SIDLEY

ROPES & GRAY

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Via Electronic Submission

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

Re: Review of Existing CDER/CDRH Regulatory and Information Collection Requirements; Request for Comments and Information (Docket Nos. FDA-2017-N-5101 and FDA-2017-N-5105)

These comments are submitted on behalf of the Medical Information Working Group (MIWG), in response to two Federal Register notices published by the Food and Drug Administration (FDA) on September 8, 2017 (82 Fed. Reg. 42,499 and 82 Fed. Reg. 42,494) (collectively, the September 8 Notices). The MIWG is a coalition of medical product manufacturers focused on improving the regulatory and enforcement environment affecting manufacturer communications about drugs and medical devices, including development-stage products and new uses of lawfully marketed products.[1]

In the September 8 Notices, FDA requested comments and information to help the agency "identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing [the agency] to achieve [its] public health mission and fulfill statutory obligations."[2] The September 8 Notices are intended to implement Executive Order 13,771, Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), and Executive Order 13,777, Enforcing the Regulatory Reform Agenda (Feb. 24, 2017).

Although the MIWG believes that in some cases it is appropriate for FDA to eliminate existing regulations—such as where they lack clarity or are inconsistent with current policy reflected in guidance documents—we also believe that, in some areas, regulatory burdens are alleviated when agencies promulgate *new* regulations to clarify their expectations and practices.

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[1] The members of the MIWG are: Allergan plc; Amgen, Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharms. Inc.; Bristol-Myers Squibb Company; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceutical Corporation; Pfizer Inc.; Sanofi US; and Samumed, LLC. The MIWG's prior submissions to FDA are available at www.miwg.org.

[2] 82 Fed. Reg. at 42,500; *id.* at 42,496.

As the Commissioner of Food and Drugs recently stated, FDA has "actually deregulate[d] by regulating—by issuing regulations."[3]

For example, in elucidating the standards that FDA will apply in evaluating premarket submissions for the broad range of products within the agency's authority, researchers and manufacturers are assisted by clear rules describing the mandatory content and format of required submissions, and the circumstances in which FDA will grant or deny marketing authorization.[4] Similarly, FDA has developed rules for the efficient enforcement of the agency's statutory authorities by engaging in notice-and-comment rulemaking. FDA is currently, for example, engaged in such rulemaking to implement the Drug Quality and Security Act.[5] FDA has also used rulemaking to maintain rules implementing earlier legislation, including in areas of regulation applicable to manufacturer speech.[6]

In the absence of regulations, regulated entities cannot consistently conform their conduct to regulatory expectations. In addition, without the kinds of clear, binding rules that can only be devised through notice-and-comment rulemaking, industry is forced to allocate significant resources to identifying applicable norms through regulatory intelligence gathering, legal and regulatory analysis, and other resource-intensive compliance activities. These measures are less necessary if the applicable rules are readily discernible in the governing law itself—that is, in codified regulations adopted through notice-and-comment procedures. These procedures are not optional, but rather must, as a matter of law, be followed if FDA intends for its regulatory policies and their interpretations to be binding and enforceable.[7]

Moreover, in the area of manufacturer communications, the First and Fifth Amendments require FDA to explain in advance, through binding regulations that provide clarity and precision, the differences between permitted and prohibited conduct under the FDCA. In several prior submissions, the MIWG identified recent developments in the case law governing FDA regulation of manufacturer speech, including particularly decisions that explain the application of the Due Process Clause of the Fifth Amendment in this area of FDA regulation.

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[3] National Press Club Headliners Luncheon with FDA Commissioner Dr. Scott Gottlieb (Nov. 3, 2017) (http://bit.ly/2xssGHj).

[4] *See, e.g.,* 21 C.F.R. § 314.50.

[5] *See, e.g.,* FDA, DQSA Regulatory Policy Information (last updated 9/18/2017), http://bit.ly/2juTHnN.

[6] FDA recently proposed to amend existing health claim rules to change the circumstances in which food labeling can permissibly describe the relationship between soy protein consumption and the risk of coronary heart disease. *See* 82 Fed. Reg. 50,324, 50,329 (Oct. 31, 2017).

[7] Only "legislative rules" issued through notice-and-comment rulemaking have the "force and effect of law." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-03 (1979); *see also Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203-04 (2015).

In our March 1, 2013 submission, for example, we explained in detail the Supreme Court's decision in *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307 (2012) ("*Fox II*"), which involved the Federal Communications Commission's interpretation of a statutory provision prohibiting "obscene, indecent, or profane language." In invalidating "Notices of Apparent Liability" issued by the FCC to two broadcasters based on a new interpretation of the statutory prohibition that had not been the subject of notice to regulated entities, the Supreme Court held that the agency's "lack of notice" violated the Due Process Clause by failing to provide "'a person of ordinary intelligence fair notice of what is prohibited.'"[8] A copy of our March 1, 2013 submission is included with this comment letter for convenient reference.

