UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CA No. 1:11cv01187 (RMC)
	)	Judge Collyer
UNITED STATES FOOD AND DRUG, ADMINISTRATION,	)	
	)	
	)	
Defendant.	)	
	)	

BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN OPPOSITION TO
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND
IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Daniel J. Popeo
Richard A. Samp
(D.C. Bar No. 367194)
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave, NW
Washington, DC 20036
(202) 588-0302
rsamp@wlf.org

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Counsel for *Amicus Curiae*

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending free enterprise principles, individual rights, a limited and accountable government, and the proper use of our state and federal administrative systems. To that end, WLF has frequently appeared in this and other federal and state courts to ensure that administrative agencies adhere to the rule of law. *See, e.g., Shinseki v. Sanders*, 556 U.S. 396 (2009).

In particular, WLF focuses much of its work on the activities of the Food and Drug Administration. WLF has repeatedly criticized FDA for failing to comply with the Administrative Procedure Act (APA) when adopting new rules intended to have broad application. For example, litigation filed by WLF on behalf of patients and doctors forced FDA in 1994 to retract rules regarding the regulation of allograft heart valves, after FDA conceded that it had not complied with the APA's notice-and-comment procedures before adopting the rules. *Washington Legal Found. v. Shalala*, No. 93-5279 (D.C. Cir. 1994). *See also ViroPharma Inc. v. Hamburg*, No. 11-5143 (D.C. Cir., dec. pending). Since 2006, WLF has operated its "OPDP Watch" project, which critiques warning letters and "untitled" letters issued by FDA's Office of Prescription Drug Promotion (formerly known as DDMAC). A recurring theme of WLF's critiques is that OPDP regularly announces new legislative rules by means of its warning letters, yet does so without abiding by the APA's notice-and-comment procedures.

WLF views FDA's June 2011 draft guidance relating to product-jurisdiction matters – "Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues" – as yet another example of FDA adopting a new, legislative rule without complying with the APA's notice-and-comment procedures. FDA's

decision to classify Plaintiff Prevor's Diphoterine® Skin Wash ("DSW") as a combination product rather than as a device is an application of that new legislative rule. WLF agrees with Prevor that FDA's classification decision is based on an interpretation of 21 U.S.C. § 321(h) – the federal statute that defines a "device" for purposes of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq*. – that is wholly implausible. WLF is filing separately to focus on an additional issue – FDA's failure adhere to the APA's notice-and-comment procedures when adopting its new legislative rule.

WLF has no ties to Prevor, financial or otherwise. It became aware of this lawsuit only after it began work on its comments to FDA (ultimately filed in September 2011) on the June 2011 Draft Guidance, and discovered that FDA had already applied its new legislative rule to Prevor's application. Accordingly, WLF can provide the Court with a perspective not shared by any of the parties. In particular, WLF wishes to point out the danger of permitting FDA, or any administrative body, to amend its rules without any advance notice and without providing stakeholders with an opportunity to comment on the impact of those amendments. WLF feels strongly that when (as here) FDA seeks to adopt a rule that effectively amends a prior legislative rule, it ought to provide advance notice of its intent and provide interested stakeholders an opportunity to comment on the amendment before adopting it in final form.

STATEMENT OF THE CASE

As explained in detail in Prevor's memorandum of points and authorities in support of its Motion for Summary Judgment ("Pltf. Br."), DSW is a product designed to protect workers against spills of toxic chemicals. The product consists of a cannister containing a liquid that is 96% water and 4% diphoterine. When activated, the cannister propels the liquid onto skin

exposed to a chemical spill or splash. The physical impact of the liquid striking the chemical removes the chemical from the skin. Just as is the case with water showers (the standard of care for minimizing toxic chemical burn injuries), DSW physically displaces and dilutes the toxic chemical through the addition of water and diphoterine, thus protecting the worker from a severe chemical burn. Pltf. Br. at 3.

