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April 14, 2014

Via Electronic Submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and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)

These comments are submitted on behalf of the Medical Information Working Group (MIWG) in response to FDA's January 14, 2014, notice (79 Fed. Reg. 2449) announcing the availability of a draft guidance for industry entitled "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (Draft Guidance).[1]

The MIWG appreciates FDA's effort to provide guidance addressing interactive promotional media. Still, the MIWG believes that the Draft Guidance advances legally impermissible interpretations of FDA authority that must be corrected in the final version. First, the Draft Guidance sets forth an ambiguous and overly broad interpretation of FDA's authority to regulate manufacturer speech. The Draft Guidance refers to various forms of digital engagement as categories of manufacturer speech over which FDA has "promotion" authority, implying that all such categories of communications are subject to FDA regulation. Part I of our comments addresses this issue. Second, the Draft Guidance describes manufacturer "influence or control" (used by the Agency in identifying online communications for which a manufacturer will be held accountable) in a manner that is inconsistent with and broader than both the governing statutory provisions and previous Agency statements. The Draft Guidance provides no reasoned explanation for the change in policy. Part II addresses this issue.[2]

The Draft Guidance's ambiguous and overly broad interpretation of FDA's authority to regulate manufacturer speech is particularly troubling in light of the Supreme Court's holdings in Sorrell v. IMS Health, Inc., 131 S. Ct. 2653 (2011), and FCC v. Fox Television

[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.

[2] In its comments, the MIWG does not address every issue presented by the Draft Guidance. Instead, the MIWG focuses its comments on the issues presented by the Draft Guidance that are central to the MIWG mission of promoting federal regulation of manufacturer speech that is both clear and consistent with statutory and constitutional limitations.

Stations, 132 S. Ct. 2307 (2012), which reiterate the First and Fifth Amendment requirements for clarity in the rules governing manufacturer communications. FDA can better respect constitutional limitations by interpreting the scope of its regulatory authority in a clear manner that is consistent with the Federal Food, Drug, and Cosmetic Act (FDCA). In addition, the Draft Guidance presents issues under the Administrative Procedure Act, which prohibits an agency from acting in ways that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Consistent with this requirement, FDA may not depart from established prior practices without a reasoned explanation for doing so. In the Draft Guidance, FDA adopts—without a reasoned explanation—a broader interpretation of the concept of "influence or control" than it had previously in this context.

I. The Draft Guidance Sets Forth an Ambiguous and Overly Broad Interpretation of FDA's Authority to Regulate Manufacturer Speech

The Draft Guidance states that it "describes FDA's current thinking on what the Agency considers to be interactive promotional media," and refers to examples of "interactive promotional media," including "blogs, microblogs, social networking sites, online communities, and live podcasts." Draft Guidance at 1. The Draft Guidance thus implies that all manufacturer use of these categories of interactive media is manufacturer speech over which FDA has "promotion" authority and is subject to FDA regulation. Similarly, the Draft Guidance also asserts that "FDA's regulation of prescription drug product promotion extends . . . to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf." Id. at 2 & 4 (emphasis added).

FDA's authority is circumscribed by the FDCA, and does not extend to all manufacturer use of the enumerated types of "media" or to "activities." As the MIWG explained in previous submissions to the Agency,[3] FDA has the authority to regulate "labeling" and "advertising." FDA cannot directly regulate the content of any communication that falls outside the scope of "labeling" and "advertising" (although oral statements are widely regarded as fitting within the scope of the "intended use" regulation, 21 C.F.R. § 201.128, and therefore are indirectly subject to FDA regulation).

As set forth in our earlier submissions, the FDCA defines "labeling" to mean "written, printed, or graphic matter" upon the article or "any of its containers or wrappers," or "accompanying such article." 21 U.S.C. § 321(m). The Supreme Court in Kordel v. United States addressed whether written material could "accompany" a drug, and thus qualify as labeling, even when it was distributed separately from the package. 335 U.S. 345, 348 (1948). The Court held that written materials comprise "labeling" when they: (1) have the same origin as the drug; (2) have the same destination; (3) are designed for use in the sale and distribution of the drug; and (4) have a "textual relationship" or "constitute[] an essential supplement" to the label. Id. at 348, 350 (emphasis added). As subsequent decisions have explained, "labeling does not include every writing which bears some relation to the product. There is a line to be drawn, and, if the statutory purpose is to be served, it must be drawn in terms of the function served by the writing." United States v. An Undetermined Number of Cases . . . "Sterling Vinegar and Honey . . . ," 338 F.2d 157,158-59 (2d Cir. 1964).

