Docket No. FDA-2015-N-2002

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 82 FED. REG. 14319 (MARCH 20, 2017)

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments Docket No. FDA-2015-N-2002, 82 Fed. Reg. 14319 (March 20, 2017)

Dear Sir/Madam:

Washington Legal Foundation (WLF) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) request for input on issues related to the Final Rule published in the Federal Register on January 9, 2017; to a February 8, 2017 Citizen Petition filed in response to the Final Rule; and to "'intended uses' generally."

On November 24, 2015, WLF filed comments on the proposed "intended uses" rule—published in the Federal Register on September 25, 2015. WLF's comments were generally supportive of the Proposed Rule, albeit we urged FDA to take additional steps to protect the First Amendment rights of manufacturers to speak truthfully about off-label uses of their FDA-approved medical products. We were very disappointed with the January 9, 2017 Final Rule, which we viewed as a retreat from the positive aspects of the Proposed Rule. We were quite pleased, therefore, that FDA responded to the February 8, 2017 Citizen Petition, filed by the Medical Information Working Group (MIWG) and others, by agreeing to delay the effective date of the Final Rule until March 19, 2018 and to accept comments regarding the important issues raised by the Citizen Petition.

Our concerns with the Final Rule are both procedural and substantive. The Final Rule was not adopted in compliance with procedures required by the Administrative Procedure Act because the Proposed Rule failed to provide notice sufficient to alert interested parties regarding the regulation to be adopted. The Final Rule announced an entirely new standard—the "totality of the evidence" standard—for determining the "intended use" of a drug or medical device. The totality-of-the-evidence standard is not a "logical outgrowth" of anything FDA had said previously; certainly, nothing in the Proposed Rule provided interested parties with any indication that FDA was contemplating adoption of that standard. The APA therefore requires invalidation of the Final Rule. FDA should either issue a revised regulation that is consistent

with the Proposed Rule or develop a new proposed rule and restart notice-and-comment procedures.

The Final Rule is also deficient because it is inconsistent with FDA's statutory mandate. The Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to prevent the distribution and sale of any drug or device without FDA approval or clearance, and broadly defines a "drug" or "device" as an article "intended" for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of the body. 21 U.S.C. § 321(g) & (h). But as the FDCA states explicitly, once an FDA-approved medical product has been sold, FDA is not authorized to regulate its use. FDA has now adopted an "intended use" regulation that asserts the authority to examine "the totality of the evidence" for purposes of determining whether a manufacturer "intends" its product to be used in an unapproved manner, including evidence regarding how an FDA-approved product is actually used and the manufacturer's knowledge of that use. FDA's assertion of such authority far exceeds its statutory mandate.

The Final Rule is also constitutionally deficient. As explained in more detail in WLF's November 24, 2015 comments, the First Amendment provides significant protection to manufacturers that seek to speak truthfully about off-label uses of their FDA-approved products. By asserting the right to use all such speech as evidence of alleged criminal intent, the Final Rule runs afoul of the First Amendment.

Finally, the Final Rule embodies unsound health-care policy. Manufacturers for years have desperately sought guidance from FDA regarding the sorts of off-label activities in which they are permitted to engage without fear that those activities may subject them to government enforcement actions or private tort suits. The Proposed Rule, by indicating that mere knowledge of off-label use would not be deemed evidence of a new "intended use," took a small step in the right direction. The Final Rule, by adopting a totality-of-the-evidence standard and thereby granting FDA a blank check to arrive at *ad hoc* new-intended-use determinations, takes a major step in the wrong direction.

I. *Interests of WLF*

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. In particular, WLF has devoted substantial resources over the years to promoting free-speech rights of consumers and merchants in the marketplace, appearing before numerous federal courts in cases raising First Amendment issues. *See, e.g., Sorrell v. IMS Health Inc*., 564 U.S. 552 (2011); *Nike v. Kasky*, 539 U.S. 654 (2003). WLF has successfully challenged the constitutionality of FDA restrictions on speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51

(D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). As a result of that litigation, FDA is subject to a permanent injunction limiting FDA authority to suppress manufacturer dissemination of certain journal articles/medical texts discussing off-label uses of their FDA-approved products. More recently, WLF played a key role in overturning—on First Amendment grounds—the criminal conviction of a pharmaceutical representative for conspiring to violate the FDCA; the representative's "crime" consisted of speaking truthfully about off-label uses of a drug manufactured by his company. *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). WLF also regularly appears in court proceedings to ensure that FDA and other federal agencies adhere to the procedural requirements of the APA. *See, e.g., Prevor v. FDA*, 67 F. Supp. 3d 125 (D.D.C. 2014).