DSW also can help to neutralize certain toxic chemicals that might not have been washed off; the combination of water and diphoterine is deemed superior to water alone in neutralizing those chemicals. *Id.* at 3-4. But studies submitted by Prevor to FDA indicate this chemical action contributes less than 10% of the therapeutic effect of the liquid.

Prevor, a French company, markets DSW in numerous countries around the world and now seeks FDA approval to market within the United States. In 2009, it asked FDA's Office of Combination Products (OCP) to classify DSW's liquid component as a "device," and to assign its application to CDRH for review.[1] In its October 2009 response, OCP stated that DSW's liquid component is a "drug" because (according to OCP) it "achieves its primary intended purposes, *at least in part*, through chemical action." A.R. 676 (emphasis added). OCP deemed DSW a "combination product" because one its components (the liquid) was a drug and another component (the cannister) was a device. It then concluded that DSW's Primary Mode of Action (PMOA) was as a drug and thus that DSW should be assigned to CDER as the lead FDA center for regulation.

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[1] FDA's Center for Devices and Radiological Health (CDRH) is the FDA division generally responsible for review and approval of marketing applications for medical devices. Applications to market new drugs are generally handled by FDA's Center for Drug Evaluation and Research (CDER).

Prevor then sought review of OCP's determination by FDA's Office of Special Medical Programs (OSMP). In an April 2011 letter, OSMP affirmed OCP's determination that DSW's liquid is a "drug" and that the product's marketing application ought to be reviewed by CDER. Although at no time did OSMP ask for additional information about Prevor's studies demonstrating that the chemical action of DSW's liquid provides less than 10% of its therapeutic benefit, the letter called into question the reliability of those studies. Neither OSMP nor OCP (which had not even commented on the studies) pointed to any evidence suggesting that the chemical action of DSW's liquid provides some greater percentage of DSW's therapeutic benefit.

SUMMARY OF ARGUMENT

FDA's determination that DSW should be regulated as a "drug" rather than as a "device" is contrary to law and should be reversed. Under the FDCA, the principal characteristic that distinguishes a drug from a medical device is whether it "achieves its primary intended purposes through chemical action within or on the body of man or other animals." 21 U.S.C. § 321(h)(3). If the product does so, it is a drug; if it does not do so, it is a medical device – provided, of course, that it also meets the other requirements of § 321(h). FDA's determination was based on its newly adopted rule that hinges primarily on its erroneous interpretation of the term "primary intended purposes."

According to FDA, *any* intended therapeutic effect of a product should be deemed a "primary" intended purpose of the product, regardless whether that therapeutic effect is relatively minor in comparison to other therapeutic effects of the product. That interpretation of § 321(h) effectively writes the word "primary" out of the statute and cannot be squared with congressional intent. Prevor introduced evidence demonstrating that the chemical effects of administering

DSW (neutralizing certain toxic chemicals that may not have been washed away by DSW's physical effects) account for less than 10% of DSW's therapeutic benefit. An intended chemical action providing such a small percentage of a product's therapeutic benefit does not fall within any commonly understood definitions of the product's "primary" intended purposes. In the absence of evidence from FDA that the chemical action actually provides a significantly larger percentage of the product's therapeutic benefit, the decision to classify DSW's liquid component as a "drug" cannot stand.

But even if FDA's interpretation of "primary intended purposes" were plausible (which it is not), FDA's challenged action could not withstand APA review. The June 2011 draft guidance document issued by FDA regarding product classification (the "Guidance Document") makes plain that FDA's rejection of Prevor's August 2009 request for designation was based on a newly adopted rule regarding product classification. The evidence is overwhelming that the Guidance Document represents a major shift in FDA policy, such that numerous medical products that previously would have been regulated as devices will now be regulated as drugs. Moreover, the new rule is properly classified as "legislative" or "substantive" rather than "interpretive" in character. The APA prohibits FDA from adopting new legislative rules without first engaging in notice-and-comment rulemaking – which it concededly has not done in this case.

