IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 1:11-cv-01187

PREVOR'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTORY STATEMENT

Prevor's Diphoterine Skin Wash ("DSW") product is a device because it fits squarely within the Federal Food, Drug and Cosmetic Act's ("FDC Act") definition of a "device," 21 U.S.C. § 321(h). DSW "does not achieve its primary intended purposes through chemical action within or on the body of man." *Id*. The U.S. Food and Drug Administration's ("FDA") Memorandum in Opposition to Prevor's Motion for Summary Judgment ("Def. Opp. Br.") does not cite any legal standard or evidence to contradict this.

The heart of FDA's argument is that the term "primary intended purposes" in the FDC Act means that more than one purpose can be primary. *See* Def. Opp. Br. at 2, 13-20. But Prevor has never disputed that a product can have more than one primary intended purpose. DSW, however, has only one primary intended purpose.

In classifying Prevor's product as a drug, FDA has effectively sought to amend the statutory definition of "device" by removing the word "primary" and adding the words "even in part," for the first time in its long history of regulating device and drug products. These revisions have no basis in the statute, its legislative history, or in FDA's regulations.

This case presents a striking example of an agency changing the rules it applies without prior notice, let alone notice and comment rulemaking. Prevor demonstrated in its Memorandum in Support of its Motion for Summary Judgment ("Pl. Br.") that in classifying DSW as a drug, FDA applied a new standard for "device" classification: a product that achieves any intended therapeutic purpose, even in part, by chemical action will be deemed a drug.

FDA does not assert, let alone establish, that this standard existed before it was applied to DSW. Nowhere does the government identify a single example of another product regulated on the same grounds as it now regulates DSW. FDA never acknowledges that it has changed standards, or provides any explanation for making the change.

By relying on unsupported generalizations, the government vainly tries to make it appear as though the Agency provided the legally mandated reasoned explanation of its new standard as applied to DSW, which it did not. FDA never communicated the bases for applying a new standard, never meaningfully addressed the data or precedents Prevor provided, and never identified the data used to conclude that neutralization is a "primary intended purpose" of DSW. For these reasons, and those described in Prevor's

Memorandum in Support of its Motion for Summary Judgment, this Court should conclude that DSW meets the definition of device and vacate FDA's classification of DSW.

II. THE COURT OWES NO DEFERENCE TO FDA HERE.

FDA's new interpretation of "device" is not entitled to deference here. The government claims that because FDA evaluated scientific information in this case, its decision should be accorded great deference. *See* Def. Opp. Br. at 21. This *Chevron* II argument misses the point.[1] Unlike an FDA decision that warrants deference to scientific expertise, the dispositive issues in this case have nothing to do with scientific analysis, and thus do not require deference. The key questions are ones of statutory construction and procedure: whether FDA's interpretation of the "device" definition comports with the statute, and whether FDA changed the statutory standard for defining a device without observance of the procedure required by law. This Court is not required to reach any scientific issues nor review scientific data to determine that FDA acted outside its statutory authority here. It is disingenuous of the government to assert otherwise given that the FDA decision at issue is devoid of any scientific analysis, and instead rests on conclusory statements.

[1] FDA asserts that if *Chevron* deference is not applicable because the statute is ambiguous, FDA's interpretation is entitled to "some deference" under another standard. *See* Def. Opp. Br. at 15. Prevor does not understand this argument. If *Chevron* applies at all to FDA's decision in this case, *Chevron* II would apply if the statute were deemed ambiguous.

FDA's new "even in part" standard is not tied to the statute. The statute states that a device "does not achieve its primary intended purposes through chemical action within or on the body." 21 U.S.C. § 321(h). The government pointedly avoids acknowledging that it modified this plain language when it determined that DSW "depends, even in part, on chemical action within or on the body to achieve any of its primary intended purposes." AR 786. However, FDA does not, and indeed cannot, identify its basis for introducing this language into the device definition.