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[3] See MIWG, Comments re: Scientific Exchange at 8-10, Docket Nos. FDA-2011-N-0912 and FDA-2011-D-0868 (Mar. 27, 2012) and MIWG, Citizen Petition at 12-15, Docket No. FDA-2013-P-1079 (Sept. 3, 2013).

The scope of the "advertising" definition is similarly limited. Although the statute itself does not include a definition, it is clear that "advertising" refers to forms of manufacturer speech that are "published" or "broadcast" – references that clearly reflect FDA's recognition of the need to truncate required disclosures because space for them may not be practicable in many media. 21 C.F.R. § 202.1(l)(1) (advertisements "include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems").

In the Draft Guidance, FDA cites 21 C.F.R. § 202.1(l)(2) as though it functions as a regulatory interpretation of the statutory definition of "labeling" in Section 201(m) of the FDCA (21 U.S.C. § 321(m)). See Draft Guidance at 3 ("Examples of promotional labeling pieces are described at 21 CFR 202.1(l)(2).") FDA has previously cited 21 C.F.R. § 202.1(l)(2) in a similar fashion. See, e.g., FDA, Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009). In litigation, however, FDA has acknowledged that 21 C.F.R. § 202.1(l)(2) is not a straightforward regulation of definition, but rather operates to exclude certain forms of manufacturer communication from the scope of the advertising provisions of the FDCA and FDA regulations. Def.'s Summ. J. Reply at 22-23, Allergan v. United States, No. 09-1879 (D.D.C. filed Mar. 29, 2010). The only applicable legal definition of labeling therefore arises out of the statutory text itself (21 U.S.C. § 321(m)), a general regulatory definition of labeling in 21 C.F.R. § 1.3(a), and relevant case law.

In revising the Draft Guidance, FDA should explicitly recognize these limitations that arise from the FDCA. FDA's authority does not reach all manufacturer communications on "blogs, microblogs, social networking sites, online communities, and live podcasts," or manufacturer "promotional activities" generally. FDA cannot regulate communication—or "activities"—that fall outside the scope of the "labeling" and "advertising" definitions. In the final guidance, FDA should make clear that its authority, as applicable to the social media context, extends only to those communications that constitute "labeling" or "advertising" under the FDCA. Any other approach would have both statutory and constitutional consequences.[4]

II. The Draft Guidance's Discussion of Manufacturer Influence or Control Exceeds the Scope of FDA's Authority and Is Broader Than Previous Agency Statements

In the Draft Guidance, FDA adopts—without an accompanying reasoned explanation[5]—an approach to "influence or control" that is both inconsistent with the FDCA and broader than the Agency had taken previously. Consistent with the FDCA, FDA generally maintains that a company is responsible only for communications made "by or on behalf of" the firm. Section 502(n) of the FDCA imposes content requirements on prescription drug "advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to th[e] drug." 21 U.S.C. § 352(n). In addition, the phrase "by or on behalf of" appears in FDA regulations at 21 C.F.R. § 202.1(l)(2) (stating

[4] See MIWG, Comments re: Scientific Exchange, Docket Nos. FDA-2011-N-0912 and FDA-2011-D-0868 (Mar. 27, 2012), MIWG, Comments, Docket Nos. FDA-2011-P-0512 and FDA-2011-D-0868 (Mar. 1, 2013) and MIWG, Citizen Petition, Docket No. FDA-2013-P-1079 (Sept. 3, 2013).

[5] Under the APA, FDA may not act in ways that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Consistent with this requirement, FDA may not depart from its established prior practices without a reasoned explanation for doing so. E.g., FCC v. Fox Television Stations, 129 S. Ct. 1800, 1811 (2009).

that "pieces of printed, audio, or visual matter descriptive of a drug . . . disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act" (emphasis added)). With respect to both labeling and advertising, the FDCA and FDA implementing regulations establish that FDA's authority extends only to the manufacturer's own materials. FDA has thus confirmed that it "does not generally investigate what parties other than the NDA holder have to say about prescription drugs." See FDA, Response to Citizen Petition, Docket No. 02P-0171/CP1 (May 28, 2003).

