WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
(202) 588-0302

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By Electronic Submission
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Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2015-N-2002-2030, Proposed Amendments to Regulations on "Intended Uses"

To Whom It Concerns:

Washington Legal Foundation (WLF) submits this comment in response to the FDA's proposed amendments to the agency's "intended uses" regulations for drugs and medical devices.[1]

Founded in 1977, WLF is a public-interest law firm and policy center with supporters nationwide. WLF often appears before federal courts and administrative agencies to promote free enterprise, individual liberty, limited government, and the rule of law. To that end, WLF routinely defends commercial speech rights by appearing as an amicus in state and federal courts in important First Amendment cases.[2]

WLF has also litigated in favor of First Amendment limits on the Food and Drug Administration's (FDA) authority to restrict manufacturer speech.[3] As a

[1] Regulation Regarding "Intended Uses," 85 Fed. Reg. 59,718 (Sep. 23, 2020).

[2] *See, e.g.*, *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011); *Merck & Co. v. U.S. Dep't of Health & Human Servs.*,962 F.3d 531 (D.C. Cir. 2020); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

[3] *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

result of that litigation, the FDA is subject to a permanent injunction curtailing the agency's authority to bar manufacturers from sharing peer-reviewed medical texts and journal articles about off-label uses of their FDA-approved products.

In previous comments, WLF raised serious First Amendment concerns about earlier drafts of the proposed Rule.[4] As the U.S. Supreme Court has recognized, the need to ensure the free flow of truthful information "has great relevance in the fields of medicine and public health, where information can save lives."[5] The dissemination of truthful off-label speech, for example, allows physicians to make better informed prescribing decisions, thereby improving clinical outcomes and lowering healthcare costs. Although "there is no statute that specifically prohibits off-label marketing," the FDA "continues to prosecute the conduct by patching together the misbranding and adulteration regulations, thereby criminalizing conduct that it is not entirely clear Congress intended to criminalize."[6]

In its latest draft, the FDA now proposes to add language "to clarify that a firm's knowledge that health care providers are prescribing or using its approved or cleared medical product for an unapproved use would not, by itself, automatically trigger" liability for misbranding.[7] The FDA also proposes to insert a clause into the regulations clarifying that intended use "may be shown by" not only promotional claims ("expressions") but also by "the design or composition of the article."[8]

The FDA concludes that the Rule, "if finalized, would be consistent with the First Amendment."[9] Because intended use "is only one element of an alleged violation" of the Food, Drug & Cosmetic Act (FDCA), FDA claims, "this rule does not itself implicate the First Amendment."[10]

We see it differently. The Rule identifies many types of evidence of intended use that comprise constitutionally protected speech. "Evidence of intended use may include, but is not limited to ... any claim or statement" that "explicitly or implicitly

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[4] *See* Comment of Washington Legal Foundation, FDA-2015-N-2002-2008 (Feb. 5, 2018); Comment of Washington Legal Foundation, FDA-2015-N-2002-1990 (May 19, 2017); Comment of Washington Legal Foundation, FDA-2015-N-2002-0008 (Nov. 24, 2015).

[5] *IMS Health, Inc.*, 564 U.S. at 566.

[6] *United States v. Facteau*, No. 15-cr-10076-ADB, 2020 WL 5517573, at *1 (D. Mass. Sep. 14, 2020).

[7] 85 Fed. Reg. at 59,720.

[8] 85 Fed. Reg. at 59,729.

[9] 85 Fed. Reg. at 59,723.

[10] 85 Fed. Reg. at 59,722.

promotes a product for a particular use."[11] Under this approach, almost any statement by a manufacturer *about* its product may seem like an *implicit* promotion of that product. Of course, under the First Amendment, the FDA may not consider "all scientific claims" about a drug or device to be "presumptively untruthful or misleading."[12] Unfortunately, the FDA's approach to intended-use misbranding comes dangerously close to doing just that, as it fails to distinguish between true and false claims or statements.