The "legislative" or "substantive" character of the new rule is readily discernable from the text of the Draft Guidance. The document makes plain that FDA's new rule did not come about simply because FDA officials suddenly realized that the agency's previous understandings of the phrase "primary intended purposes" did not accurately capture Congress's intent. Rather, the change came about because FDA officials decided that, in light of what it viewed as changed

conditions in the medical product field, more in-depth product review (*i.e.*, the type of review associated with drugs) was warranted for products of the sort at issue here. A rule characterized by an agency's effort to expand its regulatory footprint has long been deemed the hallmark of a "legislative" or "substantive" rule that is subject to APA notice-and-comment requirements. *See, e.g.*, *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997).

ARGUMENT

I. FDA'S DETERMINATION THAT DSW SHOULD BE REGULATED AS A "DRUG" RATHER THAN A "DEVICE" WAS BASED ON AN ERRONEOUS INTERPRETATION OF THE FDCA'S DEFINITION OF 'DEVICE"

Prevor introduced studies demonstrating that less than 10% of DSW's therapeutic benefit is provided by the chemical action of its liquid component on certain toxic chemicals. FDA put forward no evidence suggesting a higher figure. Under those circumstances, FDA erred as a matter of law in determining that the chemical action is a "primary intended purpose" of DSW, and thus that DSW should be regulated as a drug.

Congress adopted the FDCA to regulate the sale and distribution of drugs and medical devices to the public. The FDCA defines a "device" as a 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 conceded in the Guidance Document (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."

The plain language of § 321(h)(3) demonstrates that Congress intended to exclude from a "device" classification only those products that have a "primary" intended purpose achieved through chemical action. Congress did not exclude from the device definition every product that has *any* chemical effect. Instead, Congress specifically qualified the phrase "intended purposes" with the term "primary," which means "predominant," or "first in importance."[2] Thus, if a product has a chemical intended purpose that is *not* "primary," "predominant," or "first in importance," the statute dictates that the product be classified as a "device." FDA argues that an intended purpose can still be "primary," "predominant," or "first in importance" so long as the medical product has more than a "*de minimis* chemical effect." FDA Br. 28. That argument does violence to the definition of the word "primary" and all but writes the word out of the statute.

In denying Prevor's request for designation, OCP explicitly relied on this overbroad understanding of the word "primary." It concluded that DSW did not meet the statutory definition of a device because it "achieves its primary intended purposes, *at least in part*, through chemical action." A.R. 676 (emphasis added). By using the phrase "at least in past," OCP conveyed its understanding that *any* intended therapeutic effect of a product should be deemed a

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[2] http://www.merriam-webster.com/dictionary/primary (last visited Jan. 15, 2012); http://www.thefreedictionary.com/primary (last visited Jan. 15, 2012).

"primary" intended purpose of the product, regardless whether that therapeutic effect is relatively minor in comparison to other therapeutic effects of the product.

The "at least in part" language is echoed in the June 2011 Guidance Document: "[A] product that depends, *even in part*, on chemical action within or on the body of man to achieve any one of its primary intended purposes, would not be a device." Guidance Document at 4-5 (emphasis added). The document was explicit that FDA deems *every* intended therapeutic effect to constitute a "primary intended purpose":

> In addition, if a product has multiple therapeutic benefits, 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. at 5. FDA makes no effort to explain how an intended purpose can be "primary" if the therapeutic effect(s) in question are dwarfed by the therapeutic effects of other intended purposes.

FDA arguments in support of its statutory interpretation rest almost entirely on Congress's use of the plural in the phrase "primary intended purposes." FDA Br. 13-19. It accuses Prevor of reading § 321(h)(3) as though it read, "primary intended purpose." *Id.* at 2. FDA is mischaracterizing Prevor's argument. Prevor has never asserted that a product can have only one "primary intended purpose." Rather, Prevor asserts that, in light of the plain meaning of the word "primary," whether an intended purpose is "primary" depends on how the intended therapeutic effect compares to the therapeutic effect of other intended purposes. Because Congress used the plural word "purposes," it is reasonable to conclude that Congress intended that a "purpose" could be "primary" even though other purposes provide greater therapeutic

effects, so long as the two (or more) intended purposes are roughly comparable in magnitude. But where, as here, the therapeutic effects from the neutralization of certain toxic chemicals (the intended purpose that entails "a chemical action") constitute less than 10% of the overall therapeutic effects and are dwarfed by therapeutic effects of the other intended purpose (to flush chemicals from the skin and to dilute them by the addition of water and diphoterine), the "neutralization" intended purpose cannot plausibly be deemed "primary."

