter posted August 4, 2010 on the FDA website).¹ The letter recognizes that Novartis submitted its “website content” to the FDA, but Novartis did not submit the “shared content” that website visitors could access by clicking on the Facebook Share widget.²

Although the shared content actually was generated by the Facebook Share widget, Novartis’s website developer added the plug-in to the Novartis website and coded the meta tags and link(s) that were incorporated by the widget. The FDA determined that this content was completely controlled by Novartis because Facebook users could not modify the content.³ The drug product information ultimately posted via the Facebook widget did not include any of the required risk disclosures. The FDA found that the communication was misleading even though the shared content contained a hyperlink to appropriate drug product safety information.⁴

Fortunately for pharmaceutical companies, the FDA letter to Novartis does not indicate that the FDA is concerned about promotion through social media marketing channels per se. There are no regulations that prohibit the use of certain types of media to promote drugs.⁵ Rather, the letter focuses solely on compliance with existing FDA regulations in all media. But is the FDA ignoring the realities of internet usage and space-limited social media marketing tools?

Eighty-two percent of American adults use a mobile communication device,⁶ and six in ten now have wireless access to infor-

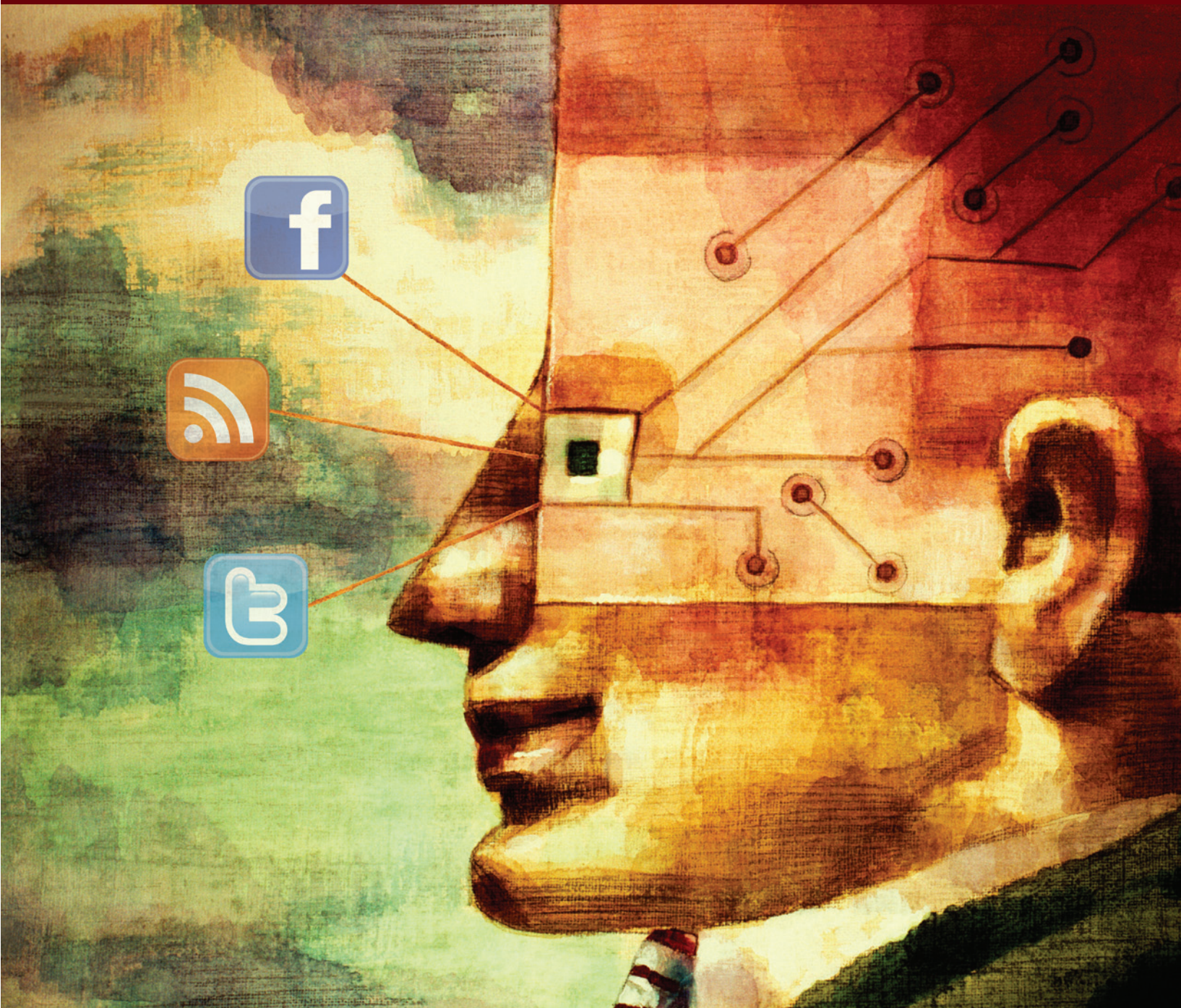
FACEBOOK’S USER POPULATION IS NOW LARGER THAN THAT OF THE U.S., MEXICO, AND FRANCE COMBINED.