FDA's decision also must be rejected because it directly conflicts with FDA's earlier interpretations of the statute. An agency interpretation that conflicts with the agency's prior interpretation is entitled to considerably less deference than a consistently held agency view. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 515 (1994); *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993). Lesser deference is particularly applied by courts where, as here, the agency's position results in "unfair surprise." *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170-71 (2007). An agency's change in direction from a previously announced intention is a danger signal that triggers careful scrutiny to ensure that the agency's change of course is not based on impermissible or irrelevant factors. *See Nalco v. EPA*, 786 F. Supp. 2d 177, 184 (D.D.C. 2011) (citing *Robbins v. Reagan*, 780 F.2d 37, 48 (D.C. Cir. 1985)).

The government fails to acknowledge that its new standard for "device" reflects a reversal of the criteria used in FDA's previous device classification decisions. But it

does, and the resulting "unfair surprise" to Prevor and the entire device industry can receive no deference from this Court.

III. DSW IS A DEVICE.

A. DSW meets the statutory definition of "device."

As described in Prevor's appeal to FDA's Office of Special Medical Programs ("OSMP"), and its earlier brief, DSW meets each of the elements of the statutory definition of a device. *See* AR 734-36; Pl. Br. at 5, 7, 12-15. The only element in dispute is whether DSW "does not achieve its primary intended purposes through chemical action within or on the body of man." 21 U.S.C. § 321(h). The government argues that DSW has two primary intended purposes, one of which is achieved through chemical action (neutralization). In fact, DSW has only one primary intended purpose—the physical washing of chemicals from the skin. Prevor agrees that DSW also neutralizes chemicals remaining on the skin, but this effect is at most secondary because it represents a minor contribution to the overall therapeutic purpose of the product. This Court should find, as a matter of law, that DSW has only one primary intended purpose. Because there is no dispute on any other element of the "device" definition, this Court should rule that DSW is a device.

Even if DSW is analyzed as two separate components, the DSW liquid and canister, DSW still should be regulated as a device. Both the liquid and canister meet the regulatory requirements of having a "device mode of action." 21 C.F.R. § 3.2(k)(2). As a result, DSW is a single entity (device-device) product, rather than a combination product. Because the product is not a combination product, which by definition is

composed of two different components (i.e., drug-device, drug-biologic, or device-biologic), it is unnecessary to reach an analysis of the product's primary mode of action ("PMOA"), on which FDA relied and the government uses to distract from the determinative issue.

B. Neutralization is not a "primary" intended purpose of DSW.

The government spends approximately one sixth of its brief arguing that the phrase "primary intended purposes" means that a product analyzed under the statutory device definition may have multiple primary intended purposes. *See* Def. Opp. Br. at 15-20. That point is not in dispute. Prevor has never contended that products in general are limited to one "primary intended purpose," just that DSW has only one.

The salient issue, and a point that the government's brief minimizes, is that "primary intended purpose" and "intended purpose" are not synonymous. Congress' use of the word "primary" precludes FDA from excluding a product for which chemical action contributes to an intended purpose from the "device" definition unless the intended purpose in question is a "primary" one.

The government concedes that DSW's washing effect is a "primary intended purpose" and that it is achieved through physical action. *See* Def. Opp. Br. at 2. Therefore, the only disputed issue is whether DSW liquid also has a *second* "primary intended purpose" that is achieved through chemical action. FDA asserts that neutralization is another "primary intended purpose," but Prevor has demonstrated that neutralization is actually a secondary or minor purpose rather than a "primary intended

purpose." This Court should rule as a matter of law that FDA erred, based on the statutory language and FDA's lack of a legal basis for its decision.

1. According to FDA's own interpretation of "primary," the statute dictates that neutralization is not "primary."

FDA never articulated how it concluded that the neutralization purpose of DSW's liquid is a "primary intended purpose." In an attempt to retrospectively provide support for FDA's conclusion, the government cites OSMP's statements that DSW helps prevent and mitigate burns through chemical neutralization as a basis for its determination. *See* Def. Opp. Br. at 23; AR 786. But Prevor has never argued otherwise—chemical neutralization is an intended purpose of the product.[2] More to the point, OSMP's statements do not constitute a reasoned analysis to support that the chemical effect is a "*primary* intended purpose" unless one erroneously presumes that all intended purposes are "primary intended purposes," which FDA apparently does here.