WLF also regularly participates in FDA administrative proceedings in support of expanded First Amendment rights. *See, e.g.*, FDA Docket No. FDA-2016-N-1149 (January 3, 2017) (response to FDA request for comments on manufacturer off-label communications); FDA Docket No. FDA-2008-D-0053 (May 15, 2014) (response to revised FDA Draft Guidance on distributing scientific and medical publications on off-label uses); FDA Docket No. FDA-2013-N-1430 (April 14, 2014) (response to FDA Draft Guidance on postmarket submissions to FDA of inter-active promotional media); FDA Docket No. FDA-2011-D-0868 (March 29, 2012) (response to FDA Draft Guidance on unsolicited requests for off-label information); FDA Docket No. 2008-D-0053 (April 21, 2008) (response to FDA Draft Guidance on good reprint practices); FDA Citizen Petition No. 2006P-0319/CPI (August 11, 2006) (documenting repeated First Amendment violations by FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) and calling on DDMAC to conform to constitutional constraints on its activities); FDA Docket No. 02N-0209 (October 28, 2002) (response to FDA's request for public comments on First Amendment issues). As noted above, WLF also filed comments in this docket in November 2015 in connection with the Proposed Rule.

II. ***The Final Rule Flunks the APA's "Logical Outgrowth" Requirement***

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 appeals 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).

Those purposes are undercut when an agency's final rule deviates substantially from its proposed rule. The final rule will not be "tested via exposure to diverse public comment" if the final rule was not fairly encompassed within the proposed rule on which the public commented. "Fairness to affected parties" cannot be assured if the proposed rule did not provide those parties with fair warning regarding the provisions of the final rule. Finally, affected parties will not have an "opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review" if they object to provisions in the final rule that the proposed rule did not include. The Final Rule adopted by FDA in January 2017 differed substantially from the 2015 Proposed Rule and thereby violated 5 U.S.C. § 553(b) & (c).

The Proposed Rule contemplated only one significant change in FDA's then-existing "intended use" regulations, 21 U.S.C. § 201.128 (drugs) and 21 U.S.C. § 801.4 (devices). It proposed deletion of the final sentence of those regulations, which read as follows:

> But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

Manufacturers had long been concerned by this sentence, which seemed to indicate that they were required to seek supplemental approval from FDA for a new product use whenever they became aware that doctors were prescribing one of their FDA-approved products for an unapproved use, even when they had done nothing to encourage the use. FDA had provided assurances that "the Agency would not regard a firm as intending an unapproved new use for an approved or cleared medical product based *solely* on the firm's knowledge that such product was being prescribed or used by doctors for such use." Proposed Rule, 80 Fed. Reg. at 57757 (emphasis added). Manufacturers nonetheless repeatedly sought repeal of the quoted sentence, fearing that it might well be used against them either in FDA enforcement proceedings or in lawsuits filed by private litigants. Accordingly, the Proposed Rule's deletion of the controversial sentence was reasonably interpreted by many in the regulated community as FDA's assenting to manufacturers' repeated requests. The comments filed in response to the Proposed Rule reflected that understanding.

In a surprise switcheroo, the Final Rule reinstated the sentence in question, in a somewhat revised form. Moreover, the opening clause of the revised sentence adopted a brand-new totality-of-the-evidence standard that signals to manufacturers that FDA claims authority to rely on *any* evidence it deems relevant to intended use—including, as pertinent here,

manufacturers' knowledge of off-label use by others. As revised in the Final Rule, the sentence now states:

> ~~But if~~ And if the totality of the evidence establishes that a manufacturer ~~knows, or has knowledge of facts that would give him notice~~, objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ~~the~~ ones for which ~~he offers~~ it is approved, (if any), he is required ~~to provide~~, in accordance with section 502(f) of the Federal Food, Drug, and Cosmetic Act, or, as applicable, duly promulgated regulations exempting the drug from the requirements of section 502(f)(1), to provide for such drug adequate labeling ~~for such a drug which~~that accords with such other intended uses~~to which the article is to be put~~.

Final Rule, 82 Fed. Reg. at 2217. Indeed, by adding the phrase "objectively intends," FDA could not have been clearer that it claims authority to make "intended use" determinations based not merely on what a manufacturer actually says about its product's uses but also on any other evidence that it deems relevant to determining intent.

