UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CA No. 1:13-cv-01177 (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

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law firm 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 making policy choices that lack grounding in its statutory mandate and/or that are adopted in a manner that does not comply with the Administrative Procedure Act (APA). 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. *Washington Legal Found. v. Shalala*, No. 93-5279 (D.C. Cir. 1994). WLF filed two *amicus curiae* briefs in prior litigation that challenged FDA's 2009-2011 classification of Diphoterine® Skin Wash ("DSW") as a drug, asserting that the decision was arbitrary and capricious. *See Prevor v. FDA*, 895 F. Supp. 2d 90 (D.D.C. 2012) ("*Prevor I*").

WLF agrees with Prevor that FDA's second (May 24, 2013) classification decision is similarly arbitrary and capricious and is based on an implausible 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*. WLF is filing separately to focus on one particularly egregious aspect of the second decision (hereinafter the "Remand Response"): FDA's determination that it should abandon its prior understanding of what constitutes a product's "intended purposes," as that term is used in § 321(h). Under FDA's new, never-previously-

articulated interpretation of "intended purposes"—an interpretation that elevates the word "purpose" to the highest possible level of generality—medical products will only rarely have more than one intended purpose. WLF deems that to be an implausible statutory interpretation because Congress clearly understood that products would have both "primary" and non-primary intended purposes. WLF also believes that FDA's post-remand policy reversal constitutes "arbitrary and capricious" action in violation of the APA because FDA failed to provide a reasoned explanation for its reversal.

WLF has no ties to Prevor, financial or otherwise. It became aware of the Prevor/FDA litigation only after it began work on its comments to FDA (ultimately filed in September 2011) on a June 2011 Draft Guidance[1] (a document that proposed substantial revisions in FDA product classification policies), and discovered that FDA had already applied those proposed new policies to Prevor's application. Incredibly, and in apparent response to the Court's 2012 decision striking down FDA's first product classification decision, FDA states that it now plans to issue yet another draft guidance without first attempting to adopt a final version of the June 2011 Draft Guidance or to respond to Commenters' numerous criticisms of that document. *See* Remand Response at 4 n.3 ("FDA intends to revise its [June 2011] draft guidance on product classification to more fully explain its classification process.").

Because it has no direct interest in this lawsuit, 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 adopt policies without reference to its

[1] *See* "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).

legislative mandate.

STATEMENT OF THE CASE

As explained in detail in Prevor's two briefs, 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.

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. 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.[2] In its October 2009 response, OCP stated that DSW's liquid component is a "drug" because (according to OCP) it "achieves its primary intended

[2] 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).

purposes, *at least in part*, through chemical action." *Prevor I*, 895 F. Supp. 2d at 94 (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. In an April 2011 letter, FDA's Office of Special Medical Programs (OSMP) affirmed OCP's "drug" determination.

Prevor filed a lawsuit challenging that determination. In September 2012, this Court concluded that FDA's determination was arbitrary and capricious, vacated that determination, and remanded the case to FDA "for further action consistent with" the Court's opinion. *Id.* at 101. The Court concluded that the determination lacked a "reasoned basis" because "FDA failed to provide any details regarding its 'qualitative evaluation' [of] the 'scientific information' on which it based the particular decision that one of the *primary* purposes of the DSW solution is achieved through chemical action." *Id*. at 97 (emphasis in original). It stated, "FDA failed to address or explain what makes the chemical effect here a 'primary intended purpose' of DSW." *Id.* It also criticized FDA for failing to offer any "reasoned basis" for interpreting "primary intended purpose" broadly so as to include "a purpose that occurs 'at least in part' or 'even in part' with other actions," noting that the dictionary definition of "primary" "does not readily" lend itself to such a broad interpretation. *Id.* at 99.

On remand, FDA affirmed its initial determination that DSW should be classified as a drug-device combination with a drug PMOA, and thus that it should be regulated by CDER. It did so, however, on the basis of a completely new rationale. In its initial evaluation, FDA had determined that DSW had two "intended purposes": (1) to wash splashes of acidic or basic

substances off the skin; and (2) to neutralize the chemical that is on the skin. *Id.* at 94. It had determined that both of those intended purposes qualified as "primary" within the meaning of 21 U.S.C. § 321(h). *Id.*