FDA argues that its interpretation of § 321(h) is entitled to deference, citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). But even assuming that *Chevron* deference is applicable to proceedings of this sort, the Supreme Court made clear that deference to agency interpretations of a congressional statute is never appropriate when, as here, the statute is neither "silent" nor "ambiguous" with respect to the issue in question. *Id*. at 843.

In sum, FDA erred as a matter of law when it concluded that neutralization of certain toxic chemicals is a "primary intended purpose" of DSW. In the absence of any "primary intended purposes" that entail a chemical action, the Court should direct FDA to regulate DSW as a "device" and to assign review to CDRH.

II. FDA VIOLATED THE APA BY ADOPTING A NEW STANDARD FOR DEFINING "DEVICES" WITHOUT COMPLYING WITH APA NOTICE-AND-COMMENT REQUIREMENTS

As Prevor has demonstrated, its effort to classify DSW as a "device" was rejected pursuant to a new FDA standard that defines "devices" more narrowly than did the agency's previous definition. That new standard is evidenced by the June 2011 Guidance Document. FDA adopted its new standard without complying with the APA's notice-and-comment

requirements, set forth in 5 U.S.C. § 553(b) & (c). Because the new standard does not qualify as a mere "interpretive rule," 5 U.S.C. § 553(b)(3)(A), it may not be put into effect until after FDA complies with the notice-and-comment requirements. Accordingly, FDA's action should be set aside because it was undertaken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

There are two separate grounds for concluding that the new FDA standard does not qualify as an "interpretive rule" that is exempt from the notice-and-comment requirements. First, FDA has adopted formal regulations that set forth its previous understanding of the meaning of the phrase "primary intended purposes." Case law is clear that, unless it complies with notice-and-comment requirements, an agency may not effect what amounts to a revision of a previously adopted regulation under the guise of providing a new "interpretation" to the regulation. Second, a careful reading of the Guidance Document makes clear that it is not merely an effort by FDA to provide clarity to an arguably ambiguous statute and regulation. Rather, the change came about because FDA officials decided, in light of what it viewed as changed conditions in the medical product field, that more in-depth product review (*i.e.*, the type of review associated with drugs) was warranted for products of the sort at issue here. A rule characterized by an agency's effort to expand its regulatory footprint has long been deemed the hallmark of a "legislative" or "substantive" rule that is subject to APA notice-and-comment requirements.

A. FDA Must Comply With Notice-and-Comment Requirements When, As Here, It Seeks To Amend Existing Regulations

Congress adopted the current statutory definition of a "device" (including the pivotal "primary intended purposes" language) in 1990. Thereafter, FDA adopted regulations for the

purpose of determining which division of the agency (*e.g.*, CDRH or CDER) would be assigned an application for approval of a new medical product. *See* "Assignment of Agency Component for Review of Premarket Applications," 56 Fed. Reg. 58,754 (Nov. 20, 1991). Rather than adopting any specialized definition of a "device," the new regulations made clear that it was interpreting the congressional "device" definition in a straightforward manner, *i.e.*, in accord with the most natural interpretation of the statutory language. *See* 21 C.F.R. § 3.2(f) (the term "device" has "the meaning given the term in section 201(h) of the" FDCA, 21 U.S.C. § 321(h)).