Agencies are entitled, of course, to make *some* changes to proposed rules without re-opening the comment period. As the D.C. Circuit has explained, if no changes were permitted, a principal "purpose of notice and comment—to allow an agency to reconsider, and sometimes change, its proposal based on the comments of affected persons—would be undermined. Agencies would either refuse to make changes in response to comments or be forced into perpetual cycles of new notice and comment periods." *Assoc. of Battery Recyclers, Inc. v. EPA*, 208 F.3d 1047, 1058 (D.C. Cir. 2000).

But the APA notice requirement limits such changes by mandating that any final rule adopted by an agency must be "a logical outgrowth of the rule proposed." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). The totality-of-the-evidence standard included in the Final Rule does not satisfy the "logical outgrowth" requirement because nothing in the Proposed Rule alerted affected parties that FDA was contemplating adopting that standard in its final rule.

In a significant majority of cases in which a court determined that an agency's revised regulation satisfied the "logical outgrowth" requirement, the preamble to the proposed regulation explicitly stated that the agency was contemplating the very revision that was later adopted. *See, e.g., Miami-Dade County*, 529 F.3d at 1062 (in proposing a regulation governing injection of effluents into underground wells, EPA explicitly asked whether its rule should be extended to all future wells; thus, the final rule's extension of the rule to all future wells was a logical outgrowth of the proposed rule); *City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007) (similar); *Owner-Operator Independent Drivers Ass'n v. Federal Motor Carrier Safety Admin.*, 494 F.3d

188, 209-210 (D.C. Cir. 2007) (similar). In contrast, courts have determined that a final rule was not a "logical outgrowth" where "the proposed rule gave no indication that the agency was considering a different approach, and the final rule revealed that the agency had completely changed its position." *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009).

Key to any "logical outgrowth" determination is whether the "purposes of notice and comment have been adequately served" by the agency's rulemaking procedures. *Battery Recyclers*, 208 F.3d at 1059. If affected parties could reasonably be expected during the initial comment period to have raised objections to features belatedly added to the final rule, then the "logical outgrowth" standard is satisfied and there would be little point in requiring a new round of comments. But the standard is not satisfied "unless all interested persons would reasonably be expected to perceive," based on the proposed rule, that the agency was contemplating adding the very features that were ultimately added to the final rule. *Council Tree*, 619 F.3d at 255.

In its March 20, 2017 request for comments, FDA insists that the totality-of-the-evidence standard represents no change in longstanding agency policy. It claims that it has always considered itself free to rely on *any* evidence it deemed relevant to determining "intended use." 82 Fed. Reg. at 14320. But if that were really so, there would have been no reason for manufacturers to have lobbied for (and for the Proposed Rule to acquiesce in) deletion of the final sentence of the intended-use regulations. Moreover, FDA has been unable to point to *any* occasion prior to issuance of the Final Rule on which it articulated a totality-of-the-evidence standard.

Certainly, nothing in the Proposed Rule itself placed interested parties on notice that FDA was contemplating adoption of a totality-of-the-evidence standard. While they would have understood that there was a possibility that FDA would ultimately reject the Proposed Rule and leave the intended-use regulations unchanged, the standard adopted in the Final Rule represents a significant (and unanticipated) change from the *status quo ante*.

Perhaps the strongest evidence that the totality-of-the-evidence standard added to the Final Rule was not a "logical outgrowth" of the Proposed Rule is that *no* commenters (among the several thousand comments filed) discussed the appropriateness of adopting an intended-use standard at all similar to the totality-of-the-evidence standard that the Final Rule embraced. If the Proposed Rule actually provided fair notice to affected parties that re-insertion of a revised final sentence embracing a totality-of-the-evidence standard was on the table, one could reasonably expect that at least some comments would have addressed the issue. As the Third Circuit has explained, "[T]he proper question under the APA [is] whether the agency had provided notice to all interested parties. ... [T]he inferential notice purportedly provided by the [agency] did not satisfy that standard." *Council Tree*, 619 F.3d at 256 (citations omitted). When, as here, an agency's efforts to demonstrate "logical outgrowth" amount to nothing more

than claims that it was misunderstood and that commenters should have read its mind, it should be deemed to be "us[ing] the rulemaking process to pull a surprise switcheroo on regulated entities," *Environmental Integrity Project* v. EPA, 425 F.3d 992, 996 (D.C. Cir. 2005), not providing them with the adequate notice mandated by the APA.