On remand, however, FDA adopted a new definition of "intended purposes" and, based on that new definition, concluded that DSW had but a single intended purpose: to prevent and minimize accidental burn injuries. Remand Response at 5. FDA concluded that "intended purpose" should be defined at an extremely high degree of generality; that is, a product's "intended purpose" is its proposed FDA-approved indication. FDA apparently concluded that its prior definition, by focusing on a product's "intended purpose" at a more detailed level, was not as faithful to the statutory language. Applying this new definition, FDA concluded that its previous conclusion that DSW had two "primary intended purposes" was erroneous:

> FDA erred in earlier ascribing two primary intended purposes to DSW, washing away chemicals and neutralizing acids and bases, by conflating how the product may achieve its intended purpose (*how* the product is claimed to work) with the product's intended purpose (*what* the product is claimed to do). Upon re-examining Prevor's RFD and related materials, FDA has revised its assessment of DSW's primary intended purposes and determined that its primary intended purpose, indeed its only intended purpose, is *what* the product is claimed to do, to help prevent and minimize accidental chemical burns.

Id.

Having thus succeeded in eliminating from its analysis any consideration of the word "primary" (the word that FDA had likely misinterpreted, this Court concluded in *Prevor I*), FDA then considered whether DSW "achieved" its sole intended purpose (prevention and minimization of accidental chemical burn injuries) "through chemical action within or on the body of man." 21 U.S.C. § 321(g). FDA recognized that DSW was intended to accomplish its purpose in three ways: (1) physically displacing irritating and corrosive chemicals; (2)

neutralizing acids and bases; and (3) diluting acids and bases. *Id.* at 5-6. FDA stated that it considered neutralization to be a "chemical action." Thus, as FDA viewed the matter, the question for decision was whether a product (or product component) that "achieve[d] its primary intended purpos[e]" in part through "chemical action" was thereby subject to § 321(h)'s "device" exclusion.[3] To resolve that issue, FDA adopted yet another entirely new statutory interpretation: it concluded that a product "does not achieve its primary intended purposes through chemical action within or on the body of man" only if the evidence indicates that chemical action does not "meaningfully contribute to" its primary intended purposes. *Id.* at 8. FDA did not explain from whence it derived its "meaningfully contribute" standard, other than to suggest that the phrase "meaningfully contribute to" is synonymous with the word "achieve." Indeed, WLF has found no evidence that FDA ever previously used that standard in evaluating how much "chemical action" is necessary to trigger the Device Exclusion Clause.

Applying that standard, FDA determined that neutralization "meaningfully contributed" to DSW's intended purpose of preventing and minimizing accidental chemical burns, and thus that the liquid solution component of DSW should be classified as a drug. *Id.* at 8-11.[4] FDA thus determined that DSW is a combination product with a drug constituent part (the solution)

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[3] For the purposes of conforming to FDA's terminology, WLF hereinafter refers to this statutory language as "the Device Exclusionary Clause." When grappling with how to construe the Clause's meaning, FDA conceded that the Clause "does not expressly state how much chemical action suffices for a product to be excluded from the device definition." *Id.* at 7.

[4] FDA supported its determination by pointing to a newly minted default rule: "if a product meets the drug definition but there is uncertainty about whether it meets the device definition, the Agency generally classifies the product as a drug." *Id*. at 4. FDA did not explain why it was adopting the default rule, which is in considerable tension with existing FDA regulations. *See, e.g.*, 21 C.F.R. § 3.4(b).

and a device constituent part (the canister) and that DSW overall had a "drug" Primary Mode of Action. *Id.* at 11-14.

In August 2013, Prevor filed this second lawsuit, once again challenging FDA's classification of DSW. Prevor asserted that FDA failed to comply with the Court's September 2012 order by failing to defend its initial, neutralization-is-a-primary-intended-purpose rationale for its "drug" classification and instead adopting an entirely new rationale for reaching the same result. Prevor also contended that FDA's conduct was "arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, in excess of authority granted by law, and without observance of procedure required by law," all in violation of the APA. Complaint ¶¶ 36-44. Among other items, Prevor explicitly faulted FDA for adopting an insufficiently-explained new (and erroneous) definition of "primary intended purposes," *id.* at ¶ 27; for adopting an insufficiently-explained new (and erroneous) "meaningfully contributes" standard when applying the Device Exclusion Clause, *id.* at ¶ 28; for adopting an insufficiently-explained new (and erroneous) default rule whereby a product will be classified as a "drug" whenever there is uncertainty regarding whether the product qualifies as a "device," *id.* at ¶ 29; and for not providing "a legitimate reason" for failing to treat Prevor's Request for Designation (RFD) in a manner similar to its treatment of similar cases. *Id.* at ¶ 30 (quoting *Prevor I*, 895 F. Supp. 2d at 99.