This incorrect approach is consistent with FDA's recently published Draft Guidance for Industry: Classification of Products as Drugs and Devices, FDA Docket No. 2011-D-0429-0002, at 5 (hereinafter "Draft Guidance"), which states that "if a product has multiple therapeutic effects, each of these would be a 'primary intended purpose' of the product…." Thus, FDA has unlawfully constructed a framework in which each

[2] The government never justifies its flawed reliance on extra-record materials, including the 510(k) submission, to characterize DSW's primary intended purposes, and instead perpetuates this error in its brief by further quoting from the 510(k) submission in describing DSW's chemical action. *See, e.g.*, Def. Opp. Br. at 31. Although Prevor does not dispute the presence of a chemical action, it maintains its objection to FDA's use of extra-proceeding material in justifying its decision-making.

therapeutic effect is presumed to be a "primary intended purpose" without regard to the significance of the effect.

The government's brief fails to cite to a single authority that guided FDA's determination equating any therapeutic effect with a product's "primary intended purpose." In favor of its untenable statutory interpretation, OSMP unaccountably rejected the standard most closely applicable to a determination of what intended purposes are "primary," that of "primary mode of action" in the combination product context. Indeed, the government asserts that Congress deliberately modified the statutory definition of "device" to harmonize it with the phrase "primary mode of action" ("PMOA") used in the combination product provision, but in the next breath argues that FDA's past analyses of primary mode of action have no relevance to its analysis of DSW's "primary intended purposes." *See* Def. Opp. Br. at 17-18, 23.[3] On that basis, FDA dismissed several relevant precedents without consideration. *See* AR 788 ("[U]nlike the other solutions that you describe, the solution in DSW does not meet the definition of a combination product and accordingly, a PMOA analysis is inapplicable.").

In fact, in the absence of an FDA regulation or other authority to define "primary intended purpose," FDA's interpretation of "primary" in the context of PMOA analysis should govern the interpretation of that term in the "primary intended purpose" context as

---

[3] The government notes that a Senate Report on the Safe Medical Devices Act of 1990 characterized the substitution of "primary intended purposes" for "any of its principal intended purposes" as "editorial." Def. Opp. Br. at 17-18, 20. However, this change was only "editorial" in the sense that it harmonized the language of the "device" statutory section with an important statutory section detailing FDA's classification of combination products.

well. It is difficult to imagine why Congress would deliberately harmonize the language of two provisions in the same statute if it did not intend the Agency to apply those provisions consistently. *See Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co*., 522 U.S. 479, 501 (1998) (employing the basic principle of statutory construction that similar language in a statute should be accorded a consistent meaning); *Comm'r of Internal Revenue v. Lundy*, 516 U.S. 235, 250 (1996) ("The interrelationship and close proximity of these statutory provisions presents a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.") (internal quotation omitted).

FDA has defined "primary mode of action" as "the single mode of action of a combination product that provides *the most important therapeutic action* of the combination product. The most important therapeutic action is the mode of action expected to make the *greatest contribution to the overall intended therapeutic effects* of the combination product." 21 C.F.R § 3.2(m) (emphasis supplied). Similarly, to determine whether neutralization is a "primary intended purpose" of DSW, FDA should have evaluated that intended purpose's contribution to DSW liquid's overall therapeutic effect. Indeed, it is logical that for two intended purposes to both be considered "primary," they must contribute comparably to the overall therapeutic effect.

This approach is consistent with FDA's previous practices, as exemplified by its regulation of medical maggots. Medical maggots are intended for use to debride non-healing skin and soft tissue wounds by rasping (physical) and releasing proteolytic

enzymes (chemical). *See* AR 097. In 2003, FDA classified medical maggots as a device, stating that:

> Review of the information submitted suggests that maggots' secretion of the proteoloytic [sic] enzymes without the accompanying physical rasping and tearing action on the necrotic tissue is not effective therapy… [t]he proteolytic enzymes appear to aid in debridement secondarily….
>
> [M]edical maggots exert their primary intended use by a physical, not chemical, action and thus meet the definition of a device. (Moreover, they are applied to the wound by means of a medical dressing, also a device.) Therefore, they are neither a biological nor combination product, but are a device used together with another device.

