UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 13-1177 (RMC)**
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
	)	
Defendant.	)	

OPINION

After five years, Prevor and the Food and Drug Administration (FDA) continue to dispute whether Prevor's Diphoterine™ Skin Wash (DSW) should be regulated as a "drug" or a "medical device." By giving unduly expansive meanings to certain language in the Federal Food, Drug, and Cosmetic Act, FDA declared DSW to be a drug. On remand from this Court, FDA hardly changed its reading of the statute and relied on an arbitrary standard that contravenes the plain meaning of the law. Accordingly, the Court will deny FDA's motion for summary judgment. The Court will grant summary judgment in part to Prevor, finding that FDA acted arbitrarily and capriciously in violation of the Administrative Procedure Act. However, the Court will deny Prevor's request to declare DSW a device and will remand to the Agency for further proceedings consistent with this Opinion.

I. FACTS[1]

A. DSW

DSW was developed to prevent and minimize chemical burn injuries that occur in the industrial workplace due to accidental exposure to chemicals. The product "consists of a liquid substance contained in a canister propelled by pressurized gas." Administrative Record (A.R.) [Dkt. 27] at 001. "DSW is used by spraying the pressurized contents of the canister on to the skin to physically and mechanically remove splashes of acids and bases off the skin by washing them away." *Id.* "DSW is intended to: (1) remove splashes of acidic or basic substances off the skin by physically and mechanically washing the chemicals away from the skin, and (2) neutralize and dilute acids and bases." *Id.* at 002. "The first use is a physical/ mechanical mode of action (comprises approximately 90% of DSW's overall effect), while the second one is a chemical mode of action (comprises approximately 10% of DSW's overall effect)." *Id.* DSW's "purpose is to help prevent and minimize accidental chemical burn injuries." *Id.*

B. Statutory Framework

The nature of the dispute here necessitates a brief explanation of various FDA regulations and the definitions of "drugs," "medical devices," and "combination products" under the Federal Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. § 301 *et seq*. The Food and Drug Act defines a "drug," in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other

[1] The Court assumes familiarity with its prior decision regarding Prevor and FDA, which contains the full background and procedural history. *Prevor v. Food and Drug Admin.* (*Prevor I*), 895 F. Supp. 2d 90 (D.D.C. 2012).

than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B) & (C). A device is defined, in part, as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . 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, and which *does 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.

Id. § 321(h) (emphasis added). This cases hinges on the distinction that a product is not *solely* a device if it achieves "its primary intended purposes through chemical action within or on the body." *Id.* A product may, however, be both a drug and a device—this is referred to as a "combination product." *Id.* § 353(g). A combination product is defined by regulation as "[a] product comprised of two or more regulated components, *i.e.*, drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity." 21 C.F.R. § 3.2(e)(1).

To determine whether a combination product is to be regulated as a drug or a device, FDA must analyze the constituent parts of the product to determine whether the parts have a drug or device mode of action and which is the primary mode of action. *See* 21 U.S.C. § 353(g)(1); 21 C.F.R. § 3.2(k). "A constituent part has a device mode of action if it meets the [Food and Drug Act's] definition of device . . . and it does not achieve is primary intended purposes through chemical action within or on the body of man or other animals . . . ." 21 C.F.R. § 3.2(k)(2). "A constituent part has a drug mode of action if it meets the [Food and Drug Act's] definition of drug . . . and it does not have a . . . device mode of action." *Id.* § 3.2(k)(3).

A primary mode of action is defined as:

> [T]he 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). A "'therapeutic' action or effect includes any effect or action of the combination product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body." *Id.* § 3.2(k). FDA considers the DSW canister and liquid solution, as a whole, to be a combination product, where the liquid is classified as a drug and represents the primary mode of action. Prevor contends that DSW is a single-entity product (a device) that does not achieve its primary intended purposes through chemical action.[2]

C. First FDA Decision

Prevor, a French company, submitted a Request for Designation (RFD) on August 13, 2009, asking the FDA Office of Combination Products to "confirm that DSW is a device to be regulated by the Center for Devices and Radiological Health." A.R. at 001. On October 16, 2009, the Office of Combination Products notified Prevor that it had designated DSW as a combination product. *Id.* at 675. The Office first concluded that the pressurized canister that delivers the solution of DSW constitutes a device. It further concluded:

> The liquid [component of DSW] appears to have two primary intended purposes: to wash the chemical off the skin and neutralize the chemical that is on the skin. Since this liquid achieves its primary intended purposes, *at least in part*, through chemical action, it does not meet the definition of a device. The liquid does, however, meet the definition of a drug at section 201(g) of the [Food and Drug] Act (21 U.S.C. 321(g)). Accordingly, we have concluded that the liquid is a drug.

