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September 16, 2014

Via Electronic Submission

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" (Docket No.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)

The Medical Information Working Group ("MIWG")[1] welcomes the opportunity to provide the Food and Drug Administration ("FDA") with comments on the draft guidance "Internet/Social Media Platforms: Correcting Misinformation About Prescription Drugs and Medical Devices" ("*Draft Guidance*"), pursuant to the Federal Register notice dated June 18, 2014.

[1] The MIWG is a coalition of medical product manufacturers formed to consider issues relating to the federal government's regulation of truthful, non-misleading, scientifically substantiated manufacturer communications about new uses of approved drugs and approved/cleared medical devices. The members of the MIWG are: Allergan, Inc.; Amgen Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceutical Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; Purdue Pharma L.P.; and Sanofi US. The MIWG and its members have made these submissions to the Agency since 2008: (1) Comments, Draft Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses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, Docket No. FDA-2008-D-0053 (Apr. 18, 2008); (2) Amended Comments, FDA Transparency Task Force, Docket No. FDA-2009-N-0247 (Apr. 15, 2010); (3) Citizen Petition, Docket No. FDA-2011-P-0512 (July 5, 2011); (4) Comments re: Scientific Exchange and Responses to Unsolicited Requests, Docket Nos. FDA-2011-N-0912 and FDA-2011-D-0868 (Mar. 27, 2012); (5) Comments, Docket Nos. FDA-2011-P-0512 and FDA-2011-D-0868 (Mar. 1, 2013); (6) Comments, CDER Medical Policy Council, Docket No. FDA-2013-N-0206 (July 16, 2013); (7) Citizen Petition, Docket No. FDA-2013-P-1079 (Sept. 3, 2013); (8) Comments, Food and Drug Administration Safety and Innovation Act Section 907 Report (Nov. 20, 2013); (9) Comments, Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, Docket No. FDA-2013-N-1430 (Apr. 14, 2014); (10) Comments, Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses- Recommended Practices, Docket No. FDA-2008-D-0053 (May 2, 2014); (11) Comments re: FDA's Draft Strategic Priorities for 2014–2018, Docket No. FDA-2014-N-0833 (Jul. 31, 2014); and (12) Comments, Draft Guidance for Industry: Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices, Docket No. FDA-2014-D-0758 (Aug. 25, 2014). The MIWG has also participated as amicus curiae in litigation relating to the role of manufacturers in distributing information containing information about new uses. *See* Brief Amicus Curiae for MIWG, *United States v. Caronia*, No. 09-5006-CR, 703 F.3d 149 (2d Cir. 2012).

The MIWG appreciates that FDA has provided additional guidance with respect to correcting misinformation that appears online or on social media platforms. In particular, we are pleased that the Agency has explicitly acknowledged that product manufacturers are not obligated to correct misinformation generated by independent third parties, and that the *Draft Guidance* properly recognizes that a manufacturer cannot control whether an independent third party actually corrects misinformation discovered by a manufacturer.[2] Furthermore, we appreciate that FDA has acknowledged the voluminous and dynamic nature of online and social media communications by clarifying that manufacturers are not obligated to correct all misinformation on a particular forum or to monitor the forum on an ongoing basis. We are nevertheless concerned that the *Draft Guidance* advances an impermissibly broad interpretation of FDA's authority to regulate manufacturer speech by taking the position that manufacturers are accountable for third-party communications that they have influenced or with which they are involved.[3]

The *Draft Guidance*'s Standard for Determining When Manufacturers May Be Accountable for Online or Social Media Content is Overbroad

The recommendations provided in the *Draft Guidance* apply only if a manufacturer is *not* "responsible" for the product communication that contains the misinformation.[4] If a manufacturer is in the Agency's view responsible for the communication, the manufacturer is obligated to post corrective information in a manner that complies with applicable regulatory requirements related to advertising and labeling (e.g., comparable presentation of benefits and risks, submission of the material to FDA on Form 2253).[5] The *Draft Guidance* states that "[a] firm is responsible for communications that are owned, controlled, created, or influenced, or affirmatively adopted or endorsed, by, or on behalf of, the firm."[6] Further, it warns that "a firm's control over, involvement with, or influence over a product-related communication, even when generated by a third party, may result in the firm being responsible for the information as a promotional communication. Thus, firms might be responsible for [user generated content ("UGC")] that they solicit or influence, regardless of the forum."[7]

The *Draft Guidance* inappropriately considers a manufacturer's "influence" as dispositive to the threshold question of whether a manufacturer is responsible for correcting misinformation online or on social media platforms. This approach follows a concerning trend first identified in FDA's *Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, which was issued in January of 2014.[8] In that draft guidance document, the question of responsibility hinges on whether a manufacturer may have control or influence over the content—even if that influence is limited.[9] The MIWG noted in comments to

[2] *Draft Guidance* at 3, 8.
[3] Note that the concerns described herein are not exhaustive; we have limited our comments to those that are most fundamental to the MIWG's efforts in seeking FDA alignment with appropriate limits on the regulation of manufacturer speech.
[4] *Id*. at 3.
[5] *See, e.g., id*. at 4 n.6, 5.
[6] *Id*. at 3.
[7] *Id*. at 5.
[8] Docket No. FDA-2013-N-1430 (*hereinafter Draft Guidance on Interactive Promotional Media*).
[9] *Id*. at 3.

the docket that the approach was inconsistent with the Federal Food, Drug, and Cosmetic Act ("FDCA") and represented a departure from previous Agency policy.[10] Here, the Agency goes even further by suggesting that a manufacturer may be held accountable for third-party content when the manufacturer has mere "involvement with" the product-related communication.