See AR 098. In other words, medical maggots' chemical action contributes to an intended therapeutic purpose of the product, but since it is not "primary" in relation to the overall therapeutic effect, the product is a device.

Although the government attempts to distinguish medical maggots from DSW, the relevant comparison is between the analysis FDA applied to determine the "primary intended purposes" of maggots, and the analysis—or lack thereof—applied to DSW. *Cf.* Def. Opp. Br. at 34. In the case of medical maggots, FDA evaluated each of the intended purposes' contribution to the overall therapeutic effect of the product, and determined that physical action was the primary effect and chemical action was secondary. This is the proper analysis under the FDC Act. The data show, and FDA has not contradicted, that DSW liquid's physical effect considerably outweighs its chemical effect. Applying the proper analysis to DSW, chemical neutralization is not "critical" to the DSW liquid's

overall therapeutic effect, but only aids in the prevention and mitigation of chemical burns secondarily. *Cf.* Def. Opp. Br. at 10.

2. FDA's determination that neutralization is "primary" is not based on a reasoned analysis of the relevant evidence.

Administrative law principles also require that any FDA analysis of whether an intended purpose is "primary" be logically and rationally based on evidence in the record. *See Allentown Mack Sales & Serv., Inc. v. Nat'l Labor Relations Bd.*, 522 U.S. 359, 374 (1998); *Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 77 (D.C. Cir. 2006) ("ATFE has neither laid out a concrete standard for classifying materials … nor offered data specific to the [issue]…. On this record, the agency's decision cannot withstand judicial review."). FDA dismissed without adequate analysis Prevor's studies showing that neutralization is not a "primary intended purpose."

DSW's liquid has an intended purpose of neutralizing chemicals that is achieved through chemical action, but neutralizing chemicals is *not* what the liquid is primarily intended to do. FDA never establishes—or even states—that neutralization represents a primary contribution to the overall therapeutic effect, and there is nothing in the record that would support that proposition. The Agency failed to analyze Prevor's data demonstrating that neutralization provides a minor contribution to the overall therapeutic effect of the DSW liquid. Indeed, it only addressed those data in a brief footnote in the OSMP Letter. AR 786 n.1. The government's *post hoc* attempt to cast FDA's "evaluation" of the Prevor studies in a new light is the epitome of "too little, too late."

Prevor provided data from two studies demonstrating that the liquid's chemical action contributes at most ten percent of its effectiveness.[4] The first study was designed to determine the volume of DSW liquid as compared to water necessary to physically displace a basic solution, using pH as an indicator of displacement. The results of this study demonstrated that a similar amount of DSW liquid or water is required to reach a safe neutral pH of 9.0 pH, and indicate that DSW liquid has a similar displacement effect to that of water. The second study was designed to measure the liquid's chemical effect, as compared to its physical displacement effect examined in the first study. This study demonstrated that a much larger amount of DSW liquid is needed to neutralize a chemical than to physically displace it. Comparing the results of the first and second studies, Prevor concluded that chemical action contributes at most 10 percent of the DSW liquid's effectiveness, while physical displacement is primarily responsible for its overall effect. *See* AR 001, 006.

The OSMP Letter confirms that FDA treated the data as either irrelevant or secondary to its erroneous decision that the liquid component of DSW was a drug. *See* AR 786 n.1. FDA's analysis of the data was thus cursory and conclusory. *Id.* FDA never raised any issues to Prevor related to the studies at any point during the Request For Designation ("RFD") proceeding, in the OCP RFD decision letter, or during the

[4] These studies examined the action of the DSW liquid alone and concluded that the liquid itself has a primarily (roughly 90 percent) physical effect. There is additional physical action provided by forcible expulsion of the liquid from the canister component of DSW, similar to the physical action of a water shower no used to treat workers exposed to chemical spills or splashes.

agency appeal meeting. Suffice it to say, FDA's terse assertions cannot substitute for a reasoned analysis of DSW's "primary intended purposes."

IV. FDA CHANGED ITS STATUTORY INTERPRETATION WITHOUT SO ACKNOWLEDGING, WITHOUT EXPLANATION, AND WITHOUT FOLLOWING REQUIRED PROCEDURES.