SUMMARY OF ARGUMENT

WLF agrees with each of the arguments advanced by Prevor regarding why FDA has once again acted arbitrarily and capriciously in classifying DSW as a combination product with a drug PMOA and assigning it to CDER as the lead FDA center for regulation. WLF writes

separately to focus primarily on one of the many FDA errors identified by Prevor: FDA's determination that it should abandon its prior understanding of what constitutes a product's "intended purposes," as that term is used in 21 U.S.C. § 321(h). Under FDA's new, never-previously-articulated interpretation of "intended purposes"—an interpretation that elevates the word "purpose" to the highest possible level of generality—medical products will only rarely have more than one intended purpose.

That interpretation is not a plausible understanding of Congress's intent. By employing the plural of the noun "purposes," Congress conveyed its view that medical products would often have more than one "purpose" and that only "primary" intended purposes should be taken into account in determining whether a product could qualify as a "device" under § 321(h). Yet, interpreting "purpose" (as did FDA for the first time in the Remand Response) to mean a product's proposed FDA-approved indication—*i.e.*, interpreting it at its highest degree of generality—will result in most products having only one intended purpose. FDA is correct that, at a high degree of generality, an intended "purpose" of DSW is to prevent and minimize accidental burn injuries. But it is also true, as FDA recognized in its first classification decision, that at a somewhat lower level of generality, three intended "purposes" of DSW are to: (1) remove splashes of acidic or basic substances off the skin; (2) neutralize such chemicals; and (3) dilute such chemicals. Moreover, only by viewing "purpose" at a lower level of generality will an interpretation of § 321(h) conform to Congress's understanding that medical products are likely to have multiple "intended purposes."

FDA defended its adoption of a new interpretation of "intended purposes" by asserting that its prior interpretation had "conflat[ed] how the product may achieve its intended purpose

(*how* the product is claimed to work) with the product's intended purpose (*what* the product is claimed to do)." Remand Response at 5. That argument makes little sense. To say that a product's purposes include removing splashes of acidic or basic substances off the skin is not to explain "how the product is claimed to work." Rather, such an explanation would require an explanation that the DSW cannister propels the water/diphoterine solution onto skin exposed to a chemical spill or splash, and that the force of that propulsion removes chemicals from the skin. FDA's prior interpretation of "purpose" is as true to the dictionary definition of that word as is FDA's latest interpretation; it simply looks at the issue at a lower level of generality.

When this matter was before the Court in *Prevor I*, FDA insisted that its approach to determining what constituted a "primary intended purpose" was in accord with longstanding FDA policy. *See, e.g., Prevor I*, 895 F. Supp. 2d at 99 ("FDA asserts that its interpretation of 'primary intended purposes' in 'not new.' "). Following its judicial set-back, FDA now asks the Court to accept an entirely new interpretation of "primary intended purposes." Yet, the sole explanation offered by FDA for reversing course is, as explained above, nonsensical. In the absence of a reasoned basis for its new statutory interpretation, FDA's actions can only be deemed "arbitration and capricious,' in violation of the APA. Moreover, FDA's plea for deference to its new interpretation carries greatly reduced weight when as here, the interpretation conflicts with its prior interpretation of "intended purpose." *Id.* at 97.

The new interpretation ought to be rejected for the additional reason that it led directly to the interpretive quandary faced by FDA in its Remand Response: how large a role may a chemical action play in a medical product's "primary intended purpose" before the Device Exclusion Clause kicks in and the product (or component) must be classified as a drug? By

redefining the word "purpose" in a manner that conveniently eliminated the need to address the relevance of the word "primary" to Prevor's RFD, FDA left itself without any FDCA-based standard for measuring the relevance of DSW's chemical action. Accordingly, FDA was required to invent an extra-statutory standard: whether a product's chemical action "meaningfully contributes to" its intended purpose. A far more plausible interpretation of "intended purposes" is the one employed by FDA until 2013: "intended purposes" is to be determined by examining the issue at a low level of generality, not at the level of the product's proposed FDA-approved indication. Doing so is likely to lead to identification of a greater number of "intended purposes." At that point, FDA will have a statutory standard by which to determine whether the "intended purposes" it has identified disqualify the product for a "device" classification: an "intended purpose" is disqualifying if it is "primary" and the product achieves that purpose through a chemical action. It is far less likely that Congress intended (as FDA now asserts) that the word "primary" should be assigned minimal relevance and that FDA should be given unrestricted discretion to establish its own standard for determining when a chemical action becomes sufficiently important that the product being evaluated no longer qualifies as a device.

