
Docket No. FDA-2011-D-0429

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES**

Concerning

**DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF:
CLASSIFICATION OF PRODUCTS
AS DRUGS AND DEVICES AND
ADDITIONAL PRODUCT CLASSIFICATION ISSUES**

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 76 *FED. REG.* 36133 (JUNE 21, 2011)

Daniel J. Popeo
Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

September 19, 2011

**WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, DC 20036
202-588-0302**

September 19, 2011

Via Email

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

**Re: Draft Guidance for Industry and FDA Staff:
Classification of Products as Drugs and Devices
and Additional Product Classification Issues
76 Fed. Reg. 36133 (June 21, 2011)
Docket No. FDA-2011-D-0429**

Dear Sir/Madam:

The Washington Legal Foundation (WLF) appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Draft Guidance (cited above) regarding Classification of Products as Drugs and Devices and Additional Classification Issues.

The Draft Guidance sets forth how FDA intends to apply the FDCA's definition of a "device" when determining whether to classify a medical product as a device or a drug. WLF strongly objects to FDA's proposed approach and urges the agency to withdraw the Draft Guidance. FDA's proposed policy squarely conflicts with the definition of a "device" as set forth in Section 201(h) of the FDCA, 21 U.S.C. §321(h). Moreover, the proposed policy represents a sharp departure from the policy that FDA has maintained for the past 35 years and would cause numerous products to be classified as drugs that would have been classified as medical devices under existing policy. Under those circumstances, the Administrative

Procedures Act (APA) bars FDA from adopting the proposed policy set forth in the Draft Guidance unless it first complies with the APA's notice-and-comment procedures.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law and policy center with members and supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government. It devotes a substantial portion of its resources to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. Among WLF's members are doctors and patients who desire to advance health care by ensuring that innovative and safe medical products reach the market without undue delays. WLF regularly litigates in support of patients who seek expedited access to life-saving medical products. *See, e.g., Abigail Alliance for Better Access to Investigational Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 552 U.S. 1159 (2008). WLF is concerned that the Proposed Guidance, by restricting the definition of a "device" and causing the reclassification of numerous medical products from "device" to "drug" status, will interfere with the ability of patients to obtain access to the latest advances in medical technology.

II. *FDA's Statutory Authority*

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301 *et seq.*, to regulate the sale and distribution of drugs and medical devices to the

public. The FDCA defines a “device” as an product “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,” or “intended to affect the structure or any function of the body of man or other animals.” 21 U.S.C. § 321(h)(2) & (3). A product with those characteristics also qualifies as a “drug.” 21 U.S.C. § 321(g). Under the FDCA, the principal distinguishing feature between a “device” and a “drug” is set forth in 21 U.S.C. § 321(h)(3); a product qualifies as a device only if it also:

[D]oes not achieve its primary intended purposes through chemical action within or on the body of man or other animals and . . . is not dependent on being metabolized for the achievement of its primary intended purposes.

As FDA concedes (Guidance at 4), a product that meets all the requirements of § 321(h) – including § 321(h)(3)’s primary-intended-purposes requirement – is regulated as a “device,” even though it likely would also qualify as a “drug” under § 321(g). If it does not meet the primary-intended-purposes requirement, it is regulated as a “drug.”

III. The Proposed Definition of “Primary” Intended Purposes

The Draft Guidance sets forth FDA’s interpretation of the phrase “primary intended purposes,” as used in § 321(h)(3).¹ FDA concedes that a product could qualify as a medical device even if it exhibits chemical action within or on the body of man, so long as that chemical action “contributes to an effect other than a primary intended purpose of the

¹ FDA has set forth its interpretation of the phrase “chemical action” in a separate Draft Guidance, also issued in June 2011. WLF is not commenting on that document, and the definition of a “chemical action” is not relevant to the issues raised by WLF herein.

product.” Guidance at 4. But FDA then proceeds to define “primary intended purposes” extremely broadly, such that *any* therapeutic effect of a product is deemed a “primary intended purpose,” regardless whether that therapeutic effect is relatively minor in comparison to other therapeutic effects of the product. *Id.* at 5. According to FDA:

[I]f a product has multiple therapeutic effects, each of these would be a “primary intended purpose” of the product, and the product would not meet the device definition if it achieves any one of these primary intended purposes through chemical action within or on the body of man.