No matter how much FDA seeks to gloss over the fact that the definition it applied here is a departure from longstanding policy, and that it results in treating DSW differently than similar products which FDA is regulating as devices, the record proves otherwise. FDA never provides any reasoned explanation for this change, and instead rests on conclusory statements. Further, neither FDA nor the government's brief even *acknowledges* that FDA applied a new standard to Prevor and that the new standard led to its classification of DSW as a drug.

There can be no dispute that the government's use of an "even in part" standard to classify DSW is a change in FDA's policy and practice. Prevor raised this issue in its appeal to OSMP, arguing that FDA's decision was based on the application of a "novel review standard not found in or supported by law or regulation." *See* AR 725. FDA never disagreed that the standard was new, but slightly reworded OCP's new standard in the OSMP decision.[5] The government takes the same approach in its response brief. It never says—and could not say—that the "even in part" standard was the existing standard. Likewise, it studiously avoids acknowledging the fact that two reviewers believed the classification of precedential devices, RSDL and M291, would be reversed

[5] The government cited an "at least in part" standard in the OCP Letter, and an "even in part" standard in the OSMP Letter. For purposes of this memorandum, Prevor uses "even in part" to reference both modifications to the device definition.

under FDA's new standard. *See* AR 046, 048-049, 057-058 (indicating that RSDL and M291 would "now" be considered to have a chemical PMOA rather than physical). The government's brief offers no explanation for why FDA suddenly and without notice applied a new standard to DSW.

None of FDA's prior statements or rulings applying the device definition includes the "even in part" language. A fair and considered agency position is one that is consistent with prior agency interpretations. *See U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1016 n.15 (D.C. Cir. 2002). In the 21 years since Congress adopted the current device definition, FDA has had countless opportunities to articulate an "even in part" standard. Until now, it has not. A review of FDA's website, including the publicly available RFD decision letters, did not reveal a single previous statement by FDA that articulated this standard.

Nor did the government's brief point to any example of its prior use of this standard. Notably, the single example the government references to illustrate FDA's historic interpretation that a product can have multiple primary intended purposes does not even use this language. *See* Def. Opp. Br. at 29.

FDA apparently concluded that DSW was excluded from the statutory "device" definition because one purpose of the product depends "even in part" on chemical

action.[6] *See, e.g.*, Def. Opp. Br. at 22. But this conclusion has no relation to whether an intended purpose is "primary," which must be the first step in determining whether a product or product component is excluded from the device definition.

A. FDA failed to provide a reasonable explanation for its decision-making.

FDA was required to provide Prevor with a "rational connection between the facts found and the choice made," but it did not. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). "When an administrative agency sets policy, it must provide a reasoned explanation for its action." *Judulang v. Holder*, 132 S. Ct. 476, 479 (2011). "One of the core tenets of reasoned decision-making is that 'an agency [when] changing its course . . . is obligated to supply a reasoned analysis for the change.'" *Republic Airline Inc. v. U.S. Dept. of Transp.*, No. 11-1018, 2012 WL 29193, at *3 (D.C. Cir. Jan. 6, 2012) (citing *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42) (reversing and remanding a U.S. Department of Transportation decision where DOT failed to adequately explain its departure from precedent). The government's failure to even acknowledge the change in the "device" definition mandates that FDA's decision be vacated. *See Panhandle Eastern Pipe Line Co. v. Fed. Energy Regulatory Comm'n*, 196 F.3d 1273, 1275 (D.C. Cir. 1999) (remanding agency decision with regard to tariff modifications

[6] It is futile to attempt to decipher how the government applied the new "even in part" standard, as FDA has provided no explanation but simply inserted this new language in its decision. The government's brief appears to either narrow or contradict FDA's application of "even in part." In any event, this confusion only supports Prevor's position that the government failed to properly explain how FDA identified DSW's "primary intended purposes."

because the agency failed to acknowledge or explain the change in policy represented by that decision).

