THE REVIEW OF
MEDICAL INFORMATION MANAGEMENT
FOR LITIGATION

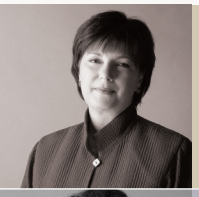
MIM REPORTER

NOVEMBER 2014 EDITION

Published by Litigation Management, Inc.

What's New at LMI

- LMI received national certification as a Women's Business Enterprise by the Ohio River Valley Women's Business Council, a regional certifying partner of the Women's Business Enterprise National Council (WBENC).
- LMI staffers have been named to several leadership positions with the Defense Research Institute (DRI): Sarah Lovequist is Program Chair of the 2015 Nursing Home/ALF Litigation Seminar; Megan Pizor is Program Vice-Chair of the 2015 Trial Tactics Seminar; Angela Browning is Chair of the Women in the Law Committee's social media subcommittee.



Elizabeth B. Juliano
Founder & Chief Executive Officer

Sarah E. Lovequist
Director, Marketing Communications

Free Speech, In 140 Characters or Less

The waiting is the hardest part
Every day you see one more card
You take it on faith, you take it to the heart
The waiting is the hardest part
~Tom Petty, "The Waiting"

Drug and device makers have been waiting for the U.S. Food and Drug Administration (FDA) to promulgate social media advertising guidelines since 2009 - prior to 2014, firm guidelines had not been issued, and drug and device companies were not given concrete guidance about what information must be included in social media communications, or their responsibility for same. The FDA has long recognized that it is behind when it comes to being prepared to handle the demands and pressures of social media.
cont. p.2 >

www.lmiweb.com

Free Speech, In 140 Characters or Less (cont.)

As stated in its 2011 Federal Register notice, "the original regulations that presently determined the FDA's position on Direct-to-Consumer (DTC) promotion were written at a time when the available media for DTC promotion were print and broadcast, and the primary audience was health care professionals. This dynamic is shifting, and evidence is needed to support guidance development." [i]

The landscape changed in June 2014 when FDA released long sought-after draft guidances on pharmaceutical and medical device companies' use of social media.[ii] Two draft guidances were presented for comment: "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices,"[iii] offers instructions on how companies should go about and/or attempt to correct product information on web sites other than the company's own; "Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices,"[iv] instructs how products, including risk benefit information, should be discussed in limited-space venues such as Twitter, or in paid search links on Google or Yahoo.

Using social media as a marketing tool makes good sense: statistics reveal that, as of January 2014, 74% of online adults use social networking sites.[v] This same percentage likely includes a large portion of existing and potential drug and device customers, making social media a relatively inexpensive way to reach millions. The drug and device industries are concerned, though, that the FDA's recent guidances are not really guidelines at all, but rather a way to deter manufacturers from engaging in social media.

The Nuts and Bolts

On July 10, 2014, FDA hosted a public webinar to explain each of the draft guidances, and to suggest ways to comply with each. For example, the "Character Space Limitations" draft guidance dictates that, regardless of a platform's character space constraints, product benefit claim messages must incorporate risk information and a link that allows direct access to a more complete discussion of the associated risks within the same message. Risk information should, at minimum, communicate the most serious risk associated with the product, with risk information and benefit information sharing equal prominence. Platforms like Twitter, online paid search platforms like Google and Yahoo "sponsored links," and future character-space-limited internet/social media platforms are all within the scope of this draft guidance. Product websites, actual web pages on social media networking platforms like Facebook, Twitter and YouTube, online web banners, and responsive web design presentations on mobile devices or tablets are not included.[vi]

FDA's chief concern is that character-limiting platforms "may not enable meaningful presentations of both benefit and risk," especially when products have complex indications or extensive serious risks. Similarly, FDA clearly advises that, if benefit and risk information cannot all be conveyed in the same message, the user should reconsider its use of a character-limiting platform to deliver its message. For every post touting a certain medication's benefit, FDA demands equal reporting of the associated risks, including a link to more information, but compacting all of this information into Twitter's 140 character limit is unrealistic. Industry now argues that this long-awaited guidance effectively limits manufacturers' marketing options on limited-character sites.