Id. In other words, FDA is declaring, without providing any reason or explanation, that *all* of the “intended purposes” of a product are “primary.” Under this interpretation, no product with a chemical therapeutic effect, even if insignificant (*e.g.*, less than 1%), could be regulated as a “device,” because FDA would consider that chemical effect to be a “primary” purpose.

IV. FDA’s New Interpretation of the Word “Primary” Is Inconsistent with the FDCA

The plain language of § 321(h)(3) demonstrates that Congress intended to exclude from a “device” classification only those products that have a “primary” chemical intended purpose(s). Congress did not exclude from the device definition a product that has *any* chemical effect. Instead, Congress specifically qualified the phrase “intended purposes” with the term “primary,” which means “predominant,” “first in importance.”² Thus, if a product has a chemical intended purpose that is *not* “primary,” “predominant,” or “first in importance,” the statute allows that product to be classified as a “device.”

² <http://www.merriam-webster.com/dictionary/primary> (last visited Sept. 15, 2011); <http://www.thefreedictionary.com/primary> (last visited Sept. 15, 2011).

The Draft Guidance's definition of "primary intended purposes" is inconsistent with that commonsense understanding of § 321(h)(3) because it does not allow for the possibility that a product has an intended purpose that is not "primary." Had Congress's intent been the same as FDA's interpretation as set forth in the Draft Guidance, § 321(h)(3)'s language would have read differently; it would have read, ". . . does not achieve its intended purposes through chemical action," with the term "primary" omitted. Therefore, FDA's interpretation contradicts, and is wholly inconsistent with, § 321(h)(3)'s requirement that a product be classified as a "device" as long as none of its primary effects are achieved via chemical action. FDA does violence to the statute and the English language by saying that "primary intended purposes" encompasses *any* therapeutic effect even if it has a small impact.³

Furthermore, FDA's interpretation is absurd and illogical. For example, a product may have three separate intended purposes (or therapeutic effects): one chemical effect (e.g., antimicrobial) and two distinct physical effects (e.g., structural support and space filler). If the manufacturer of the product demonstrates through test data that the structural support and

³ In support of its interpretation of "primary intended purposes," FDA states, "[I]f a product's chemical action contributes to an effect other than a primary intended purpose of the product, the product could fall within the scope of section 201(h)." Guidance at 4. Given FDA's conclusion that any intended therapeutic effect is a "primary intended purpose," the quoted language seems to acknowledge that FDA would be willing to classify a product as a device even though it causes a chemical action within or on the body of man, so long as the chemical action is pure happenstance that is unrelated to any therapeutic effect intended by the manufacturer. But the quoted sentence fails to explain how, under FDA's interpretation, there could ever be an "intended purpose" that is not a "primary intended purpose," because a chemical action that arises from pure happenstance could never be said to be an "intended purpose."

space filler intended purposes provide nearly all of the clinical benefit (e.g., statistically significant improvement in 95% of the intended population), while the antimicrobial effect provides an insignificant benefit (e.g., improvement in less than 5% of the intended population), the Draft Guidance says this product would be a “drug” because one of its therapeutic effects is chemical. The fact that the antimicrobial effect is insignificant and the physical/device-like effects are predominant and first in importance is irrelevant under the Draft Guidance. FDA’s interpretation of the “device” definition simply makes no sense. It is illogical to think that Congress would have wanted this hypothetical product to be regulated as a “drug” even though its chemical effect was minor and its device-like effect was predominant.

V. *FDA’s New Interpretation of the Word “Primary” Is a Radical Change from FDA’s Longstanding Policy*

One reading the Draft Guidance would likely conclude that FDA was simply tweaking a longstanding policy with respect to classifying products as either drugs or devices; there is no language indicating that anything major is afoot. In fact, however, the Draft Guidance’s proposed interpretation of the word “primary” is a radical change from longstanding FDA policy and would cause numerous products to be classified as drugs that would have been classified as medical devices under existing policy.