[2] In its Request for Designation, Prevor argued in the alternative that if DSW were determined to be a combination product, it should be regulated as a device. However, Prevor has abandoned this argument on summary judgment by arguing only that DSW is a single-entity product.

Id. at 676 (emphasis added). Because it found that DSW was comprised of both drug and device constituent parts, the Office of Combination Products determined that DSW was a combination product; it further found that the drug constituent part provided the greater contribution to the overall therapeutic effect and thus should be regulated as a drug by the Center for Drug Evaluation and Research (CDER). *Id.*

On March 24, 2010, Prevor timely sought review of that decision with FDA's Office of Special Medical Programs. On April 25, 2011, that Office affirmed the designation of DSW as a combination product that should be regulated as a drug, explaining:

> In determining whether an article is a "device," FDA must consider whether or not the article *achieves its primary intended purposes* through chemical action within or on the body of man. 21 U.S.C. § 321(h). . . . [I]f an article depends, *even in part*, on chemical action within or on the body to achieve any of its primary intended purposes, it does not meet the definition of a device.

Id. at 786 (emphases added).

D. *Prevor I*

Prevor filed suit on June 28, 2011. After full briefing, this Court concluded that "FDA's reliance on extraordinarily expansive language ('at least in part' or 'even in part') demonstrates the agency's own recognition that without such an interpretation of 'primary intended purpose,' DSW could be designated a 'device.'" *Prevor I*, 895 F. Supp. 2d at 97. While FDA maintained that its terms left room for a product with a *de minimus* chemical effect to be classified as a device, the Court was not so confident. "Inasmuch as the statute seeks to identify primary intended purposes that are achieved through chemical action, it would be significantly expanded if a primary purpose could automatically be achieved 'at least in part' or 'even in part' by chemical action." *Id.* "The addition of such language when applying the

statute substantively modifies the standard to be applied by expanding the reach of the exclusionary language." *Id.* at 99. The record also showed that FDA had treated analogous products as devices, not drugs. *Id.* at 99-100. The Court suggested that "[t]here may be solid scientific reasons for FDA's new approach but these remain unexplained, at least without defining 'primary' in a manner consistent with the law." *Id.* at 101. The matter was remanded for that purpose.

E. FDA Remand Decision

On remand, FDA again determined that "DSW is a drug-device combination product consisting of a drug solution and an aerosol spray device canister." A.R. at 839. It explained that the solution met the drug definition because it "achieve[s] its primary intended purposes through chemical action." *Id.* at 840 (citing 21 U.S.C. § 353(g); 21 C.F.R. Part 3). FDA further found that "the 'primary mode of action' of the combination product is attributable to the drug solution" because the solution "is expected to make the greatest contribution to overall intended therapeutic effect of DSW." *Id.* The solution "is expected to react with harmful chemicals to neutralize them, draw chemicals from the interior to the exterior of the skin, and physically displace chemicals from body," while "[t]he device canister plays a secondary role, aiding in delivery of the drug solution by allowing its ready delivery onto the skin as an aerosolized mist." *Id.*

Though reaching the same conclusion, FDA diverged from its prior assessment that DSW had two primary intended purposes: (1) to wash away chemicals and (2) to neutralize acids and bases. *Id.* at 843. Instead, FDA found that DSW has a single broad primary intended purpose: "to help prevent and minimize accidental chemical burn injuries." *Id.* FDA explained that it "erred in earlier ascribing two primary purposes to DSW . . . 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)." *Id.* (emphases in original).[3]

FDA also revised its interpretation that a product should be regulated as a drug if it achieves its primary purpose *in part* through chemical action. Rather, FDA "interpreted the device exclusionary clause to mean that a product (or a constituent part of a combination product). . . 'does not achieve its primary intended purposes through chemical action' if the evidence indicates that chemical action does not *meaningfully contribute* to its primary intended purposes." *Id.* at 846 (emphasis added). FDA cited no past precedent where this language has been used.