mation (using either a laptop or cell phone).⁷ Now that advanced wireless communication devices can fit in a pocket, access to interactive communication and information has become extremely portable. Susannah Fox, Associate Director, Digital Strategy with the Pew Research Center, believes that wireless access is causing a radical change in internet use: “Mobile devices are changing us [...] as internet users, making us more likely to share, more likely to access information on the go, and [...] erasing the digital divide.”⁸

As the internet’s ability to facilitate communication has evolved, a variety of advanced social media tools has emerged and been embraced by the public. In July of this year, Facebook announced that it reached a record half a billion users.⁹ Facebook’s user population is now larger than that of the U.S., Mexico, and France combined.¹⁰ Today, 61% of adult internet users use social networks (an increase of 33% since April 2009).¹¹ Moreover, Americans spend more than a third of their online time communicating and networking across social networks, blogs, personal email, and instant messaging.¹²

Patients in unprecedented numbers are turning to the internet to find health information: 61% of American adults (83% of internet users) report that they look online for health information.¹³ “The convergence of media (computers, telephones, television, radio, video, print, and audio) and the emergence of the Internet create a nearly ubiquitous networked communication infrastructure. This infrastructure facilitates access to an increasing array of health information and health-related support services and extends the reach of health communication efforts.”¹⁴

In a national survey, sixty percent (60%) of online consumers said that social media is



“a trusted resource” they use when searching for health information online.¹⁵

“76% of online consumers want to obtain [health-related] information from other people who share the same medical condition; 73% from doctors or other healthcare providers; 66% from friends and family”¹⁶

The U.S. Department of Health and Human Services Healthy People 2010 (HP2010) report stresses the importance of internet access to provide patients with relevant health information.¹⁷ One of the identified goals is to increase the proportion of households with access to the internet at home 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.”¹⁸ Moreover, “[t]he health impact of interactivity, customization, and enhanced multimedia is just beginning to be explored, and already interactive health communication technologies are being used to exchange information, facilitate informed decision making, promote healthy behaviors, enhance peer and emotional support, promote self-care, manage demand for health services, and support clinical care.”¹⁹

As internet users spend more time engaged in social media, drug companies want to participate in the dialogue. However, the reality is that pharmaceutical companies are struggling to keep up with the media preferences of today’s healthcare consumer. Considering the legal and regulatory issues involved in direct-to-consumer advertising, it is no wonder that the pharmaceutical industry isn’t exactly sure how to take advantage of new communication technologies in a responsible way.

Interactive media has raised many questions about the application of existing FDA regulations to the newer media.²⁰ The FDA has yet to provide clear guidance specifically addressing regulated promotional communication using internet and social media tools. In the meantime, the “FDA has continued enforcement actions without these clear standards,” said Jeff Francer, a lawyer



at the Pharmaceutical Research and Manufacturers of America (PhRMA).²¹

Recognizing the massive expansion of new tools and technologies (including blogs, microblogs, podcasts, social network sites, online communities, video sharing, widgets, and wikis), the agency held a public hearing in November 2009 to discuss how the statutory provisions and regulations should be applied to digital and interactive marketing media. Written comments were accepted through February of this year. Based on its Guidance Agenda, it appears that the FDA intends to publish draft guidances on advertising by the end of this year, including “Promotion of Prescription Drug Products Using Social Media Tools.”²²