The Remand Response was arbitrary and capricious for the additional reason that FDA based its classification in part on its finding Prevor failed to carry its burden of proof that DSW should be classified as a device. There is no basis in either the FDCA or its implementing regulation for imposing such a burden of proof. True, the implementing regulations permit a product sponsor to submit an RFD—a request that a product for which "primary [FDA] jurisdiction is unclear or in dispute" be assigned to a specified component of FDA. 21 C.F.R.

§ 3.7(a)(2). But a sponsor that submits an RFD is not expected to meet any evidentiary burden; to the contrary, the sponsor's submission is limited to no more than 15 pages and is deemed a mere "recommendation." 21 C.F.R. § 3.7(c) & 3.7(c)(3). Indeed, a sponsor is under no obligation to submit an RFD; if it declines to do so, FDA is still required to make a classification decision on the basis of the statutory criteria (set forth primarily in the Device Exclusion Clause) and may not adopt a "drug" classification simply because the sponsor has failed to meet some supposed burden of proof. Moreover, there is no statutory basis for the default rule adopted by FDA in its Remand Response: that FDA will classify a medical product as a drug whenever a doubt exists regarding the proper classification.

The Remand Response was arbitrary and capricious for the additional reason that FDA did not provide an adequate explanation for failing to classify DSW in a manner similar to the classification afforded to similar products. The Court explicitly warned FDA that it was required to provide such an explanation. *Prevor I*, 895 F. Supp. 2d at 99 (stating that "[t]he fact that FDA has changed its interpretation becomes most apparent when examining products that are analogous to DSW but regulated as devices by FDA. An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for doing so."). Yet the Remand Response essentially admitted that it was not treating DSW in a manner similar to the only two other products it discussed. Remand Response at 19-20 (conceding that FDA "may have erred" in regulating RSDL as a device, and describing its decision to regulate Medical Maggots as a device as "complicated by historical actions and product composition"). Merely describing Medical Maggots as "complicated" does not serve to adequately explain FDA's choice not to adhere to that classification decision in this case. If FDA believes that there are other

classification decisions that are actually consistent with the decision in this case, it has failed to cite them.

Finally, WLF agrees with Prevor that an appropriate remedy in this case would be to direct FDA to classify DSW as a device and to assign it to CDRH as the lead FDA center for regulation. Nearly five years have elapsed since Prevor requested that this matter be assigned to CDRH. FDA has had more than sufficient time to make a proper classification decision. Its failure to do so after all these years provides ample justification for the Court to step in and make the appropriate decision. Contrary to FDA's arguments, such a decision would not interfere with FDA ability to protect the public health. Prevor asks only that DSW's safety and effectiveness be evaluated by its recommended FDA component (CDRH) rather than by the component initially designated by FDA (CDER). FDA is in no position to assert that public health will in some way be compromised if CDRH ends up conducting the product evaluation.

ARGUMENT

I. FDA ACTED ARBITRARILY AND CAPRICIOUSLY BY APPLYING A NEW DEFINITION OF "PRIMARY INTENDED PURPOSES" THAT WAS BOTH INSUFFICIENTLY EXPLAINED AND ERRONEOUS

At all times prior to FDA's May 2013 Remand Response, the parties were in complete agreement that DSW had three "intended purposes" within the meaning of 21 U.S.C. § 321(h): (1) to remove splashes of acidic or basic substances off the skin; (2) to neutralize such chemicals; and (3) to dilute such chemicals.[5] In the Remand Response, FDA adopted without warning a substantially different interpretation of the statutory phrase "intended purposes."

[5] The parties also agreed that the third purpose (dilution) was quite minor. Accordingly, the Remand Response focused primarily on the other two purposes.

Prevor has amply demonstrated that FDA acted arbitrarily and capriciously in abandoning its long-time understanding of the phrase—both because it inadequately explained why it was changing its interpretation and because the new interpretation is not a plausible interpretation of the statute. The APA authorizes a reviewing court to overturn agency action, findings, and conclusions that are (as here) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

The relevant statutory language is contained in 21 U.S.C. § 321(g) (defining a "drug") and 321(h) (defining a "device"). The only significant distinction between the two definitions is contained in the Device Exclusion Clause; the Clause has long been understood to require that a medical product be classified as a device and not a drug if it:

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

21 U.S.C. § 321(h). If it *does* achieve its primary intended purposes in the manner prescribed, then the product is classified as a drug.