In its brief, the government does not disagree that a reasoned analysis is necessary, but suggests that FDA actually provided one. The OCP and OSMP letters show otherwise. The government's brief is noticeably silent about the origin of, or basis for, the "even in part" standard, and fails to explain how this standard is to be applied. On its face, the standard would mean that any chemical therapeutic effect—no matter how minor—is a primary intended purpose.

The government merely asserts that the new standard "does not exclude an article from being classified as a device based on a *de minimis* chemical effect." *See* Def. Opp. Br. at 28. But this assertion has no basis in the words FDA actually used to classify DSW as a drug. Applying those words, "even in part," FDA would exclude an article that has a *de minimis* chemical effect, because the Agency flatly asserts that a product cannot be a device if one of its primary intended purposes is achieved "even in part" through chemical effect, and then presumes that every therapeutic effect is a "primary intended purpose."[7]

[7] Neither the OCP Letter nor the OSMP Letter references a *de minimis* exception, and this Court cannot accept the government's redefinition of the standard as first advanced in litigation. *See Williams Gas Processing - Gulf Coast Co. v. Fed. Energy Regulatory Comm'n*, 373 F.3d 1335, 1345 (D.C. Cir. 2004) (refusing to uphold agency action based on "*post hoc* rationalizations by agency counsel" where the agency had failed to adequately state its reasoning in the order under review).

There are no criteria for determining how much chemical effect exceeds the *de minimis* exception that the government has created for this litigation.[8] For DSW, the neutralization effect contributes *less than 10%* of the therapeutic effect of the liquid component, but FDA seeks to characterize it as a drug rather than a device without any explanation. This is the essence of arbitrariness.

The government also asserts that the device definition "does not contain an exemption" for articles that achieve their primary intended purposes in part through chemical action. *See* Def. Opp. Br. at 31. But neither does the statute contemplate the *inclusion* of this additional "even in part" language in the device definition. What is clear is that the "even in part" standard is not derived from the statute itself and was created out of whole cloth when FDA applied it to Prevor.

Prevor made a significant showing that analogous products are regulated as devices, and FDA simply ignored that argument or failed to provide reasoned explanation for distinguishing those products from DSW. "Where, as here, 'a party makes a significant showing that analogous cases have been decided differently, the agency must do more than simply ignore that argument.'" *Republic Airline Inc.*, 2012 WL 29193, at *3 (quoting *LeMoyne-Owen Coll. v. Nat'l Labor Relations Bd.*, 357 F.3d 55, 61 (D.C. Cir. 2004)); *see also Nalco v. EPA*, 786 F. Supp. 2d at 187 (D.D.C. May 18, 2011) (despite deference to EPA's scientific expertise, finding a troubling lack of reasoning behind EPA's "unspoken conclusion" that two similar substances should be treated differently).

[8] The Draft Guidance contains no *de minimis* exception.

In FDA's first decision, it devoted a single sentence to addressing the products Prevor described at length in its RFD. *See* AR 676. Rather than attempt to distinguish these cases, FDA ignored them completely, saying that "[i]n any event, this RFD calls for us to examine the classification and assignment of this specific product." *Id.*

Again, in its appeal to OSMP, Prevor directed FDA's attention to numerous similar products. FDA's response to these products was at best meager, and focused on differences that are irrelevant to the regulatory classification decision. *See Republic Airline Inc.*, 2012 WL 29193, at *5 (finding that although DOT identified a difference between its present case and an earlier precedent, DOT's "scant analysis" fails to explain why that difference has any bearing on DOT's decision); *see also WildEarth Guardians v. Salazar*, 741 F. Supp. 2d 89, 100-02 (D.D.C. 2010) (two conclusory statements failed to demonstrate that the agency action at issue was the product of reasoned decision-making).

FDA essentially argues that unless the previously classified product was identical to the product at issue, that earlier product classification has no precedential value. But that view is not consistent with well-established case law. It also is belied by the statement on FDA's website listing past jurisdictional decision, which states that "transparency in jurisdictional decision making should result in greater predictability and consistency of decisions, and decrease ambiguity and uncertainty about FDA perspectives." *See* RFD Jurisdictional Decisions, *available at* http://www.fda.gov/CombinationProducts/JurisdictionalInformation/RFDJurisdictionalDecisions/default.htm.