As set forth in detail in Prevor's brief, in the years that followed, FDA interpreted the term "primary intended purposes" in its most usual sense. That is, FDA did not deem an intended purpose to be "primary" if the intended therapeutic effect was relatively minor in comparison to other intended therapeutic effects. Accordingly, FDA routinely classified a medical product as a "device," even though one of its intended therapeutic effects involved a chemical action, if that intended therapeutic effect was relatively minor. FDA's current protestations to the contrary (*i.e.*, that its current interpretation of "primary intended purposes" is not new) are not credible.[3]

The best evidence that FDA's interpretation has changed significantly is the numerous medical products that previously were classified by FDA as devices despite having product profiles that are substantially similar to DSW. Rather than discussing each of the products cited

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[3] The best counter-example that FDA could muster was a 2003 letter to Apotex Corp., in which FDA asserted that a medical product could have more than one primary intended purpose. FDA Br. at 29. But Prevor does not assert that there can only be one "primary" intended purpose, and FDA's example does not address the issue here: whether an intended purpose that provides less than 10% of a product's therapeutic benefit can qualify as "primary."

by Prevor, WLF focuses on just one: Reactive Skin Decontamination Lotion ("RSDL"), which FDA has cleared for marketing as a device. RSDL is approved for use in removing or neutralizing chemical warfare agents and T-2 toxins from the skin. The chief purposes of RSDL and DSW are remarkably similar: to remove dangerous chemicals from the skin. RSDL does so through use of a liquid on a foam sponge applicator, while DSW does so through use of liquid propelled from a cannister. Both products also have a second intended effect whose therapeutic benefit is, comparatively speaking, relatively minor: to neutralize chemicals that remains on the skin. In both instances, the neutralization process involves a chemical action. Yet while RSDL was approved by CDRH as a "device," FDA has determined that DSW must go through CDER's new drug application process.

FDA's efforts to distinguish RSDL are unavailing. FDA argues that it determined that RSDL should be regulated by CDRH because its "device constituent [*i.e.*, its foam sponge applicator] provided the PMOA," while the PMOA of DSW is its liquid (which FDA deemed a drug) and not its cannister (which FDA deemed a device). FDA Br. at 34. But that argument fails to explain why FDA applied such markedly different PMOA analyses to the two products. The function of RSDL's foam sponge applicator is virtually identical to the function of DSW's cannister; both play a central role in the physical removal of chemicals from the skin. The only plausible explanation for the differing treatment of the two products is that FDA has decided to tighten its definition of "devices" and thereby force a greater number of medical products to be regulated as drugs.

The Guidance Document includes numerous indications that FDA did, in fact, adopt a new policy that tightens the definition of "devices." For example, Section IV of the Guidance

Document is devoted solely to explaining the new "status" of interceptor agreements – that is, agreements entered into among three FDA divisions (CDER, CBER, and CDRH) to allocate regulatory responsibility for various product categories – and of "prior agency classification determinations." Section IV would have been wholly unnecessary if FDA's purpose had been to reduce to writing its long-standing policies, rather than (as is plainly the case) to adopt a new, more stringent definition of "devices." Section IV candidly concedes that FDA's policies have changed: it states that "in light of current scientific understanding," FDA is "currently reviewing the [interceptor] agreements to determine whether it would be appropriate to modify or replace them with new agreements." Policy Guidance at 6. The implication is clear: "scientific understanding" has changed, and those changes may necessitate scrapping the interceptor agreements. FDA goes on to state, "[T]o the extent those [interceptor] agreements appear to support determinations that are inconsistent with this guidance, this guidance supersedes those agreements with respect to such classifications." *Id.*

FDA's discussion of "the status of prior Agency classification determinations" is even more revealing. *Id.* at 6-8. It sets forth elaborate procedures for changing the product classification (from "device" to "drug," one can only assume) of products, or groups of products, that have already been approved for marketing by FDA. It states that such changes may be necessary because changes in "scientific understanding may potentially lead to a different classification" of a previously classified product. *Id.* FDA is "currently reviewing" a host of legal issue relating to such post-approval reclassifications. *Id.* at 8. This discussion makes sense only if one concludes that FDA has substantially revised its understanding regarding when it intends to classify a product as a "device" and when it intends to subject the product to more

rigorous review by classifying it as a "drug." And, as noted above, the Draft Guidance articulates a regulatory position that FDA had *never* articulated before issuing its DSW decision: *every* intended therapeutic effect of a medical product constitutes a "primary intended purpose" of the product (within the meaning of 21 U.S.C. § 321(h)(3) and 21 C.F.R. § 3.2(f)), regardless how minor that effect may be in comparison to the effects of other intended purposes. *Id.* at 5.