To support its finding that the DSW solution is a drug, FDA reviewed various publications and concluded that DSW is more effective than water in preventing and minimizing chemical burns because of its chemical properties. *Id.* at 846-49. Specifically, FDA analyzed Prevor's claims on its website and in its RFD, which explained that the diphoterine solution neutralizes chemicals, which stops corrosive agents on the skin, and draws chemicals to the surface of the skin, which prevents tissue penetration. *Id.* at 847. Other published literature indicated that much less diphoterine solution was needed, as compared to water, to bring pH to within a non-harmful range, and that DSW is superior to water rinses because of its amphoteric and hypertonic actions. *Id.* at 848. FDA also noted that a diphoterine solution may be more effective in promoting wound healing. *Id.* While this result differed slightly from DSW's

[3] In its RFD, Prevor stated that "DSW is intended to: (1) remove splashes of acidic or basic substances off the skin by physically and mechanically washing the chemicals away from the skin, and (2) neutralize and dilute acids and bases." *Id.* at 002. It further stated that DSW's "purpose is to help prevent and minimize accidental chemical burn injuries." *Id.*

intended use, FDA considered the data relevant because successful treatment of a wound lessens its ultimate severity. *Id.* at 848-49.

FDA also analyzed Prevor's own studies, rejecting Prevor's argument that DSW solution works predominantly through physical displacement and that its chemical action is secondary. *Id.* at 852-56. Specifically, it found Prevor's estimate that physical displacement comprises approximately 90% of the solution's effect and neutralization comprises approximately 10% to be "wholly unsupported by the evidence that Prevor submitted." *Id.* at 852. FDA determined that the first study, designed to show the physical displacement effect of DSW, actually showed the importance of chemical neutralization because it demonstrated that the amount of water needed to reduce the pH to neutral was greater than the amount of diphoterine solution needed. *Id.* at 853. Moreover, FDA contended the first study was flawed because it added solution to a beaker, which did not approximate DSW's method of spraying solution from a canister onto the body, and it did not account for DSW's chemical effect of drawing out contaminants that penetrate the skin. *Id.* In regard to the second study, FDA found similar flaws and asserted that it ultimately demonstrated the importance of chemical action when comparing the effects of the solution with pure water. *Id.* at 854-55. Finally, FDA considered the difference between DSW and emergency showers, noting the additional significance of chemical action in DSW, given that it had to compensate for lesser force and lesser volume than an emergency shower; moreover, while the recommended intervention time after chemical exposure for emergency showers is within 10 seconds, the recommended treatment time for DSW is within 60 seconds. *Id.* at 855.

On remand, FDA also distinguished DSW from Reactive Skin Decontamination Lotion (RSDL) and medical maggots, two products previously determined to be subject to

regulation as devices. *Id.* at 857-59. Though claiming that the RSDL sponge is different than the DSW canister because it can remove chemicals from the skin without any chemical action, FDA acknowledged the possibility that the Agency may have erred in classifying RSDL as a product with a device primary mode of action. *Id.* at 857. FDA stated that at the time of the RSDL decision, FDA had not yet promulgated the current provision dealing with products for which the primary mode of action is not readily transparent. *Id.* at 858. That regulation provides:

> In some situations, it is not possible to determine, with reasonable certainty, which one mode of action will provide a greater contribution than any other mode of action to the overall therapeutic effects of the combination product. In such a case, the agency will assign the combination product to the agency component that regulates other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole. When there are no other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole, the agency will assign the combination product to the agency component with the most expertise related to the most significant safety and effectiveness questions presented by the combination product.

21 C.F.R. § 3.4(b). According to FDA, if the Agency were to classify RSDL today, it likely would find that RSDL's primary mode of action cannot be determined with reasonable certainty, and it may well have assigned it to the CDER for possible regulation as a drug. A.R. at 858. As for its decision regarding medical maggots, FDA asserted that it was "*sui generis*, involving a highly unusual product and reflecting an interpretation of the device exclusionary clause that [Office of Combination Products] has not adopted before or since." *Id.* FDA maintained that the medical maggots decision has been distinguished in subsequent RFD decisions and is not valid precedent. *Id.* at 859. On these bases, FDA again classified DSW as a drug-device combination product and assigned it to CDER for premarket review and regulation.

II. SUMMARY JUDGMENT STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *accord Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Moreover, summary judgment is properly granted against a party who "after adequate time for discovery and upon motion . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "[t]he mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Id.* If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

III. AGENCY REVIEW

It is well-settled that the Court's analysis of FDA's interpretation of 21 U.S.C. § 321(h) and its classification of DSW is governed by *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, the Court must first determine "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If so, then

"that is the end of the matter" because both courts and agencies "must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. To decide whether Congress has addressed the precise question at issue, a reviewing court applies "'the traditional tools of statutory construction.'" *Fin. Planning Ass'n v. Sec. Exch. Comm'n*, 482 F.3d 481, 487 (D.C. Cir. 2007) (quoting *Chevron*, 467 U.S. at 843 n.9). It analyzes "the text, structure, and the overall statutory scheme, as well as the problem Congress sought to solve." *Id.* (citing *PDK Labs. Inc. v. Drug Enforcement Admin.*, 362 F.3d 786, 796 (D.C. Cir. 2004); *Sierra Club v. Envtl. Prot. Agency*, 294 F.3d 155, 161 (D.C. Cir. 2002)).