In at least one statement, the Draft Guidance generally reflects this aspect of applicable law. See, e.g., Draft Guidance at 2 ("FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf."). Elsewhere, however, the Draft Guidance sets forth an impermissible interpretation of FDA's authority.

The document provides that, in deciding whether a firm is responsible for a communication about its product(s), "the Agency considers whether the firm or anyone acting on its behalf is influencing or controlling the product promotional activity or communication in whole or in part." Id. at 2; see also id. at 3. Further, it warns that "a manufacturer is responsible if it exerts influence over a site in any particular, even if the influence is limited in scope." Id. at 3. For example, if a company "collaborates, or has editorial, preview, or review privilege, then it is responsible for its promotion on the site." Id. at 4. Under the Draft Guidance, firms are only permitted to provide "financial support (e.g., through an unrestricted educational grant)," and are otherwise unable to provide any additional support without being held responsible for the communication. The Draft Guidance thus departs from prior FDA policy, without providing a reasoned explanation for the shift.

In prior guidance, Guidance for Industry: Industry-Supported Scientific and Educational Activities (Nov. 1997) (ISSEA Guidance), 62 Fed. Reg. 64093 (Dec. 3, 1997), FDA stated that manufacturers have some ability to influence content without subjecting an "activity" to FDA regulation. The ISSEA Guidance states:

> The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators. In so doing, the agency will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or other actions designed to influence the program's content.

62 Fed. Reg. at 64097. Under this approach, influence in itself is not determinative. FDA stated, further, that manufacturers could provide technical support, including preparing slides or audiovisual materials, for an independent third-party communication, without that support converting the communication into the manufacturer's own speech. 62 Fed. Reg. 64074, 64086 (Dec. 3, 1997).

In developing the ISSEA Guidance, FDA considered but abandoned an absolute prohibition on manufacturer influence. In an earlier version of the guidance, Draft Concept Paper #1, Drug Company Supported Activities in Scientific or Educational Contexts, FDA stated: "Because this policy is intended to avoid having drug companies exert control over the actual

content of scientific programs or publications, the focus of the policy is on having the drug company secure an agreement with the entity that produces the program or publication . . . about the design of the activity and, except as [specified], to have nothing further to do with the activity." Draft Concept Paper #1, Drug Company Supported Activities in Scientific or Educational Contexts (Oct. 26, 1991) (emphasis added). This view was reflected in Agency recommendations in the Draft Concept Paper, which stated that the supporting drug company "should play no role in the selection of presenters" and "should agree not to engage in any activities, including scripting, ghostwriting of papers, preparation of audiovisual aids, training of presenters, or targeting of points for emphasis that might influence the treatment of topics." Id. In the ISSEA guidance, FDA ultimately adopted a different, less restrictive approach.[6]

The Draft Guidance's approach to manufacturer influence or control is not consistent with the approach the Agency ultimately adopted in the ISSEA Guidance. The ISSEA Guidance would permit some manufacturer collaboration without deeming an activity to be subject to FDA regulation as labeling or advertising. In contrast, the Draft Guidance provides that, if a company "collaborates on . . . the content provided," whatever the nature of the collaboration, "then it is responsible for that content." Draft Guidance at 3. The Draft Guidance cautions that "a manufacturer is responsible if it exerts influence over a site in any particular, even if the influence is limited in scope." Id. In the final guidance, FDA should adopt an approach to manufacturer influence or control that is consistent with its approach in the ISSEA Guidance and that recognizes that manufacturers may exercise limited influence or control over online content without being held responsible for the content.

In summary, FDA should, in the final guidance, recognize the statutory and constitutional limitations on the Agency's authority over manufacturer communications. In addition, FDA should adopt an approach to manufacturer influence or control that is consistent with its approach in the ISSEA guidance and that recognizes that manufacturers may exercise limited influence or control over online communications without being held accountable for the communications.

We appreciate the opportunity to comment on the Draft Guidance.

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[6] See also FDA, Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56412 (Nov. 27, 1992) (also taking a less restrictive approach than the Draft Concept Paper #1, permitting supporting companies to provide speaker suggestions in response to provider requests, "logistical assistance," and "limited technical assistance"); see also Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 88-89 (D.D.C. 1999) (enjoining FDA "from application or enforcement of any regulation, guidance, policy, order or other official action" that "prohibit[s], restrict[s], sanction[s] or otherwise seek[s] to limit any . . . manufacturer . . . from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium").

Respectfully submitted,

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