For example, consistently with the understanding of the FDCA set forth above, FDA has historically regulated products that have both physical and chemical intended purposes as “devices” as long as the chemical effect is secondary to the physical effect. One recent example of such a device is the NasalCEASE® (K102742), whose primary effect is to provide

a compressive force to stop bleeding, and its minor chemical effect is to act like an anticoagulant. According to the Draft Guidance, however, the NasalCEASE and similar product types should be regulated as “drugs,” because one of its therapeutic effects is chemical. This example is but one of many that conclusively demonstrate that FDA’s new interpretation of § 321(h)(3) is entirely contrary to what has historically been the agency’s approach to product classification.

That FDA is fully aware of the radical nature of its proposed changes is evidenced by Section IV of the Draft Guidance, whose purpose is to explain “the status of the intercenter agreements and prior agency classification determinations.” The discussion in Section IV would have been wholly unnecessary had FDA really believed that it was merely tweaking its longstanding policies. Section IV makes clear that FDA will no longer consider precedent in its classification determinations. It states, “While the classification of similar products may help to inform the classification of the product at issue, we believe that a case-by-case approach . . . is necessary to ensure that products are classified properly under the applicable statutory criteria.” Guidance at 5. FDA suggests that its willingness to jettison precedent does not necessarily signify a major policy shift but rather is based on advances in “scientific understanding”: “in light of current scientific understanding, the means by which such a product or constituent part achieves an intended use may warrant a different classification for that product or constituent part . . . than the Agency previously provided.” Guidance at 6. But nowhere does the Draft Guidance explain what is meant by “current scientific

understanding” or why it should justify a different product classification. There is no evidence that products were previously classified as medical devices because FDA failed to recognize the products’s chemical actions. In the absence of any plausible science-based justification for jettisoning precedent, there is only one plausible conclusion: FDA is well aware that the Draft Guidance represents a new statutory interpretation that conflicts with longstanding policy.

In addition, the Draft Guidance advises that the longstanding CDRH and CDER intercenter agreements should not be relied upon for assessing the classification/jurisdictional status of a product. Those intercenter agreements have served as guidance for industry on classification and jurisdictional issues for almost 20 years. Yet, FDA advises, “to the extent that those agreements appear to support classification determinations that are inconsistent with this guidance, this guidance supersedes those agreements with respect to such classifications.” Guidance at 6. That is, the documents upon which FDA and industry have relied for almost 20 years to assess the classification of products are no longer reliable policy statements. The jettisoning of the intercenter agreements is yet further evidence that the Draft Guidance represents a significant departure from established FDA policy.

VI. FDA’s New Policy on “Primary” Intended Use May Only Be Implemented, if at All, Pursuant to APA Notice-and-Comment Requirements

As demonstrated in Section IV above, FDA’s new interpretation of the phrase “primary intended purposes” is invalid because it conflicts with the language and intent of § 321(h)(3). But even if FDA’s new interpretation were an acceptable construction of the statute, the Draft Guidance would still be legally objectionable because – as demonstrated in Section V – the new

interpretation represents a dramatic shift in agency policy and thus may not be adopted by means of a guidance document. The Administrative Procedure Act requires that any such new agency position may only be adopted pursuant to the APA's notice-and-comment procedures.

A rule is legislative (and thus subject to notice-and-comment procedures) if the rule "effectively amends a prior legislative rule." *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). FDA makes no effort to demonstrate that the Draft Guidance is consistent with its prior understanding of "primary intended purposes." FDA appears to assert that its new interpretation of "primary intended purposes" is a reasonable interpretation of § 321(h)(3). Section IV demonstrates why any such assertion is without merit. But at least as importantly, that assertion does nothing to explain the inconsistency between FDA's current position and its consistently held prior position – and thus does not explain FDA's failure to comply with the APA.

As the size of the administrative state continues to grow, it is important that citizens continue to have a meaningful opportunity to participate in the operation of their government. The APA is an important part of that effort. It ensures that administrative agencies will be bound not only by the laws adopted by Congress but also by their own internal rules, unless and until the agencies take appropriate steps to change those rules – including providing affected citizens notice of the proposed changes and a meaningful opportunity to comment. If administrative agencies come to believe that formal rulemaking procedures are too cumbersome (as FDA apparently has), and are permitted to change their rules under the

pretense that they are merely interpreting existing rules, an important safeguard for our representative system of government will have been lost.