Thomas Abrams, director of the DDMAC, has indicated that the agency may issue multiple, targeted guidances instead of a single

guidance document covering all forms of online promotion to give the DDMAC flexibility in addressing new technologies.²³ Further, Abrams said that such guidances will likely address specific issues or circumstances rather than a particular media or technology.²⁴ In the meantime, the Novartis notice of violation letter partially clarifies the FDA’s viewpoint on drug product promotion in the context of social sharing:

- The FDA did not prohibit the use of social media tools to promote drugs.

The FDA applied the same standard to social media as it has to other forms of pharmaceutical promotional ads/communications.

- Appropriate safety information should be included in all direct-to-consumer promotional social media communications.

- The DDMAC will apply the “fair bal-

ance”²⁵ standard to metadata content, without exception for space-limited media tools.

- The FDA has rejected the “one-click” rule; hyperlinks to risk information are insufficient to mitigate omission of relevant information from the message.

- Because many common sharing tools create shared messages/content by combining and copying meta tags, the metadata code *on each page* of the website used by these tools should be carefully reviewed for compliance with all FDA regulatory requirements and submitted to the FDA as promotional material. Safety information must be included in meta tag descriptions if the copy will likely become generated content for promotional material.

- It is important to understand exactly how sharing tools and search engines function, how content will be developed, how meta tags may be used, and the form in which the content will be ultimately be disseminated.

- Until specific regulations or guidelines are issued, meta descriptions used by sharing widgets should not reference branded drug indications, or the meta descriptions should not be branded at all. Shared metadata/content should not exceed the character-count limitations of the social media widget.

- It may be necessary to select/develop sharing tools that allow customized control over the message without relying on metadata.

- Any and all company-controlled content intended for use by social share widgets must comply with regulations and should be submitted to the FDA as promotional material.

Notwithstanding FDA’s prior rejections of hyperlink solutions, industry stakeholders have requested that the agency reconsider the effectiveness of hyperlink disclosures in the case of technologies with severe space limitations, explaining that “[c]onsumers on the Internet are accustomed to viewing pop-ups, rollover text, links and other communication mechanisms.”²⁶ Another proposal would involve the use of an FDA-approved symbol and a standard universal warning in combination with hyperlinks and/or abbreviated descriptions in cases where it is not feasible to include complete safety information (*e.g.*, Twitter and other microblogs).²⁷

Interactive health communication technologies are already being used to exchange information, facilitate informed decision making, promote healthy behaviors, enhance peer and emotional support, promote self-care, manage demand for health services, and support clinical care.²⁸ As the primary authoritative source of information about their prescription products, pharmaceutical companies can help ensure that scientifically accurate, meaningful, and balanced product information is disseminated to all social media audiences.

¹ Food and Drug Administration. Notice of Violation Letter to Novartis Pharmaceuticals Corporation. Division of Drug Marketing, Advertising and Communications, 7/30/10, 8/4/10. Available at <<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticesofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf>>. Last accessed Oct. 7, 2010.

² Widgets, like the Facebook Share widget, are common sharing plug-ins that allow visitors to click a “button” to share/repost content to a social media site. This information may then be shared with other social media users in various ways (as in newsfeeds or wall postings).

³ See Novartis Letter, *supra* note i, pp. 1, 2.

⁴ See Novartis Letter, *supra* note i, p. 3.

⁵ Food and Drug Administration, Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Federal Register, 181. Sept. 21, 2009, p. 48085.

⁶ Lenhart, Amanda. “Cell Phones and American Adults. Pew Internet & American Life Project.” Sept. 2, 2010. Available at <<http://pewinternet.org/Reports/2010/Cell-Phones-and-American-Adults/Overview.aspx>>. Last accessed Sept. 10, 2010.

⁷ Smith, Aaron. “Mobile Access 2010. Pew Internet & American Life Project,” July 7, 2010. Available at: <<http://www.pewinternet.org/Reports/2010/Mobile-Access-2010.aspx>>. Last accessed Sept. 12, 2010.