Conversely, the "Correcting Independent Third-Party Misinformation" draft guidance encourages manufacturers to correct drug and device misinformation that it did not create. A company's own advertising or promotional labeling is excluded, as are adverse event reports and corrective messages sent in response to warning letters. Firms are generally permitted to voluntarily correct misinformation that falls within this guidance, such as communications not created by the manufacturer, third party info on a third party site, third party information posted to a company's site; "misinformation" includes both positive and negative incorrect representations or implications. Per the FDA, "if a firm corrects misinformation in a truthful and non-misleading manner per the guidance, FDA does not intend to object if appropriate corrective information does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising (if any)." FDA further explains that appropriate corrective information should include FDA-required and approved labeling, as well as the following:

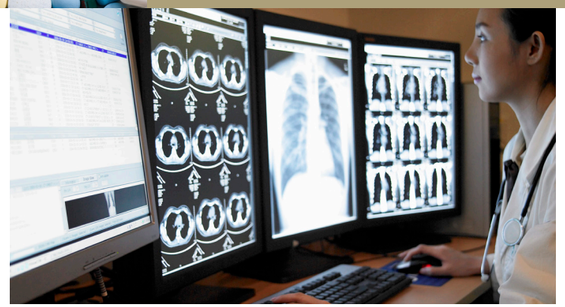
- Be relevant and responsive to the misinformation;
- Be limited and tailored to the misinformation;
- Be non-promotional in nature, tone, and presentation;
- Be accurate;
- Be supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs;
- Either be posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or should reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author); and
- Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.

If there are technological reasons why a company is unable to take these corrective steps, contacting the author or site administrator of the misinformation will also suffice. Fortunately, FDA has clearly stated that companies are not accountable for the misinformation if a third party declines to post corrective information or remove the misinformation.

Within several days of releasing guidelines for use of limited-character platforms and promoted links, FDA, on June 27, 2014, sent a warning letter to Gilead Sciences, Inc., for its promotion of Viread® tablets and powder on Google.com.[vii] Among other violations, FDA noted that Gilead's sponsored link was "misleading because it makes representations and/or suggestions about the efficacy of Viread®, but fails to communicate any risk information associated with the use of this product," including the boxed warning. Although it is actively enforcing the draft guidances, FDA has remained silent on its actual enforcement plan, again leaving the industry waiting for answers.

Industry Reactions

Various industry representatives took advantage of the initial public comment period and expressed concerns with both guidances. Numerous comments were submitted on the "Character Space Limitations" draft



Industry Reactions (cont.)

guidance, with individual comments submitted by Teva Pharmaceuticals, Eli Lilly, Novo Nordisk, and Pfizer - all comments expressed the same general concerns regarding presentation of risk and benefit information through Twitter. Several industry groups agreed with the manufacturers' comments and escalated the breadth of the debate by questioning the draft guidance's constitutionality.

1) Reactions to "Character Space Limitations" Draft Guidance

As explained above, every brand-oriented tweet must contain risk and benefit information, which leaves little room within Twitter's 140-character limit for actual messaging or marketing. Manufacturers argue that FDA's regulations defeat the purpose of social media, and infringe on companies' First Amendment rights by unnecessarily limiting free speech and branding.

The draft guidance is overreaching, according to several industry leaders. Jeffrey K. Francer, vice president and senior counsel with Pharmaceutical Research and Manufacturers of America (PhRMA), thinks the guidelines interfere with the First Amendment: "If the FDA is going to require the same type of fine print that you see in a magazine ad to be in a tweet, then the FDA is essentially taking that tool away from patients who may want to hear from companies as well as healthcare professionals . . . I assume that the FDA believes that its own tweets are truthful and not misleading. If they believe that, then why couldn't a company use Twitter in the same way that the FDA is using Twitter?" [viii]