The Administrative Procedure Act requires that any such new agency position may be adopted only 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). As the D.C. Circuit has explained, unless an agency action that modifies its prior interpretation of a formal regulation is subject to notice-and comment rulemaking requirements, "the agency could evade its notice and comment obligation by 'modifying' a substantive rule that was promulgated by notice and comment rulemaking." *Syncor*, 127 F.3d at 94-95 (quoting *Paralyzed Veterans of America v. D.C. Arena, L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997)).

When FDA adopted its applicable regulations in 1991, it gave the statutory phrase "primary intended purposes" its most natural, straightforward interpretation (*i.e.*, the word "primary" means "predominant" or "first in importance"). 21 C.F.R. § 3.2(f). Nothing in the regulatory history suggests that FDA based its regulation on an idiosyncratic definition of the word "primary." The evidence cited above makes clear that FDA has now adopted a more expansive definition of "primary intended purposes." Even if that expansive definition were a plausible interpretation of the statutory and regulatory language, the APA dictates that FDA may not adopt it without first complying with notice-and-comment rulemaking.

B. FDA Must Comply with Notice-and-Comment Rulemaking Requirements When, As Here, It Adopts a New Substantive Policy

Notice-and-comment rulemaking is also required for a second reason: FDA's new product classification policy qualifies as a substantive rule. A careful reading of the Guidance Document makes clear that it is not merely an effort by FDA to provide clarity to an arguably ambiguous statute and regulation. Rather, the change came about because FDA officials decided that, in light of what it viewed as changed conditions in the medical product field, more in-depth product review (*i.e.*, the type of review associated with drugs) was warranted for products of the sort at issue here. A rule characterized by an agency's effort to expand its regulatory footprint has long been deemed the hallmark of a "legislative" or "substantive" rule that is subject to APA notice-and-comment requirements.

Distinguishing between "interpretive rules" (which are exempt from APA notice-and-comment requirements by 5 U.S.C. § 553(b)(3)(A)) and "substantive rules" is not always easy. *Syncor* provides the following helpful discussion of distinctions between the two types of rules:

> A substantive rule has characteristics of both the policy statement and the interpretive rule; it is certainly in part an exercise of policy, and it is a rule. But the crucial distinction between it and the other two techniques is that a substantive rule *modifies* or *adds* to a legal norm based on the agency's *own authority*. That authority flows from a congressional delegation to promulgate substantive rules, to engage in supplementary rulemaking. And it is because the agency is engaged in lawmaking that the APA requires it to comply with notice and comment.

Syncor, 127 F.3d at 95 (emphasis in original). *Syncor* ultimately concluded that a publication issued by FDA in 1995 regarding its regulation of nuclear pharmacists was, contrary to the agency's contention, a substantive rule. The D.C. Circuit explained:

> It is apparent to us . . . that FDA's 1995 publication is not an interpretive rule. It does not purport to construe any language in a relevant statute or regulation; it does not interpret

> anything. Instead, FDA's rule uses wording consistent only with the invocation of its general rulemaking authority to extend its regulatory reach. . . . FDA has *concluded* that radiopharmaceuticals *should be regulated* under the drug provisions of the [FDCA].

Id. (emphasis in original).

The D.C. Circuit's description of the FDA rule at issue in *Syncor* is also an apt description of the new policy adopted by FDA for the classification of medical products. A primary focus of the Guidance Document is FDA's changing understanding of the scientific questions at issue. The document refers to "current scientific understanding" (or similar phrases) nearly a dozen times, and makes clear FDA's belief that changes in the classification system are warranted because of changes in "scientific understanding." In other words, FDA has decided to "extend its regulatory reach" by classifying more medical products as drugs (and fewer medical products as devices) because it believes that new scientific understandings warrant that extension.