The MIWG has consistently emphasized the need for FDA to respect these constitutional limitations, and to do so by engaging in notice-and-comment rulemaking, which helps to ensure the promulgation of clear and precise rules that give fair notice of what conduct is permissible or non-permissible, and that facilitate decision-making regarding potential communication activities. Although we recognize, and have expressed support for, certain aspects of guidance documents that have been issued by FDA over the years, guidance documents are not binding regulations and too often fail to provide the requisite constitutional level of clarity or the force of law that is essential to assist manufacturers' compliance. Notice-and-comment rulemaking, by contrast, is designed to "assure fairness and mature consideration of rules having a substantial impact on those regulated," "allows the agency to educate itself before adopting a final order," and "requires the agency to disclose its thinking on matters that will affect regulated parties."[9]

Currently, however, FDA regulates manufacturer speech through non-binding guidance documents, *ad hoc* warning and untitled letters, and advisory comments. Many of these documents do not solicit public input, are not publicly available, and are not internally consistent. FDA's recent draft guidance on communications consistent with the FDA-required labeling is illustrative of the Fifth Amendment issues raised by the lack of clear, binding rules. While the draft guidance takes important steps in creating greater flexibility for manufacturers to convey truthful, non-misleading information based on differing degrees of substantiation, FDA can do more to address the tension between this non-binding guidance and a long-standing FDA regulation requiring substantial evidence for promotional claims made in advertising.[10] This *ad*

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[8] *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2318 (2012) (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)).

[9] *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 245 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). *See also MCI Telecomm. Corp. v. FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995) (notice and comment ensures "public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies" and "that the agency will have before it the facts and information relevant to a particular administrative problem."); *Price v. Stevedoring Servs. of Am.*, 697 F.3d 820, 829 (9th Cir. 2012) (en banc) ("the demanding process of promulgating regulations" ensures that an agency "takes pains to understand and effectuate the congressional intent underlying the statute.").

[10] 21 C.F.R. § 202.1(e)(6). Among other things, the absence of clear, binding rules also impairs innovation. For start-up companies with limited resources, regulatory uncertainty and the potential for criminal sanctions can pose substantial—even existential—risks.

hoc approach, and the resulting lack of clear and precise regulations, means that manufacturers not only must invest significant resources into mechanisms to elicit FDA's regulatory expectations, but also must self-censor in many situations and refrain from engaging in valuable speech for fear of potentially significant liability. As FDA has recognized, patient care requires early access to accurate information about important new uses of drugs and medical devices, but the regulatory scheme as currently configured frequently frustrates such access.[11]

Accordingly, over the past ten years, the MIWG has repeatedly emphasized the need for notice-and-comment rulemaking to provide much-needed clarity and precision in the existing FDA regulatory scheme applicable to manufacturer communications. As early as the first citizen petition filed by MIWG members in 2011—predating the Supreme Court's decision in *Fox II* by a year—we "request[ed] that FDA affirm and clarify the contours of [its] . . . policies in regulations that are legally binding." We also noted our strong preference for FDA to improve the regulatory scheme through regulations rather than guidance documents. Finally, we specifically requested notice-and-comment rulemaking in requesting changes to several distinct speech-related FDA policies (*e.g.*, on responses to unsolicited requests) and in requesting that FDA establish new regulatory requirements or prohibitions (*e.g.*, potential limitations on manufacturers' ability to disseminate clinical practice guidelines describing off-label uses).

Although FDA continues to address manufacturer speech issues through guidance documents, we believe the procedures that a federal agency must follow in notice-and-comment rulemaking under the Administrative Procedure Act, 5 U.S.C. § 553, both ensure that the resulting rules satisfy the constitutional requirements of clarity and precision and better enable FDA to promote and protect the public health by helping to achieve FDA's policy objective of facilitating access to accurate information about important new uses. Consequently, we urge FDA to commit to rulemaking in the area of speech regulation instead of continuing to express regulatory expectations through non-binding and vague guidance documents, many of which remain indefinitely in even more questionable "draft" form.[12]

The MIWG believes that the regulatory scheme governing manufacturer speech would benefit from the issuance of new or revised regulations establishing clear, precise standards that conform to constitutional requirements. Well-crafted, properly promulgated regulations

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[11] *See* Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 63 Fed. Reg. 64,556, 64,579 (Nov. 20, 1998) (recognizing the "public health gains associated with the earlier dissemination of objective, balanced, and accurate information on important unapproved uses of approved products"). *See also More Information for Better Patient Care: Hearing of the Senate Comm. on Labor and Human Resources*, 104th Cong. 81 (1996) ("Pharmaceutical and biotechnology companies . . . happen to be in the best position to share information with the physician community at the earliest possible time, when it may really make a difference in treatment options.") (statement of Dr. Gregory H. Reaman, Dir., Med. Specialty Servs., Children's Nat'l Med. Ctr.).

[12] Final guidance is non-binding, but represents FDA's position on an issue. Draft guidance merely proposes an FDA position. 21 C.F.R. § 10.115.

establish clear standards that regulated entities can use to determine in advance whether their conduct is permitted or prohibited.

As we have previously explained in multiple FDA submissions, the public health would be advanced if the agency were to meet the constitutional requirements of clarity and precision in speech regulation. Enforcement of regulatory expectations is facilitated by the existence of properly promulgated *a priori* standards distinguishing permitted from prohibited conduct.

In the area of manufacturer communications, the primary deficiency in the FDA regulatory scheme is not the proliferation of regulations, but that the existing regulations lack sufficient consistency and clarity. As FDA continues to examine the range of actions it might take to respond to the two Executive Orders, we ask the agency to consider the continuing urgent need for additional rulemaking to assure the regulatory scheme gives manufacturers the clear and precise standards the First and Fifth Amendments require.

Thank you for the opportunity to comment.

Respectfully submitted,

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