Docket No. FDA-2017-N-5101

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 82 FED. REG. 42499 (SEPTEMBER 8, 2017)

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Submitted Electronically (www.regulations.gov)
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Re: Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements
Request for Comments and Information
Docket No. FDA-2017-N-5101, 82 Fed. Reg. 42499 (September 8, 2017)

Dear Sir/Madam:

The Washington Legal Foundation (WLF) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) request for input to help FDA "identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations."

FDA's request was a response to two new executive orders: Executive Order 13771, entitled "Reducing Regulation and Controlling Regulatory Cost"; and Executive Order 13777, entitled "Enforcing the Regulatory Reform Agenda." The latter document, designed to alleviate unnecessary regulatory burdens on the American people, calls on each federal agency to evaluate all existing regulations and to identify those that may merit repeal, replacement, or modification. WLF believes that a comprehensive review of all FDA regulations would identify many such objectionable regulations. For the purpose of imposing reasonable limits on the scope of its comments, WLF limits this response to a discussion of CDER's (and FDA's) use of guidance documents as an often-inadequate substitute for notice-and-comment rulemaking. The result of that practice has been the development of an entire body of "regulations" that has never been subjected to an adequate review process and, indeed, often remains in "draft" form for years on end.

There is no question that FDA guidance documents are encompassed within the review process mandated by the two executive orders. Although Executive Order 13777 mandates a review of existing "regulations," that term is very broadly defined by Section 4 of Executive Order 13771 to include any "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." FDA cannot plausibly deny that guidance documents are designed "to implement, interpret, or prescribe law or policy." While FDA routinely states that guidance documents do not operate to bind FDA or the public, it

also emphasizes that such documents embody FDA's "current thinking" on the regulatory issues being addressed, and agency enforcement personnel regularly point to guidance documents as their basis for concluding that a regulated entity is not complying with the Food, Drug, and Cosmetic Act (FDCA).

WLF submits that FDA's current heavy reliance on guidance documents (including "draft" guidances) imposes excessive burdens on the regulated community. WLF recommends that FDA focus on replacing all older guidances with formal regulations adopted by means of notice-and-comment rulemaking. Perhaps more importantly, FDA should adopt a strict rule requiring that all draft guidances not adopted in final form within two years of initial issuance must be withdrawn.

I. *Interests of WLF*

The Washington Legal Foundation is a public-interest law and policy center with supporters nationwide. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, a limited and accountable government, individual and business civil liberties, and the rule of law. To that end, WLF has frequently appeared in federal court to ensure that administrative agencies adhere to the rule of law. *See, e.g., Tennessee v. FCC*, 832 F.3d 597 (6th Cir. 2016). In particular, WLF on a number of occasions has sought invalidation of federal rules because the promulgating agency failed to comply with the notice-and-comment requirements of the Administrative Procedure Act (APA). *See, e.g., Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015); *Christopher v. SmithKline Beecham Corp*., 132 S. Ct. 2156 (2012); *Prevor v. FDA*, 67 F. Supp. 3d 125 (D.D.C. 2014).

WLF also regularly participates in FDA administrative proceedings to encourage the agency to adhere to procedural requirements and to avoid imposition of unnecessary burdens on the regulated community. *See, e.g.*, FDA Docket No. FDA-2015-N-2002 (filed May 19, 2017) (amendment to "intended uses" regulation); FDA Docket No. FDA-2016-N-1149 (filed January 3, 2017) (limits on manufacturer off-label communications); FDA Docket No. FDA-2008-D-0053 (filed May 15, 2014) (limits on distributing scientific and medical publications on off-label uses).

II. *The Frequent Use of Guidance Documents and Draft Guidances*

The Administrative Procedure Act envisions that administrative agencies created by Congress will adopt comprehensive regulations that will both govern the agencies' day-to-day procedural operations and set forth substantive rules that flesh out statutory requirements that explain to the regulated community in some detail what is expected of them. A federal agency may not adopt a substantive regulation without first providing interested parties with notice of the regulation, 5 U.S.C. § 553(b), and a meaningful opportunity to "participate in the rule

making through submission of written data, views, or arguments." 5 U.S.C. § 553(c).

Federal courts have concluded that the APA's notice-and-comment requirements are intended to achieve three distinct purposes:

> (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.

Miami-Dade County v. EPA, 529 F.3d 1049, 1058 (11th Cir. 2008); *Council Tree Communications, Inc. v. FCC*, 619 F.3d 235, 250 (3d Cir. 2010).

The APA creates a limited exception to the notice-and-comment requirements: they do not apply "to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). Thus, to the extent that an FDA guidance document merely interprets a statute or formal regulation (as opposed to creating a new rule whose outline does not flow naturally from the language of the statute or regulation), it need not by adopted in compliance with formal notice-and-comment requirements. But adherence to those procedural requirements even when not absolutely mandated has much to recommend it; doing so advances the three goals (testing the rule, fairness to affected parties, and creating an evidentiary record) that Congress had in mind when it established those requirements.

When adopting rules in recent decades, FDA has become far less likely to style them as formal regulations and to adhere to the APA's notice-and-comment requirements. Instead, it is far more likely to use a less formal title, usually denominating the proposed rule a "guidance" and thereby avoiding those requirements. By WLF's count, there are now more than 2,000 FDA draft or final guidance documents. The reason for this trend is obvious: formal rulemaking can be quite cumbersome, and FDA would prefer, when possible, to avoid the time and expense involved.