Likewise, the Biotechnology Industry Organization (BIO) points out that "the provision by a manufacturer of truthful and not misleading information about a manufacturer's products has constitutional protection under the First Amendment. A manufacturer should have flexibility to participate in the scientific and medical dialogue that is occurring constantly via Internet and social media platforms, and to share information about its products . . . so long as it does so in a manner that is truthful and not misleading, even if the precise content may be inconsistent with [the draft guidance]." [ix] The Washington Legal Foundation (WLF) also has "grave concerns regarding several provisions" of the guidance, and cautions FDA that a "de facto prohibition on use of such Internet/social media platforms is inconsistent with FDA's statutory mandate and raises serious First Amendment concerns regarding the rights of manufacturers to speak truthfully on important health care issues." [x] WLF ultimately urges FDA to completely withdraw the draft guidance and "replace it with one that respects statutory and constitutional constraints on FDA's authority."

As pointed out by the Medical Information Working Group (MIWG), the draft guidance on its face imposes both content- and speaker-based restrictions that contradict current precedent. The draft guidance advises that, "for some products, particularly those with complex indications or extensive serious risks, character space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk . . . If an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message . . ." [xi] MIWG emphasizes that the draft guidance, particularly the above advisement, contradicts FDA's own use of Twitter for drug approvals, a position echoed by PhRMA. [xii] In fact, PhRMA proposes that FDA's own Twitter usage, in which only drug benefit information is conveyed, should set the standard for appropriate use of character-limited platforms. [xiii]

From a device perspective, the Advanced Medical Technology Association (AdvaMed) generally supports FDA initiatives, but would like "FDA to adopt a more flexible approach that supports truthful and non-misleading information while better reflecting the unique attributes and use of Internet and social media tools and appropriate use of links to support these communications and future advances in evolving media." [xiv] AdvaMed fully believes that a more flexible approach "can promote the public health and meet regulatory requirements while not preempting or otherwise discouraging such online communications." To this end, AdvaMed would like to see more device-specific guidelines and/or examples from FDA so that the guidance is appropriately applied to medical devices -a-one-size-fits-all approach does not, in fact, work for the medical device industry since FDA's specific authority over devices is limited to "(i) restricted device advertising (typically for Class III devices, which are subject to premarket approval) and (ii) device labeling (Class I, II, and III)." [xv]

2) Reactions to "Correcting Independent Third-Party Misinformation" Draft Guidance

Generally speaking, commenting entities are pleased that FDA recognizes the impossibility of manufacturers policing every facet of internet communication. This draft guidance indicates that manufacturers are not obligated to correct misinformation generated by third parties, and FDA understands that manufacturers cannot control whether an independent third party actually corrects flagged misinformation.

Several respondents, including the Medical Imaging and Technology Alliance (MITA), question FDA's expectations for manufacturers when responding to third party user-generated comments about off-label use – often simply stating that the discussed use is off-label is not sufficient to address the safety concerns of off-label use, and FDA must outline how it expects manufacturers to handle such situations. [xvi] Respondents, including Novartis, BIO and AdvaMed, have requested clarification on what manufacturer behavior constitutes "control," "involvement," or "influence" over user-generated content.

WLF ultimately urges FDA to completely withdraw the draft guidance and "replace it with one that respects statutory and constitutional constraints on FDA's authority."

Industry Reactions (cont.)

Constituents are also concerned that the definition of "misinformation," as used in the draft, is broad and subject to misinterpretation.