Again, FDA is not forthright in acknowledging what it has done to the regulatory regime: repudiate past precedents. Indeed, FDA intends to reexamine already classified products to determine whether they might need to be regulated differently under this new standard. *See* Draft Guidance, at 8 ("FDA is currently reviewing issues…relating to the classification and transfer of products as appropriate that fall within the scope of this section [on existing classifications]."). This statement further confirms that FDA has revised its interpretation of the statute and has applied this new standard to DSW.

Because FDA's decision was so flawed and lacking in reasoned analysis, the government's brief resorts to restating the conclusory language in the OSMP letter, but then rewriting it to suggest that it included sufficient analysis and review. For example, the government claims that FDA "analyzed" or "explained" issues in the OSMP letter – but a few conclusory sentences do not provide the requisite analysis. The government also implies that FDA described the information to support its decision, Def. Opp. Br. at 22 ("citing information Prevor itself submitted"), but in reality FDA simply stated its conclusion, prefaced by the ambiguous phrase "[b]ased on the information provided." *See* AR 768. In another part of the brief, the government suggests that FDA conducted a full analysis and discussion of the studies Prevor submitted. *See* Def. Opp. Br. at 24 ("OSMP's evaluation found the studies to be flawed"). But FDA's only "evaluation" of these studies was contained in three dismissive sentences relegated to a footnote. AR 786 n.1.

B. In place of reasoned and sound explanation, the government engages in *post hoc* rationalization to distinguish the precedents cited by Prevor.

Prevor identified in the administrative record several products that are similar to DSW in their modes of action, which FDA's own regulations say are controlling in classification decisions. 21 C.F.R. § 3.4(b). FDA's cursory reference to these products was wholly inadequate. Now, in its response brief, the government lawyers attempt to impermissibly expand the record by creating *post hoc* justifications for how these products differ from DSW. As noted earlier, the Court may not accept counsel's *post hoc* rationalizations for FDA's action. *See Republic Airline Inc.*, 2012 WL 29193, at *6 (citing *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 50 (1983)); *see also Manin v. Nat'l Transp. Safety Bd.*, 627 F.3d 1239, 1243 (D.C. Cir. 2011) ("[T]he law does not allow us to affirm an agency decision on a ground other than that relied upon by the agency.").

Neither the OCP letter nor OSMP letter provides the discussion the government includes in its brief; instead, they simply assert without discussion that the precedents differ from DSW "with regard to intended use, components, and/or ingredients." *See* AR 676, 787. Yet, these distinctions are ancillary to the product classification decision, which hinges on primary intended purpose. The expanded explanation the government now provides only supports a finding by this Court that FDA has implemented new legal criteria for DSW. It is evident from the government's discussion of precedents that only a product identical to DSW would have been considered persuasive, and given the change in standards, even that is not certain.

As described in the administrative record, RSDL is almost identical to DSW with respect to the characteristics FDA mistakenly highlights (*e.g.*, intended use, components, and/or ingredients). These similarities were all presented to FDA:

Product	Components and/or ingredients	Intended Use
DSW	A liquid within its own cartridge contained in a pressurized canister	Intended to wash away chemical spills or splashes on the skin to prevent and mitigate chemical burns, and to neutralize chemicals remaining on the body
RSDL	A lotion impregnated on a foam sponge applicator pad	Intended to remove or neutralize chemical warfare agents and T-2 toxin from the skin

AR 001, 009. Both DSW and RSDL act to physically apply the lotion or liquid and remove the chemicals from the skin through scrubbing or spraying. Both products also react with and neutralize chemical splashes through chemical action, but the primary effect is the physical removal of the chemicals. Even under the government's restrictive view of precedents, RSDL and DSW must be regulated similarly.

The government now tries to distinguish RSDL on the grounds that the physical effect of scrubbing with RSDL's "sponge applicator" component provides the PMOA for that product, as opposed to the chemical neutralizing or physical removal effects provided by the lotion. Yet in FDA's own press release at the time it cleared RSDL, FDA describes the lotion as the component that physically and chemically removes chemical agents from the skin:

> RSDL is a liquid decontamination lotion intended to remove or neutralize chemical warfare agents and T-2 fungal toxin

> from the skin. The lotion is impregnated in a sponge pad packaged as a single unit in a heat-sealed foil pouch. When exposed to chemical warfare agents, the user wipes the exposed skin with the lotion. ***The lotion removes the agents or the T-2 toxin*** and also reacts with the chemical agents, rapidly neutralizing them so they are non-toxic.