It is not WLF's purpose here to challenge specific guidance documents as invalid because they were not (but should have been) promulgated in accordance with APA requirements— although WLF believes that to be true with respect to at least some FDA guidances. Rather, our purpose is to suggest that this increasing resort to informal rulemaking procedures has real costs to the regulated community. Because guidance documents are not "binding" on the agency, they create (by definition) considerable uncertainty about future FDA enforcement action; a regulated entity can never fully rely on them when engaging in longer-term planning. At the same time, a regulated entity ignores a "non-binding" guidance (whether final or in draft form) at its peril, even when compliance is extremely expensive and the entity strongly believes that the guidance misstates statutory or constitutional law. And the relative

ease with which FDA can adopt draft guidances results in promulgation of many more restrictions than would otherwise be the case. Moreover, those burdensome restrictions are likely less to be fully justified than they would have been had FDA decided to adhere to formal rulemaking requirements.

III. Widespread Objections to the Increased Use of Guidance Documents

WLF is not alone in its concern about the proliferation of FD guidance documents issued without adherence to formal rulemaking. For example, four Senators on the Health, Education, Labor, and Pensions Committee (including Chairman Lamar Alexander) have written to FDA "to express our concerns regarding the use of draft guidances to make substances policy changes" and "our concerns that draft guidances are not being revised, finalized, or withdrawn in a timely manner." In a May 6, 2016 letter, the Senators stated:

> Doctors and companies continue to express concerns with how the FDA prepares and uses draft guidances in carrying out the Agency's regulatory responsibilities and feel no choice but to follow draft guidances as if final, even if the most up-to-date science would suggest an alternative path. For example, we have heard concerns that the FDA is sending—and sometimes publicizing—"Untitled" or "It has come to our attention" letters that use new thinking only seen in draft guidance to raise concerns about regulated products.

As the letter noted, FDA's draft guidances routinely state that the views expressed therein will represent the Agency's current thinking only "when finalized." Yet, scores (if not hundreds) of FDA "draft" guidances have remained on the books for many years—an indication to most industry participants that the Agency expects them to abide by those draft guidance. Under those circumstances, even the abridged commenting opportunity that FDA provides to "Level 1" guidance documents (*see* FDA Good Guidance Practices, 21 C.F.R. § 10.115) becomes largely meaningless, because the draft guidance in essence takes effect as soon as it is released.

WLF recognizes that very narrow technical or scientific issues may be difficult to address in the context of formal rulemaking. Advances in scientific knowledge can sometime move much more quickly than can rulemakers adhering to the APA. However, FDA has not limited its use of guidance documents to topics subject to rapid change. Professor Law Noah charges that FDA use of guidance documents is "spreading like kudzu," explaining that:

> FDA does not reserve guidance documents for narrow and technical facets of its work. Large swaths of important agency activities depend entirely on such nonbinding pronouncements. ... Nowadays, it seems, legislative rulemaking only happens when Congress insists on that course of action. In some cases, FDA uses guidance to update regulations promulgated long ago. For instance, rather than go

> to the trouble of amending its then-25-year-old regulation delineating "current" good manufacturing practices for drugs, FDA decided to issue guidance for the adoption of innovative quality control technologies by the pharmaceutical industry.

Lars Noah, *Guidance Gone Wild?: FDA's Regrettable Retreat from Legislative Rulemaking*, WLF Legal Backgrounder (Oct. 9, 2015).

IV. FDA Regulation of Advertising and Off-Label Communications

For the past several decades, WLF has actively litigated First Amendment limitations on FDA's authority to restrict manufacturer speech. WLF is thus familiar with FDA efforts to regulate speech, particularly the dissemination of information regarding off-label uses of FDA-approved products. FDA's speech restrictions have followed the pattern described above. Rather than issue formal regulations governing manufacturer speech, it has chosen to regulate through the issuance of a series of guidance documents—many of which have remained in draft form for years. WLF submits that this manner of regulation has resulted in untold confusion and has unnecessarily delayed final judicial resolution of the important constitutional issues at stake.

FDA's attempted regulation of dissemination of medical texts and peer-reviewed journal articles has been particularly inept. FDA in 1996 issued guidance documents that sought to impose significant limitations on such dissemination. WLF challenged the documents, and a federal district court permanently enjoined FDA from enforcing them or any similar policies. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 73-74 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). The permanent injunction remains in place.

FDA nonetheless has subsequently issued several *draft* guidances on the same topic; each proposed imposition of restrictions on dissemination of medical texts and peer-reviewed journal articles. For example, in 2008 it issued "Draft Guidance for Industry on 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," 73 Fed. Reg. 9342 (Feb. 20, 2008). FDA rescinded that guidance in 2014 and issued a new document entitled, "Revised Draft Guidance for Industry on Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices," 79 Fed. Reg. 11793 (Mar. 3, 2014). The second guidance remains in draft form, nearly four years after its initial issuance. FDA has never sought to invoke those documents in connection with an enforcement action, and thus there has never been an opportunity for a court to determine whether the documents comply with the permanent injunction issued by the federal district court and/or with the First Amendment. They nonetheless have undoubtedly chilled a significant amount of truthful speech by manufacturers who fear the consequences of defying FDA's speech restrictions.

V. Recommendations

WLF urges FDA, in connection with its efforts to comply with the two Executive Orders, to carefully reconsider its increasing reliance on guidance documents as its principal means of regulating the drug and device industries. WLF believes that that reliance has substantially increased the burden on regulated entities. WLF recommends that FDA, at a minimum, adopt the following policies:

- Any draft guidance not placed into final form within two years of its initial issuance shall be automatically abrogated;

- Any guidance that has been in effect for at least five years will be subjected to formal review to determine whether the subject matter of the guidance would more properly be incorporated into a formal regulation; and

- No guidance will be issued in draft or final form until after FDA has made a formal determination that use of formal APA notice-and-comment procedures is not feasible.

Sincerely,

/s/ Richard A. Samp
Richard A. Samp

/s/ Cory L. Andrews
Cory L. Andrews

Washington Legal Foundation