MIWG is particularly troubled that manufacturers may be responsible for content they "influence" or are tangentially involved with, and urges FDA to hold manufacturers accountable for online and social media content only to the extent the content was developed or posted by or on behalf of the manufacturer; if a manufacturer has disengaged from a conversation, it should not incur responsibility for user-generated content.[xvii]

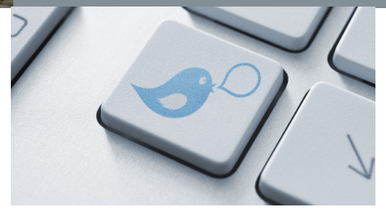
Likewise, PhRMA raises "two fundamental concerns" with the draft guidance: "that a biopharmaceutical manufacturer can be held accountable for content written by third-parties on third-party web sites if the company merely influences the third party . . . [and that] the Draft Guidance appears to recognize that some statements on social media correcting misinformation are neither labeling nor advertising, but fails to give guidance as to what kinds of statements would be regulated as such."[xviii] Both MIWG and PhRMA believe "influence" as it is set out in the current draft is overbroad, and FDA should eliminate the "influence" test in determining whether manufacturers are responsible for third-party online communications; the final guidance must clearly define when manufacturers are responsible for third-party communications.

Conversely, the National Physicians Alliance (NPA) applauds FDA's efforts, and further urges the FDA to hold companies responsible for the accuracy of all product information that appears to be promotional, whether or not the company chooses to correct the information, and regardless of whether the company is the direct or indirect source of the information. According to NPA, "only a strict requirement to correct misinformation would ensure that patients are not misled."[xix] The Patient, Consumer, and Public Health Coalition agrees with NPA's position, and points out anticipated problems with web sites like Wikipedia because the content, specifically related to medical products, varies greatly in balance and accuracy.[xx] Comments like these illustrate the balancing act FDA must perform when crafting draft guidances. While accurate information and patient safety are the goals, rules that potentially infringe on constituents' free speech rights risk creating an imbalance.

Conclusion

While both draft guidances appear complete and even include instructive examples, several industry questions remain unanswered: is the manufacturer responsible for retweets of its original, compliant tweet? What about if the original tweet sparks an online conversation in which the manufacturer does or does not engage? How should space-limited, but not character-limited, platforms like Facebook and YouTube be used? Based on comments submitted in response to the draft guidances, the drug and device industry needs FDA to retool its current thinking.

To date, the FDA has defended its limited-character platform restrictions as necessary protection for the public health. Thomas Abrams, Director of the FDA's Office of Prescription Drug Promotion, states in his



blog that the guidances were designed to benefit patients. "These documents strive to ensure that the information provided by drug and device companies is accurate and will help patients to make well-informed decisions in consultation with their health care providers. We understand that communicating on electronic Internet sites with character space limitations can be challenging. But, no matter the Internet source used, benefit claims in product promotions should be balanced with risk information. And companies should provide a way for consumers to gain direct access to a more complete discussion of risks associated with their products."[xxi] The public comment period for these two guidances originally closed on September 16, 2014, but, on September 29, 2014, it was reopened by FDA for an additional month; the new comment period closed on October 29, 2014. By reopening the comment period, FDA acknowledges that the guidances are not flawless, and appears to be concerned with meeting industry expectations.

Generally speaking, until draft guidance revisions are made, the industry has limited social media options: it can continue to do very little social media advertising or it can continue to engage in non-product based social media advertising. The industry must also continue to actively monitor third-party information about specific products in order to find misinformation, positive and negative, and determine if it is egregious enough to warrant correction. Consistent corrective action is necessary, and correcting only "cherry picked" information goes against FDA's purpose. While FDA is aware of potential First Amendment free speech challenges to the current versions of the guidances, manufacturers must remember that speech that violates the law is not protected speech under the First Amendment, and product promotion that violates current regulations will not be protected. FDA will hopefully continue to refine and expand its social media guidances, and, with industry assistance, craft guidances that are mutually acceptable.

THANK YOU for subscribing to the MIM Reporter!