Critical to the DSW classification decision, then, is a determination of DSW's "intended purposes." Throughout *Prevor I*, FDA assured the Court that it had determined DSW's "intended purposes" in accordance with its longstanding understanding of that phrase. *See, e.g.*, *Prevor I*, 895 F. Supp. 2d at 99 ("FDA asserts that its interpretation of 'primary intended purposes' in 'not new.' "). It was thus quite surprising when FDA suddenly adopted a substantially altered interpretation of "intended purposes" in connection with the Remand Response, an interpretation that has never been memorialized in either a regulation or a guidance document and that (to WLF's knowledge) has never been applied to another RFD.

A. FDA Has Not Adequately Explained Its Decision to Adopt a New Interpretation of the Phrase "Intended Purposes"

FDA is the agency charged with administering the FDCA. As such, it is not forever bound by previous interpretations of the statute. Nonetheless, when it decides to adopt a new interpretation of the FDCA, it is required to provide a satisfactory explanation for its decision. *Prevor I*, 895 F. Supp. 2d at 97. As the D.C. Circuit has explained, "One of the core tenets of reasoned decision-making is that an agency [when] changing course . . . is obligated to supply a reasoned analysis for the change." *Republic Airline Inc. v. Dep't of Transp*., 669 F.3d 296, 300 (D.C. Cir. 2012). "Where the agency has failed to provide a reasoned explanation, . . . the court must undue its action." *Prevor I*, 895 F. Supp. 2d at 97 (quoting *Cnty. of Los Angeles v. Shalala*, 182 F.3d 1005, 1021 (D.C. Cir. 1999)). The Remand Response is arbitrary and capricious because FDA failed to provide a reasoned explanation for its decision to significantly alter its definition of the phrase "intended purpose."

The Remand Response concluded that, contrary to its prior interpretation, the phrase "intended purpose" should be defined at an extremely high level of generality. That is, a product's "intended purpose" is its proposed FDA-approved indication—in the case of DSW, FDA concluded, the "intended purpose" was to prevent and minimize accidental burn injuries. FDA's complete explanation for its interpretative about-face was as follows:

> FDA erred in earlier ascribing two primary intended purposes to DSW, washing away chemicals and neutralizing acids and bases, by conflating how the product may achieve its intended purpose (*how* the product is claimed to work) with the product's intended purpose (*what* the product is claimed to do). Upon re-examining Prevor's RFD and related materials, FDA has revised its assessment of DSW's primary intended purposes and determined that its primary intended purpose, indeed its only intended purpose, is *what* the product is claimed to do, to help prevent and minimize accidental chemical burns.

Remand Response at 5.

That argument makes little sense. To say that a product's purposes include removing splashes of acidic or basic substances off the skin is not to explain "how the product is claimed to work." Rather, an explanation of "how the product is claimed to work" would require an explanation that the DSW cannister propels the water/diphoterine solution onto skin exposed to a chemical spill or splash, and that the force of that propulsion removes chemicals from the skin. FDA's prior interpretation of "purpose" is as true to the dictionary definition of that word[6] as is FDA's latest interpretation; it simply looks at the issue at a lower level of generality.

Strikingly, FDA has not repeated its newly minted definition of "intended purpose" in any other forum of which WLF is aware. When, as here, an agency articulates a facially implausible reason for revising its interpretation of a statute, one is left with the strong suspicion that the agency has acted for the sole purpose of reaching a pre-determined administrative result, rather than based on a good-faith re-appraisal of congressional intent. Very conveniently, the new interpretation relieved FDA of the obligation to explain—as requested by this in Court in *Prevor I*—why neutralization of spilled chemicals was a "primary" intended purpose of DSW. By concluding that DSW had but one "intended purpose," FDA was able to avoid all consideration of the word "primary," since (as FDA proudly proclaimed, Remand Response at 5) a product's "only intended purpose" is by definition its "primary intended purpose." Such unreasoned changes in previously accepted statutory interpretations are the epitome of "arbitrary

[6] *See, e.g., Webster's New Collegiate Dictionary* (G. & C. Merriam Co. 1981) (defining "purpose" as "something set up as an object or end to be attained : INTENTION.").

and capricious" agency action.[7]

B. FDA's Old Interpretation of the Phrase "Intended Purposes" Is the Far More Plausible Interpretation of Congressional Intent