It is no answer for FDA to assert that the Draft Guidance is unobjectionable because it creates no binding obligations but rather merely, “when finalized, will represent [FDA’s] current thinking on this topic.” Guidance at 2. That might be an adequate response if FDA were defending itself in federal district court lawsuit alleging that issuance of the final guidance violated the APA. But the proper question for consideration at this stage is whether it is appropriate for FDA to be issuing a guidance document that radically transforms FDA policy in this area without first complying with the APA’s notice-and-comment procedures. The answer to that question is an unequivocal “no.” No court would permit FDA to apply its new policy to a manufacturer seeking approval to market a new product unless the agency first complied with the APA’s notice-and-comment procedures. So it makes little sense to issue a guidance document describing a new policy that could never be enforced against a manufacturer seeking to rely on FDA’s longstanding interpretation of § 321(h)(3), particularly since FDA is likely to receive each year numerous product-approval applications for products whose only “primary intended purposes” involve no chemical action but for which one minor therapeutic effect involves a chemical action. Issuing a final guidance document under those circumstances would cause massive confusion among product manufacturers while also leading to APA lawsuits (which FDA would almost surely lose) by any manufacturer whose product had been classified as a drug pursuant to the terms of the guidance document. *See Syncor Int’l*

Corp. v. Shalala, 127 F.3d 90 (D.C. Cir. 1997) (striking down FDA “guidance” announcing that the agency intended to expand the reach of its new-drug jurisdiction over PET radiopharmaceuticals, on the grounds that FDA failed to comply with APA procedures before issuing the guidance). As a federal district court held recently in striking down FDA efforts to begin asserting jurisdiction over pharmacy compounding, when FDA’s “longstanding policy” had been to “permit, and even promote” such compounding, “FDA cannot simply upset the expectations it helped create through decades [] without explanation.” *United States v. Franck’s Lab*, ___ F. Supp. 2d ___, 2011 U.S. Dist. LEXIS 102560, at *133 (M.D. Fla., Sept. 12, 2011).

VII. The Draft Guidance Would Negatively Affect a Significant Number of Manufacturers

FDA’s new interpretation of the term “primary intended purposes” will have a major negative impact on a significant number of manufacturers who in the past had reasonably assumed that their products were properly classified as devices. For example, the Draft Guidance explains that FDA is currently reviewing regulatory and legal options relating to the transfer of products that have been classified but that do not fall within an existing classification regulation. Guidance at 7. One of the options proposed in the guidance document is the withdrawal of the existing approval for those products and to require new approvals under a new drug classification. Guidance at 8. Wound gels and irrigation solutions are examples of products that have been regulated as devices for over 10 years for which there is no classification regulation. Most of the wound gels and irrigation solutions have secondary chemical

intended purposes and, if the principles in the Draft Guidance are followed, those products would likely be reclassified as “drugs.” That would be a significant change in regulatory requirements for those product manufacturers. Yet FDA proposes to overturn decades of regulatory precedents through a guidance document. Medical device manufacturers require predictability in the regulatory process. FDA has acknowledged the need for clear requirements. This Draft Guidance document represents the antithesis of regulatory predictability.

CONCLUSION

WLF respectfully requests that FDA withdraw Sections III and IV the Draft Guidance. FDA has issued a new and substantive interpretation of the FDCA’s definition of a “device.” That interpretation is inconsistent with 21 U.S.C. § 321(h)(3). Moreover, it significantly deviates from the agency’s longstanding approach to classification determinations. Under the APA, before FDA may apply this new interpretation to the application of any product manufacturer, it is required to comply with the APA’s notice-and-comment requirements. In the absence of such compliance, the Draft Guidance should be withdrawn.

Sincerely,

/s/ Daniel J. Popeo
Daniel J. Popeo
Chairman and General Counsel

/s/ Richard A. Samp
Richard A. Samp
Chief Counsel

cc: Office of Combination Products