⁸ Fox, Susannah. “The Power of Mobile, Commentary. Pew Internet & American Life Project.” Sept. 13, 2010. Available at <<http://www.pewinternet.org/Commentary/2010/September/The-Power-of-Mobile.aspx>>. Last accessed Sept. 13, 2010.

⁹ Johnson, Robert. Scaling Facebook to 500 Million Users and Beyond. July 21, 2010. Facebook.com. Available at <<http://www.facebook.com/notes/facebook-engineering/scaling-facebook-to-500-million-users-and-beyond/409881258919>>. Last accessed Sept. 10, 2010.

¹⁰ Pepitone, Julianne. Facebook Hits 500 Million Users. July 21, 2010, CNN Money.com. Available at <http://money.cnn.com/2010/07/21/technology/facebook_500_million/index.htm>. Last accessed Sept. 12, 2010.

¹¹ Madden, Mary. “Older Adults and Social Media. Social Networking Use.” Aug. 27, 2010. Available at <<http://pewinternet.org/Reports/2010/Older-Adults-and-Social-Media.aspx>>. Last accessed Oct. 7, 2010.

¹² “What Americans Do Online: Social Media And Games Dominate Activity.” The Nielsen Company. Aug. 2,

2010. Last updated Aug. 6. Available at <http://blog.nielsen.com/nielsenwire/online_mobile/what-americans-do-online-social-media-and-games-dominate-activity>. Last accessed Sept. 12, 2010.

¹³ Fox, Susannah and Jones, Sydney. “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.” June 2009. Available at <<http://www.pewinternet.org/Reports/2009/8-The-Social-Life-of-Health-Information/02-A-Shifting-Landscape/1-Americans-are-tapping-into-a-widening-network-of-both-online-and-offline-sources.aspx>>. Last accessed Oct. 7, 2010.

¹⁴ HHS, Healthy People 2010 vol. 1, ch. 11, “Health Communication.” Available at <<http://www.healthypeople.gov/document/HTML/Volume1/11HealthCom.htm>>. Last accessed Oct. 7, 2010.

¹⁵ Rodale Inc. “Prevention Magazine Releases 13th Annual DTC Survey Results.” July 15, 2010. Available at <<http://www.rodaleinc.com/newsroom/ipreventioni-magazine-releases-13th-annual-dtc-survey-results>>. Last accessed Sept. 13, 2010.

¹⁶ *Id.*

¹⁷ See Healthy People 2010, *supra* note xiv.

¹⁸ See Healthy People 2010, *supra* note xiv, Goal 11-1.

¹⁹ See Healthy People 2010, *supra* note xiv.

²⁰ Food and Drug Administration, Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Federal Register, 181 (21 September 2009), p. 48085.

²¹ Heavy, Susan and Richwine, Lisa. “Outgunned FDA Tries To Get Tough with Drug Ads.” Sept. 3, 2010. Available at <<http://www.reuters.com/article/idUSTRE6821PN20100903>>. Last accessed Sept. 12, 2010.

²² FDA. “Guidance Agenda: New Draft Guidances CDER is Planning to Publish During Calendar Year 2010.” Available at <<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079647>>. Last accessed Oct. 7, 2010.

²³ “DDMAC: Social Media Guidance Likely To Be Split Into Multiple Documents.” June 15, 2010. Available at <<http://www.thompson.com/public/newsbrief.jsp?cat=FOODDRUG&id=2906>>. Last accessed Oct. 7, 2010.

²⁴ *Id.*

²⁵ In direct-to-consumer advertising, fair balance refers to the presentation of accurate and fair assessment of the risks as well as the benefits of the drug. See Federal Food, Drug, and Cosmetic Act, Part 202: Prescription Drug Advertising (21 CFR 202.1(e)(7)(viii)).

²⁶ Francer, Jeffrey K. “Pharmaceutical Research and Manufacturers of America, Statement of Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools.” Nov. 12-13, 2009. Available at <http://www.phrma.org/issues/fda_issues/phrma_comments_about_promotion_fda_regulated_products_using_internet_and_social_me>. Last accessed Oct. 7, 2010.

²⁷ *Id.*

²⁸ See Healthy People 2010, *supra* note xiv.

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