FDA asserts that the Court should defer to its interpretation of § 321(h); it argues that even assuming that Prevor's competing interpretation is reasonable, "the agency's interpretation must control because it is a permissible construction in light of the statutory ambiguity, which is all that is required." FDA SJ Br. at 14-15 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984)). But FDA fails to acknowledge that it has substantially altered its interpretation of the phrase "intended purposes," and as this Court noted, "An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view." *Prevor I*, 895 F. Supp. 2d at 97 (quoting *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n. 30 (1987)).[8] Still less is deference warranted when an agency has not announced its new interpretation as part of a well-considered, formal process. As the Supreme Court has explained, "The weight accorded to an administrative judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with

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[7] FDA compounded its APA violation by failing to engage in notice-and-comment rulemaking before amending its prior interpretation of the FDCA. There is no plausible basis for granting deference to a new FDA interpretation that was adopted in a procedurally inappropriate manner. *See* 5 U.S.C. § 553(b) & (c).

[8] Case law relied on by FDA, *see* FDA SJ Br. at 11-12 & n.9, provides no support for its claim that its newly minted statutory interpretation is entitled to deference. *King Broadcasting*, relied on by FDA in support of its deference argument, explicitly refused to recognize any role for administrative deference where the agency had altered its prior analysis, particularly in light of the agency's failure to provide a "cogent explanation" of the inconsistency with its prior analysis. *King Broadcasting Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988).

earlier and later pronouncements, and all those factors which give it the power to persuade . . . [T]he overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication." *United States v. Mead Corp.*, 533 U.S. 218, 228, 230 (2001).[9]

At least as importantly, FDA's current interpretation of "intended purposes" is not nearly as plausible as its former interpretation. A great many FDA-approved products have only a single FDA-approved indication.[10] Thus, if FDA were correct that a product's "intended purposes" means its proposed FDA-approved indication, then the great majority of medical products would have only a single "intended purpose." If that had been Congress's intent, it would have been unlikely to have used the plural form, "intended purposes." Inclusion of the word "primary" is further indication that Congress contemplated that most medical products would have more than one intended purpose and that it intended to make only a subset of those intended purposes relevant in the product classification process. FDA's former interpretation of "intended purposes," which viewed "purposes" at a lower level of generality, is more consistent with the statutory language. By recognizing that DSW has multiple lower-level purposes, all of which are subsets of the product's overall goal of preventing and minimizing accidental burn injuries, FDA's former interpretation dovetails much more closely with the actual language of § 321(h). Only by identifying "intended purposes" with significant specificity can § 321(h)

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[9] FDA's consideration of Prevor's RFP did not, of course, involve either notice-and-comment rulemaking or formal adjudication.

[10] Among those with more than one FDA-approved indication, WLF is unaware of any product that achieves one FDA-approved indication through chemical action and another approved indication through some other means.

serve its evident purpose of focusing on a product's numerous purposes and differentiating those that are "primary" from those that are not.

FDA's new interpretation of "intended purposes" is rendered still less plausible because it is directly responsible for creating the interpretive quandary that FDA faced in its Remand Response: how large a role may a chemical action play in a medical product's "primary intended purpose" before the Device Exclusion Clause kicks in and the product (or component) must be classified as a drug? By redefining the word "purpose" in a manner that conveniently eliminated the need to address the relevance of the word "primary" to Prevor's RFD, FDA left itself without any FDCA-based standard for measuring the relevance of DSW's chemical action. Accordingly, FDA was required to invent an extra-statutory standard: whether a product's chemical action "meaningfully contributes to" its intended purpose.

A far more plausible interpretation of "intended purposes" is the one employed by FDA until 2013: "intended purposes" are to be determined by examining the issue at a lower level of generality, not at the level of the product's proposed FDA-approved indication. Doing so is likely to lead to identification of a greater number of "intended purposes." At that point, FDA will have a statutory standard by which to determine whether the "intended purposes" it has identified disqualify the product for a "device" classification: an "intended purpose" is disqualifying if it is "primary" and the product achieves that purpose through a chemical action. It is far less likely that Congress intended (as FDA now asserts) that the word "primary" should be assigned minimal relevance and that FDA should be given unrestricted discretion to establish its own standard for determining when a chemical action becomes sufficiently important that the

product being evaluated no longer qualifies as a device.[11]

II. FDA IMPROPERLY IMPOSED ON PREVOR THE BURDEN OF PROVING THAT DSW SHOULD BE CLASSIFIED AS A DEVICE

FDA's brief argues that to the extent there are gaps in the evidence regarding whether DSW achieves a significant portion of its primary intended purposes through chemical action, the fault lies with Prevor. It asserts, "FDA's regulation governing the filing of requests for designation clearly places the burden on the sponsor, not FDA, to provide information on how the product works; thus, it follows that the burden to demonstrate a particular classification falls on the sponsor." FDA SJ Br. at 6 n.4. That assertion finds no support in either the FDCA or its implementing regulations.