And while intended use may be only one element of a violation under the FDCA, that does not alter the constitutional analysis. The FDA cannot escape the important developments in case law over the past decade that further undermine the validity of government restrictions, whether through intended use or otherwise, on truthful off-label speech.[13] "[E]ven if speech can be used as evidence of a drug's intended use," the Second Circuit has explained, "adopt[ing] the government's construction of the FDCA's misbranding provisions to prohibit manufacturer promotion alone" would "unconstitutionally restrict free speech."[14]

To avoid grappling with these potential First Amendment defects, the Second Circuit has construed the FDCA's misbranding provisions as not prohibiting truthful off-label promotion of FDA approved products.[15] The FDA had every chance to appeal from that decision, but it chose not to do so. Although the FDA, in its preamble, tries to dismiss or distinguish *Caronia* and other authorities, it never meaningfully confronts the core First Amendment question. The FDA instead relies on non-binding dictum in a footnote written by the dissenting judge in *Caronia*.[16]

No matter the FDA's evasions, a blanket prohibition on truthful off-label speech by drug and device manufacturers and their representatives remains constitutionally suspect. "As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the

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[11] 85 Fed. Reg. at 59,722.

[12] *Friedman*, 13 F. Supp. 2d at 68.

[13] *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

[14] *Caronia*, 703 F.3d at 168.

[15] *Ibid.*

[16] 85 Fed. Reg. at 59,724 (citing *United States ex rel. Polansky v. Pfizer, Inc.*, 82 F.3d 613 n.2 (2d Cir. 2016)).

efficiency and integrity of FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs."[17]

To be sure, the FDA's congressionally assigned task of protecting the public health is a critical one. A robust regulatory regime is both desirable and necessary to prevent the dissemination of deceptive and misleading speech about drugs and devices. But "regardless of the strength of the government's interest," the "level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox."[18] Drug and device manufacturers are uniquely well-positioned to give healthcare professionals the most accurate and timely scientific and medical data. If that information is truthful, the government has no constitutionally acceptable justification for restricting it.

Nor are the First Amendment's interests limited to speakers. A necessary corollary to the First Amendment's right to speak freely is the right to hear and receive valuable information.[19] Such interests are particularly acute when, as here, the intended recipients are treating physicians, and the information at stake concerns potentially life-saving therapies for patients. As the FDA recognizes, manufacturer dissemination of information about off-label uses of approved or cleared medical products is often vital to advancing patient care and public health. The proposed Rule, WLF contends, fails to meaningfully balance these interests against those of the government.

WLF proposes that the FDA revise its proposed regulations by adding these statements: (1) the FDA recognizes manufacturers' First Amendment right to speak truthfully about their products in appropriate settings without fear that such statements will be used to create new "intended uses" for the products; (2) in determining intent, the FDA will mostly focus on statements either on the product label or on immediately accompanying material—and less so on statements in widely circulated marketing materials; and (3) in determining intended uses, the FDA will abide by constitutional restrictions on FDA authority recognized in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015), *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), and similar First Amendment decisions.

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[17] *Caronia*, 703 F.3d at 166-67.

[18] *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 74-75 (1983).

[19] *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) ("[M]anufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information."); *Red Lion Broad. Co v. FCC*, 395 U.S. 367, 390 (1969) (confirming that the Constitution requires protection of "the right of the public to receive" speech).

In sum, any final Rule must not only respect manufacturers' First Amendment right to speak truthfully about their products, but it must also balance the government's valid interests against treating physicians' right to access vital information for their patients. Unfortunately, the proposed final Rule refuses to acknowledge the heavy First Amendment burden the FDA bears when it seeks to restrict truthful manufacturer speech. The FDA's failure to take seriously the constitutional bounds of its authority when crafting regulations will have a chilling effect on legally protected speech. If adopted in its current form, the Rule would invite a First Amendment challenge.

Sincerely,

/s/ Cory L. Andrews
Cory L. Andrews
Vice President of Litigation