AR 176 (emphasis added). FDA clearly views the RSDL lotion as having significant physical *and* chemical effects that contribute to the product's overall therapeutic effect.

The government also tries to argue that DSW's canister "does not directly remove chemicals from the body," unlike RSDL's sponge applicator, which removes chemicals. *See id*. This is preposterous. A sponge sits inanimately on a surface until a person actively rubs it back and forth on the skin using some lubricant to remove the chemical. In short, it operates like a pressurized canister, which itself does nothing, but with liquid can forcefully spray off the chemical. Neither the sponge nor the canister is effective alone; they work in conjunction with the lotion or liquid to remove chemicals from the skin.

FDA's attempt to distinguish precedents leads to an absurd result. RSDL has two components, a lotion and a sponge. FDA determined that the lotion component has a physical and chemical effect, and that dual modes of activity play a significant role in achieving the benefit of the product. Yet, FDA regulates RSDL as a device. Similarly, DSW is viewed as having two components, a liquid and a canister – the liquid component has a predominant device mode of action (~90%), and only a minor drug mode of action (<10%). FDA seeks to regulate DSW as a drug. FDA's classification of DSW cannot be squared with precedent.

C. The government's response lacks any discussion of why this change did not need to meet appropriate notice and comment procedures.

Because the government fails to acknowledge that the "even in part" standard is new, the government also fails to address the Administrative Procedure Act ("APA") requirements that an agency can only lawfully implement a new, binding standard after following notice and comment rulemaking procedures. Until now, FDA had consistently applied the statutory definition of "device," and its interpretation. Its application of a new standard substantively modified FDA's long-standing policy, completely altering the regulatory requirements for DSW.[9] The APA requires an agency to conduct notice and comment rulemaking before substantially altering a well established regulatory interpretation. *See* 5 U.S.C. §§ 553, 706(2)(D); *see also Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997). FDA failed to do that here, violating the APA.

V. CONCLUSION

As set forth in this Memorandum, and in Prevor's earlier Memorandum, FDA's determination that DSW is a drug-device combination product to be regulated as a drug by CDER is contrary to the plain language of the statute in that FDA writes the word "primary" out of the statutory device definition by assuming that all intended purposes are primary. Moreover, it is not supported by the administrative record, and rests on an

[9] The government accuses Prevor of seeking to circumvent the "onerous" drug regulation scheme. *See* Def. Opp. Br. at 1. In reality, Prevor only seeks to avail itself of the appropriate regulatory scheme. Congress has established a comprehensive regulatory regime for devices, which recognizes the fundamental differences between drugs and devices and is designed to ensure the safety and effectiveness of devices.

abrupt and unexplained departure from long-standing policy and precedents. This Court should grant Prevor's Motion for Summary Judgment and deny the government's Cross-Motion.

Dated: January 19, 2012

Respectfully submitted,

PREVOR

By: /s/ Anne K. Walsh

Jeffrey N. Gibbs (D.C. Bar No. 385294)
John R. Fleder (D.C. Bar No. 176123)
Anne K. Walsh (D.C. Bar No. 464858)
Jennifer M. Thomas (D.C. Bar No. 987518)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I, Anne K. Walsh, hereby certify that I caused the forgoing Reply Memorandum in Support of Prevor's Motion for Summary Judgment and in Opposition to Defendant's Motion for Summary Judgment an Proposed Order to be served via e-mail and the District Court's Electronic Filing System (ECF) upon:

JOHN W.M. CLAUD
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington D.C. 20044
Attorney for Federal Defendant

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
White Oak 31, Room 4550
Silver Spring, MD 20993-0002
Of Counsel for Federal Defendant

This 19th day of January, 2012.

/s/ Anne K. Walsh

Anne K. Walsh (D.C. Bar No. 464858)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329