The FDCA sets forth rules governing which FDA center (*e.g.*, CDRH or CDER) should regulate a medical product. 21 U.S.C. § 353(g). Regulations adopted by FDA make clear that those rules govern not only the treatment of "combination products" but also of products for which (as here) "primary [FDA] jurisdiction is in dispute." 21 C.F.R. § 3.7(a)(2). The statute and regulations impose on *FDA* (not the product sponsor) the duty to determine (based on the best available evidence) how the product should properly be classified. Thus, there is no legal basis for FDA to "punish" a product sponsor by designating the product as a drug rather than a device if the sponsor fails to provide detailed information regarding how the product achieves its

[11] Even if FDA's current interpretation of "intended purposes" were correct and even if DSW could plausibly be deemed to have only a single intended purpose, WLF nonetheless concurs with Prevor that FDA's adoption of its extra-statutory "meaningfully contributes to" standard does violence to the statutory language. The result of that extra-statutory standard is to ensure that all medical products whose proposed FDA-approve indication is brought about by a process that entails more than an insignificant degree of chemical action will henceforth be classified as a drug. That standard sounds suspiciously like the *de minimis* standard that FDA unsuccessfully sought to defend in *Prevor I*.

primary intended purposes. True the implementing regulations permit a product sponsor to submit an RFD—a request that the product be assigned to a specified component of FDA—and to accompany the request with a limited quantity of information that supports its requested assignment.[12] But the sponsor is not required to submit an RFD or to provide any specific information; if it declines to submit an RFD, FDA is still required to make a classification decision on the basis of the statutory criteria (set forth primarily in the Device Exclusion Clause) and may not adopt a "drug" classification simply because the sponsor has failed to meet some supposed burden of proof.

FDA complains that it often lacks sufficient information to make a fully informed product classification decision, particularly because at the product development stage the sponsor itself may not have a clear understanding regarding how important a role chemical actions are to play in achieving the product's "primary intended purposes." Remand Response at 7-8. But just because FDA's job sometimes requires it to make decisions based on less-than-complete scientific information is not a reason for it to ignore its statutory mandate. If the best-available evidence indicates that a medical product does not achieve its primary intended purposes "through chemical action within or on the body of man or other animals," then FDA is required to classify the product as a device without regard to concerns that the evidence was not as complete as FDA would have liked. 21 U.S.C. § 321(h). Indeed, by including the word "primary" in the statute, Congress made clear that it expected FDA to engage in precisely the sort of "relative contribution of a chemical versus a non-chemical action" analysis that FDA has concluded can be very difficult to undertake. Remand Response at 8.

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[12] FDA strictly limits such submissions to 15 pages. 21 C.F.R. § 3.7(c).

WLF was particularly disturbed by a statement in the Remand Response indicating that FDA has adopted a new default rule that favors a "drug" classification in uncertain cases: "If a product meets the drug definition but there is uncertainty about whether it also meets the device definition, the Agency generally classifies the product as a drug." Remand Response at 4. This default rule is unsupported by either the FDCA or FDA regulations. Only the very rare case can legitimately be deemed to be in equipoise. If FDA determines, based on whatever evidence is available, that a product is 50.01% likely to meet § 321(h)'s definition of a device, then FDA is required to classify the product as a device. FDA apparently has concluded, as a policy matter, that: (1) it would prefer to subject medical products to the most rigorous possible safety and effectiveness analysis before allowing them to be marketed; (2) on average, the safety and effectiveness analysis tends to be somewhat more rigorous for drugs than for devices; and therefore (3) when it has any doubts about product classification, it would prefer that the product be classified as a drug and thus be made subject to somewhat more rigorous testing. If FDA does, indeed, have such a policy preference, it should inform Congress and suggest that Congress make appropriate statutory changes. But it is wholly inappropriate for FDA to adopt extra-statutory default rules of this sort that are inconsistent with FDA's statutory mandate.