III. *The Final Rule Exceeds FDA Statutory Authority by Seeking to Regulate the Practice of Medicine*

The FDCA bars distribution and sale in interstate commerce of any "drug" or "device" without FDA approval or clearance. FDA plays a central role in government regulation of medical products, by: (1) determining whether a product meets the FDCA's definitions of a "drug" or "device"; (2) if so, ensuring that the product is not distributed and sold in interstate commerce without FDA approval; (3) ensuring that FDA-approved products are manufactured and labeled in accordance with FDA-approved specifications; and (4) ensuring that manufacturers make no false claims about their products.

FDA is not, however, authorized to regulate the practice of medicine. Once FDA has approved a drug or device, doctors are free to prescribe the product for any use they deem appropriate—subject only to regulation by state medical boards. Indeed, doctors routinely prescribe FDA-approved products for off-label uses, and FDA readily concedes that, in some fields of medicine, such prescriptions are an essential component of optimal medical care. Any effort by FDA to prevent doctors from writing off-label prescriptions as they deem appropriate would exceed FDA's statutory authority.

WLF respectfully submits that regulating the practice of medicine is precisely FDA's intent in drafting an expansive intended-use regulation. As such, FDA is improperly interfering with such practice. The FDCA grants FDA broad authority over the labeling of FDA-approved products. That authority is more than sufficient for FDA to ensure that a product's label is limited to discussing product uses that FDA has approved as safe and effective. FDA's authority to regulate prescription drug advertising permits it to ensure that manufacturers make no false claims about their products. But so long as manufacturers comply with labeling and advertising regulations, FDA has no basis for attempting to discern a supposed, unexpressed manufacturer desire that its products be prescribed for off-label uses. Certainly, a manufacturer's mere knowledge that some doctors are exercising their right to prescribe a product off-label has no bearing on FDA's statutory mission. Even if a manufacturer silently cheers when doctors exercise that right and ensures that pharmacies have sufficient supply to accommodate all off-label prescriptions, FDA lacks any statutory basis for sanctioning a drug or device manufacturer that properly labels its products and engages in no false advertising. When FDA nonetheless attempts to sanction a manufacturer, its only plausible rationale is to discourage the writing of off-label prescriptions—an activity that Congress has expressly removed from FDA's bailiwick. *See, e.g.*, 21 U.S.C. § 396.

In its March 20 notice, FDA asserts that its totality-of-the-evidence standard is necessary because some manufacturers make no explicit claims that would come within the FDCA's drug/device definitions, yet their conduct or other circumstantial evidence leaves no doubt that their product is being marketed as a "drug" or "device." 82 Fed. Reg. at 24321-22 (citing, *e.g.*, "[p]ersons distributing substances which are known to be used recreationally to get high" and "[p]ersons distributing synthetic drugs, such as synthetic marijuana, labeled as incense, potpourri, or bath salts."). But such examples have little relevance to manufacturers whose products have already been classified as "drugs" or "devices" by FDA and have obtained marketing authority from the agency. There is no need for FDA to determine whether such products' intended uses meet the FDCA's definitions of a "drug" or "device"; they obviously do. The only apparent purpose of applying the "intended use" regulation to FDA-approved products is to reduce the prevalence of off-label prescriptions, a purpose not authorized by the FDCA.

IV. *The First Amendment Protects Truthful Manufacturer Speech About Off-Label Uses of FDA-Approved Products*

Over the past several decades, federal courts have repeatedly held that FDA's restrictions on manufacturer speech are subject to significant First Amendment constraints and that those speech restrictions are constitutionally impermissible. *See, e.g.*, *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

In light of that history, WLF's November 24, 2015 comments urged FDA to amend the Proposed Rule in order to clarify that FDA recognizes that the First Amendment protects commercial speech. In particular, WLF urged FDA to add the following statements to the "intended use" regulations: (1) FDA recognizes manufacturers' First Amendment rights 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, FDA will focus principally on language contained either on the product label or on immediately accompanying material—and to a lesser extent on language contained in widely circulated advertising material; (3) isolated truthful statements by manufacturers or their representatives will not by themselves be sufficient to create an intended use; and (4) in determining intended uses, FDA will abide by restrictions on FDA authority imposed by federal courts in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), and similar First Amendment decisions.

WLF does not repeat here its previous First Amendment analysis; none of the case law we cited in 2015 has been superseded. Instead, we reply briefly to several of FDA's responses (set forth in the preamble to the Final Rule) to our to First Amendment arguments.