As we stated in our comments to the January 2014 *Draft Guidance on Interactive Promotional Media*, the standard FDA has proposed to assess manufacturer responsibility for online or social media content is overbroad. The FDCA authorizes FDA to regulate manufacturer communications only so long as they constitute "advertising" or "labeling." Section 502(n) of the FDCA establishes content requirements for "advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer. . . ."[11] The description of labeling in FDA regulations is similarly limited to materials disseminated "by or on behalf" of the manufacturer.[12] With respect to both advertising and labeling, then, the FDCA and FDA implementing regulations clarify that FDA's authority covers only the manufacturer's own materials. The Agency has accordingly confirmed that it "does not generally investigate what parties other than the NDA holder have to say about prescription drugs."[13] Furthermore, FDA has indicated in prior guidance, *Guidance for Industry: Industry-Supported Scientific and Educational Activities* ("*ISSEA Guidance*"), that manufacturers may exert limited influence over third-party content without converting it to the manufacturer's own speech. The *ISSEA Guidance* lists a number of factors relevant to the determination of whether a particular activity is independent of the manufacturer, and none of those factors are solely determinative to the inquiry—regardless of whether some amount of manufacturer influence has occurred. FDA explicitly stated in connection with the *ISSEA Guidance*, moreover, that manufacturers could engage with third parties by providing limited technical support,[14] making clear that manufacturer involvement with the third-party communication is appropriate in some circumstances.[15]

The *Draft Guidance*, by contrast, indicates that manufacturers may be responsible for content that they influence or are involved with, even if the content is generated by a third party. In addition to the lack of statutory authority and precedential support for this standard, as described above, it is impracticable in the internet and social media context, where interactive communications are the norm and UGC is unpredictable. On Facebook pages, Twitter feeds, online message boards, and similar fora, companies routinely engage prescribers, patients, and caregivers. The examples cited in the *Draft Guidance* fail to address a common practice in which manufacturers initiate conversations with third parties but do not engage in promotional

[10] Comments, Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, Docket No. FDA-2013-N-1430 (Apr. 14, 2014), at 3-5.
[11] 21 U.S.C. § 352(n).
[12] 21 C.F.R. § 202.1(l)(2).
[13] *See* FDA, Response to Citizen Petition, Docket No. 02P-0171/CP1 (May 28, 2003).
[14] 62 Fed. Reg. 64074, 64086 (Dec. 3, 1997).
[15] In developing the *ISSEA Guidance*, FDA abandoned an earlier effort to prohibit all manufacturer influence on third-party content. *See* Draft Concept Paper #1, Drug Supported Activities in Scientific or Educational Contexts (Oct. 26, 1991) (describing an earlier standard under which manufacturers were to "have nothing further to do with the activity" once the agreement had been executed). *See also* Comments, Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, Docket No. FDA-2013-N-1430 (Apr. 14, 2014), at 3-5.

messaging or invite UGC related to a particular product.[16] Whether the manufacturers' communications are in the form of unbranded disease-awareness (e.g., providing tips for maintaining a heart-healthy diet) or are simply meant to generate goodwill (e.g., encouraging participation in a charitable giving campaign), they are certainly not aimed at inducing product communications—much less communications that lack fair balance, contain off-label or inaccurate information, or otherwise fail to comply with regulatory requirements for advertising and labeling. The overbroad responsibility standard articulated in the *Draft Guidance*, however, does not clearly foreclose product-specific UGC posted in response from being considered the company's responsibility on the ground that the company "influenced" or was otherwise "involved" in the conversation—even if the firm posts a single message and then disengages from the discussion. The *Draft Guidance* additionally provides that UGC may be attributable to the firm when it is "prompted by the firm in any particular,"[17] a term that raises similar concerns of overbreadth. Indeed, it is difficult to envision a scenario in which a manufacturer's participation in an interactive online or social media forum would not meet the low bar established by the *Draft Guidance*; the *Draft Guidance* notably does not include a single example whereby a manufacturer participates in a forum by posting content but is not deemed accountable for misinformation subsequently posted by a third party. At a minimum, we submit that a company should not incur responsibility for such UGC once the company has disengaged from the conversation.

We therefore urge FDA to reconsider its approach in the *Draft Guidance* and 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. Additionally, we ask the Agency to provide more examples of when manufacturers are and are not responsible for correcting misinformation found online and on social media, in a manner consistent with the limits described above.

We appreciate the opportunity to comment.

[16] Of the relevant examples, Example 2 addresses manufacturers that post only positive information about their products, and Example 4 addresses manufacturers that do not participate in discussions but simply monitor posts for profanity and obscenity.
[17] *Id*. at 4.

Respectfully submitted,

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