If you would prefer to receive your copy of the MIM Reporter electronically, please send us an email containing your name, firm name and email address to: **research@lmiweb.com**

Litigation Management, Inc. 6000 Parkland Boulevard, Mayfield Heights, Ohio 44124
Published as an educational service to the Corporate, Insurance and Defense Legal Community.

references

i "Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Online Direct-to-Consumer Prescription Drug Promotion (Notice)," Federal Register 76:82 (April 28, 2011) p. 23821. Available from: ProQuest Congressional; Accessed: 6/30/11.

ii FDA also released a draft guidance, "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics," in January 2014; same is not discussed within.

iii U.S. Department of Health and Human Services, Food and Drug Administration, "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices," Center for Drug Evaluation and Research, June 18, 2014, August 25, 2014, http://www.fda.gov/downloads /Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

iv U.S. Department of Health and Human Services, Food and Drug Administration, "Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices," Center for Drug Evaluation and Research, June 18, 2014, August 25, 2014, http://www.fda.gov /downloads /Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.

v "Social Networking Fact Sheet," Pew Research Center Internet Project, January 26, 2014, October 14, 2014, http://www.pewinternet.org/fact-sheets/social-networking-fact-sheet/.

vi "Social Media Guidance Webinar," U.S. Food and Drug Administration, July 10, 2014, August 25, 2014, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm403810.htm.

vii Oluwaseun A. Asnte and Samuel M. Skariah, FDA Warning Letter to Naumann Chaudry at Gilead Sciences, Inc., Department of Health & Human Services, Food and Drug Administration. June 27, 2014, August 25, 2014.

viii Alexandra Sifferlin, "The FDA is Cracking Down on Big Pharma Social Media," TIME, July 11, 2014, August 25, 2014, http://time.com/2976537/the-fda-is-cracking-down-on-big-pharma-social-media/.

ix Jeffrey S. Peters, Biotechnology Industry Organization (BIO), "Docket No. FDA–201-D-0397: Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices," letter, addressed to Dockets Management Branch of the Food and Drug Administration, September 16, 2014.

x Richard A. Samp and Cory L. Andrews, Washington Legal Foundation (WLF), "Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices Docket No. FDA-2014-N-0168, 79 Fed. Reg. 34759 (June 18, 2014)," letter, addressed to Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xi U.S. Department of Health and Human Services, Food and Drug Administration. "Internet/Social Media Platforms with Character Space Limitations . . .", *supra.*

xii Coleen Klasmeier, Paul E. Kalb, Alan Bennett, Joan McPhee, Medical Information Working Group (MIWG), "Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations - Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Docket No. FDA-2014-D-0397)," letter, addressed to Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xiii Jeffrey K. Francer, Pharmaceutical Research and Manufacturers of America (PhRMA), "Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations - Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Docket No. FDA-2014-D-0397)," letter, addressed to Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xiv Khatereh Calleja, Advanced Medical Technology Association (AdvaMed), "Docket No. FDA-2014-D-0397; Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations; Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices," letter, addressed to Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xv *Id.*

xvi Gail Rodriguez, Medical Imaging & Technology Alliance (MITA), "Federal Register Docket # FDA-2014-D-0447-0001, "Draft Guidance for Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices"," letter, addressed to Margaret Hamburg, September 16, 2014.

xvii Coleen Klasmeier, Paul E. Kalb, Alan Bennett, Joan McPhee, Medical Information Working Group (MIWG), "Draft Guidance for Industry: "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" (Docket No. FDA–2014–D–0447)," letter, addressed to Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xviii Jeffrey K. Francer, Pharmaceutical Research and Manufacturers of America (PhRMA), "Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Docket No. FDA-2014-D-0447)," letter, addressed to Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xix Lisa Plymate and William Jordan, National Physicians Alliance (NPA), "FDA-2014-D-0447-0001," letter, September 16, 2014.

xx Members of the Patient, Consumer, and Public Health Coalition, "Comments of members of the Patient, Consumer, and Public Health Coalition on Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices Docket No. FDA-2014-D-0447," letter, Division of Dockets Management of the Food and Drug Administration, September 16, 2014.

xxi Thomas Abrams, "FDA Issues Draft Guidances for Industry on Social Media and Internet Communications About Medical Products: Designed with Patients in Mind," FDAVoice, U.S. Food and Drug Administration, June 17, 2014, http://blogs.fda.gov/fdavoice/index.php/2014/06/fda-issues-draft-guidances-for-industry-on-social-media-and-internet-communications-about-medical-products-designed-with-patients-in-mind/.