FDA asserts that the First Amendment does not prohibit the evidentiary use of speech—even truthful speech—"to establish the elements of a crime or to prove motive or intent." Final Rule, 82 Fed. Reg. at 2209. But FDA fails to acknowledge that the Second Circuit explicitly held, in the context of truthful manufacturer speech about an FDA-approved drug, that the First Amendment prohibited the use of such speech to prove that the drug was being marketed for a new intended use (and thus that the drug was misbranded because it was not properly labeled for that new use). *Caronia*, 703 F.3d at 166-67.

FDA questions the continued vitality of *Caronia*, asserting (among other things) that "*Caronia* based its analysis on a legal theory that is more proscriptive than the one FDA actually holds" and citing a post-*Caronia* Canadian study "showing an association between unapproved uses and adverse drug events." *Id.* at 2210-11. But the United States had a full and fair opportunity to present its position to the Second Circuit; if it disagreed with the Second Circuit's legal analysis, it should have sought review of the panel's decision. Having made the decision not to seek Supreme Court review, the Executive Branch is in no position to second-guess the Second Circuit's First Amendment analysis. FDA's citation to the Canadian study as a basis for challenging *Caronia* is surprising, given the agency's repeated endorsements of off-label prescribing as an essential component of effective health care. Moreover, if FDA wants to take action to reduce off-label prescriptions, it ought to begin by asking Congress to lift the prohibition against FDA efforts to regulate the practice of medicine.

FDA cites a Supreme Court decision for the proposition that "content-based restrictions on protected expression are sometimes permissible, and that principle applies to commercial speech." 82 Fed. Reg. at 2211 (citing *Sorrell v IMS Health Inc.*, 564 U.S. 552, 579 (2011)). FDA is no doubt correct that speech restrictions imposed on drug and device manufacturers are "sometimes permissible." But FDA bears a heavy burden when it seeks to impose such restrictions on truthful manufacturer speech, and it fails to acknowledge that courts have repeatedly invoked the First Amendment to strike down FDA speech restrictions of that nature.

V. *The Final Rule Should Be Repealed on Policy Grounds*

FDA should repeal the Final Rule for the additional reason that it constitutes unsound healthcare policy. Manufacturers have been pleading with FDA to provide them with guidance regarding how to market their products without incurring government sanctions or tort liability. The Final Rule provides manufacturers with no guidance whatsoever; the totality-of-the-evidence standard simply warns them that *any* manufacturer conduct potentially could subject them to new-intended-use liability.

By adopting a totality-of-the-evidence standard, FDA has written itself a blank check that it can fill in as the need arises. It permits the agency to determine that a manufacturer possesses whatever intent FDA officials desire to find by applying an *ad hoc* formula to whatever evidence

is available. As the Supreme Court has noted in another context, a "totality" standard is "not a test at all but an invitation to make an *ad hoc* judgment." *City of Arlington v. FCC*, 133 S. Ct. 1863, 1874 (2013). The Final Rule provides that even knowledge that doctors are writing off-label prescriptions can, in appropriate circumstances, be used as evidence that the manufacturer intends to market its product for those off-label uses—even though any relationship between knowledge and intent is highly attenuated. If government prosecutors and private tort lawyers can rely on "mere knowledge" as evidence of intent to market an FDA-approved product for an unapproved new use, manufacturers have been stripped of all safe harbors; they will be forced to accept prosecutors' repeated demands for criminal pleas and massive fines.

WLF respectfully suggests that FDA's we-know-improper-promotion-when-we-see-it policy harms public health and violates the First Amendment. It chills the free exchange of new, life-saving information about advances in medical care. It diverts FDA's limited resources away from more pressing concerns, including ensuring regulation of products whose manufacturers make unsubstantiated claims regarding the diagnosis, care, mitigation, treatment, or prevention of disease. And it forces drug and device manufacturers to devote an outsized portion of their capital to addressing enforcement issues rather than focusing on the development of new medical products.

VI. *Conclusion*

WLF appreciates this opportunity to submit these comments relating to FDA's regulation of "intended uses" and to issues raised by MIWG's February 8, 2017 Citizen Petition. For the reasons set forth herein, WLF urges FDA to withdraw the Final Rule and, in its place, issue a revised rule that is consistent with the Proposed Rule. WLF also urges FDA to propose a new "intended use" regulation containing the First Amendment-friendly language outlined in Section IV and WLF's November 24, 2015 comments.

Sincerely,

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/s/ Mark S. Chenoweth
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