It is true that the Draft Guidance includes several sentences that focus on the meaning of statutory phrase "primary intended purposes." But there is nothing in the document to suggest that FDA is changing its policy because – after a careful examination of the language and history of § 321(h) – FDA has concluded that its previous interpretations of § 321(h) misinterpreted congressional intent. Rather, the discussion of the statute's meaning appears – at most – to be an after-the-fact effort to justify FDA's new policy initiative and to explain why the new policy did not violate the intent of Congress. Under those circumstances, FDA cannot realistically be deemed to have issued an "interpretive rule."

WLF is not alone in its view that FDA must comply with notice-and-comment rulemaking before adopting its new policy. A number of organizations in addition to WLF filed

comments with FDA in response to the Draft Guidance; all were in agreement that the document evidenced a substantial change in FDA classification policy. *See* Comments to FDA Docket No. 2011-D-0429, *available at* http://www.regulations.gov/#!docketDetail;det=FR%252BPR%252BN%252BO%252BSR%252BPS;rpp=10;po=0;D=FDA-2011-D-0129. A recent article in a magazine published by the Food and Drug Law Institute reached a similar conclusion. It stated that the Guidance Document (in conjunction with a companion guidance document addressing the meaning of "chemical action"):

> [P]rovide FDA with greatly expanded flexibility and potentially overbroad discretion in assigning or reassigning existing single entity or combination products as drugs. As currently drafted, they can be read to create *less* certainty as to the regulation of products previously regulated as medical devices. At a minimum, the criteria developed by FDA in these companion documents appear on an initial basis to overlook portions of the existing FDCA statutory language in ways that could have far-reaching and unanticipated effects on medical device and drug manufacturers.

Randy Prebula, *et al.*, *Two Draft Guidances Seek to Clarify and Potentially Expand FDA Classification of Device and Drug Products – Hidden Risks and Unexpected Benefits*, UPDATE at 61 (November/December 2011).

FDA's response to Prevor's request for designation makes clear that FDA was implementing its new regulatory policy when it concluded that DSW should be regulated as a drug. OCP's October 2009 response stated that DSW's liquid component is a "drug" because (according to OCP) it "achieves its primary intended purposes, *at least in part*, through chemical action." A.R. 676 (emphasis added). The "at least in part" language is substantially similar to the language FDA used in the Guidance Document to describe its new policy: "[A] product that depends, *even in part*, on chemical action within or on the body of man to achieve any one of its primary intended purposes, would not be device." Guidance Document at 4-5 (emphasis added).

The Guidance Document goes on to make clear that FDA deems *every* intended therapeutic effect to constitute a "primary intended purpose," no matter how minor that therapeutic effect may be. *Id.* at 5. Accordingly, the decision to classify DSW as a drug should be set aside as a violation of the APA, 5 U.S.C. § 706(2)(D), because it was made pursuant to an FDA policy that was not adopted in compliance with notice-and-comment requirements.

When, as here, an agency seeks to extend its regulatory footprint, sound public policy requires that – before any changes are effected – stakeholders have a full opportunity to comment on the proposed changes. This case presents an issue that is far broader than the fate of one company and its efforts to prevent FDA from overhauling the product approval process. 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.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court deny FDA's motion for summary judgment and grant Prevor's motion for summary judgment.

Respectfully submitted,

/s/ Richard A. Samp
Daniel J. Popeo
Richard A. Samp (D.C. Bar No. 367194)
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave., N.W.
Washington, DC 20036
Tel.: (202) 588-0302
Fax: (202) 588-0386
Email: rsamp@wlf.org

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Attorneys for *Amicus curiae*

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of January, 2012, I deposited copies of the foregoing *amicus curiae* brief of WLF in the U.S. Mail, addressed as follows:

Jeffrey N. Gibbs
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, DC 20005

John W. M. Claud
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044

I further certify that I sent copies of the brief to the above counsel by email.

/s/ Richard A. Samp
Richard A. Samp