III. FDA ACTED ARBITRARILY AND CAPRICIOUSLY BY FAILING TO EXPLAIN ADEQUATELY WHY IT DID NOT CLASSIFY DSW IN A SIMILAR MANNER TO SIMILAR PRODUCTS

Prevor I chastised FDA for providing "ephemeral" distinctions between DSW and other products that FDA previously classified as devices; it concluded that FDA "appears to treat similar products differently without a reasoned explanation." 895 F. Supp. 2d at 100. The Court

remanded the case with the clear expectation that FDA would provide just such a reasoned explanation; it warned FDA, "An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so." *Id.* at 99 (quoting *Independent Petroleum Ass'n of American v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996)). The Court added, "The disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious." *Id.* (quoting *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 2d 20, 28 (D.D.C. 1997)).

Despite the Court's warning, FDA still has not provided an adequate explanation for failing to classify DSW in a manner similar to the classification afforded to similar products. Indeed, the Remand Response essentially admitted that FDA was not treating DSW in a manner similar to the only two other products it discussed. Remand Response at 19-20 (conceding that FDA "may have erred" in regulating RSDL as a device, and describing its decision to regulate Medical Maggots as a device as "complicated by historical actions and product composition"). Merely describing Medical Maggots as "complicated" does not serve to adequately explain FDA's choice not to adhere to that classification decision in this case. If FDA believes that there are other classification decisions that are actually consistent with the decision in this case, it has failed to cite them.

FDA contends that its assignment of DSW to CDER is "consistent with other assignments of combination products in which . . . the product's 'primary mode of action' was provided by the drug constituent." FDA SJ Br. at 29. But given Prevor's contention that DSW is not a combination product at all (because both constituent parts are devices), it is incumbent upon FDA, if it wants to demonstrate consistent treatment between DSW and other medical

products, to demonstrate that other products with similar product profiles have been assigned to CDER. FDA has identified no such products. FDA is correct that it if it concludes that the law has changed since it made a "device" determination for RSDL, it should not be bound by that "inconsistent past practice." FDA SJ Br. at 33. But FDA does not make a credible case that the law has really changed, given that RSDL continues to be regulated as a device and FDA can point to no other products that have been handled in the same manner as DSW.

IV. THE COURT SHOULD DIRECT FDA TO CLASSIFY DSW AS A DEVICE AND ASSIGN IT TO CDRH

WLF agrees with Prevor that an appropriate remedy in this case would be to direct FDA to classify DSW as a device and to assign it to CDRH as the lead FDA center for regulation. Nearly five years have elapsed since Prevor requested that this matter be assigned to CDRH. FDA has had more than sufficient time to make a proper classification decision. Its failure to do so after all these years provides ample justification for the Court to step in and make the appropriate decision.

FDA asserts that the FDCA grants FDA sole authority to classify products and assign it to a specific FDA center for regulation. FDA SJ Br. at 34. That assertion is incorrect. Indeed, 21 U.S.C. § 360bbb-2(c) explicitly provides that if FDA fails to provide an adequate response to an RFD within 60 days of filing, courts are authorized to order FDA to comply with the relief requested by the sponsor who submitted the RFD. Section 360bbb-2(c) states, "[T]he recommendation made by [the person who submitted the RFD] shall be considered to be a final determination by the Secretary of such classification of the product, or the component of [FDA] that will regulate the product, as applicable." If it is within the power of a federal court to order compliance with an RFD if FDA fails to act for 60 days, then that power should also authorize

the court to act when FDA has (as here) failed to provide an appropriate response to an RFD for nearly five years.

FDA also contends that a classification decision made by the courts would interfere with FDA ability to protect the public health. FDA SJ Br. at 34. That assertion is based on a misinterpretation of the relief sought by Prevor. It does not seek a court determination that DSW is safe and effective for its intended uses. Rather, it asks only that DSW's safety and effectiveness be evaluated by its recommended FDA component (CDRH) rather than by the component initially designated by FDA (CDER). Given CDRH long history of evaluating the safety and effectiveness of products quite similar to DSW, FDA is in no position to assert that public health will be in some way compromised if CDRH ends up conducting the product evaluation. Indeed, as FDA itself has pointed out on several occasions, the safety and effectiveness of DSW have not been determined. Prevor is merely asserting that a thorough safety and effectiveness evaluation be undertaken by CDRH instead of CDER.

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,

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of January, 2014, I electronically filed this *amicus curiae* brief with the Clerk of the Court for the U.S. District Court for the District of Columbia by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system on the following counsel:

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