If, however, "the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. In making such an assessment, "considerable weight" is generally accorded to "an executive department's construction of a statutory scheme it is entrusted to administer[.]" *Id.* Indeed, "under *Chevron*, courts are bound to uphold an agency interpretation as long as it is reasonable—regardless whether there may be other reasonable, or even more reasonable, views." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1321 (D.C. Cir. 1998). An interpretation is permissible and reasonable if it is not arbitrary, capricious, or manifestly contrary to the statute. *Mount Royal Joint Venture v. Kempthorne*, 477 F.3d 745, 754 (D.C. Cir. 2007).

In determining whether an action was arbitrary and capricious, a reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation marks and citation omitted). "The requirement that agency action not be arbitrary or capricious includes a requirement that the

agency adequately explain its result." *Pub. Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993). An agency action usually is arbitrary or capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). As the Supreme Court has explained, "the scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Id.* Moreover, when an agency has acted in an area in which it has "special expertise," courts should be particularly deferential to the agency determination. *Sara Lee Corp. v. Am. Bakers Ass'n Ret. Plan*, 512 F. Supp. 2d 32, 37 (D.D.C. 2007) (quoting *Bldg. & Constr. Trades Dep't, AFL-CIO v. Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988)); *see also Franks v. Salazar*, 816 F. Supp. 2d 49, 55 (D.D.C. 2011) ("Federal courts are particularly deferential towards the 'scientific determinations' of the agency, which are 'presumed to be the product of agency expertise.'" (quoting *Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983))).

IV. ANALYSIS

In *Prevor I*, the Court charged FDA to narrow its definition of "primary intended purpose" and to explain its conclusion that the chemical effect of DSW achieves a primary, as opposed to secondary, intended purpose. 895 F. Supp. 2d at 97, 100-101. Much to the angst of Prevor and its *amici*, FDA avoided the Court's instruction to define "primary" and instead substituted an abrupt conclusion that DSW has only a single purpose, thereby obviating the need to consider multiple purposes and define which is/are primary. In addition, FDA dropped its

reliance on a standard that only required a *de minimus* chemical effect as sufficient to regulate a combination product as a drug. Instead, FDA substituted "meaningfully contributes to" as the new standard by which it will determine if a chemical effect is significant enough to warrant treating a product as a drug. Thus, FDA's proposal short circuits the statutory construction question for which the case was remanded by selecting a single "purpose" at the highest level of generality and requiring only "meaningful" chemical action. The Court finds that FDA reasonably relied on Prevor's own description of DSW to define a single primary purpose. However, the Court cannot accept FDA's substitution of "meaningfully contributes to" for "achieve," as it constitutes a failure to follow clear statutory language requiring that a combination product's chemical action must "achieve" a product's "primary purpose" to be classified as a drug. 21 U.S.C. § 321(h). *See Chevron*, 467 U.S. at 842-43 ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

A. Primary Intended Purpose

FDA initially determined that DSW had two primary intended purposes: "to wash the chemical off the skin and neutralize the chemical that is on the skin." *Prevor I*, 895 F. Supp. 2d at 94 (quoting A.R. at 676). On remand, however, FDA found a single primary purpose: "to help prevent and minimize accidental chemical burn injuries." A.R. at 840. FDA explained the shift in its position, stating that it "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)." *Id.* at 843. FDA further stated:

> Upon re-examining Prevor's RFD and related materials, FDA has revised its assessment of DSW's primary intended purpose, indeed its only intended

> purpose, is *what* the product is claimed to do, to help prevent and minimize accidental chemical burn injuries. . . . [T]he product appears to achieve this purpose through several actions, including neutralizing and washing away chemicals.

Id.

This newly stated purpose—to help prevent and minimize accidental chemical burn injuries—is far broader than the dual purposes previously advanced by FDA. In selecting one purpose alone, FDA conveniently avoids distinguishing between primary and secondary purposes. However, the Court cannot find unreasonable FDA's determination on remand that DSW's primary purpose is "to help prevent and minimize accidental chemical burn injuries." *Id.* Indeed, that was the purpose advanced by Prevor itself in its RFD. *Id.* at 002 ("[DSW's] purpose is to help prevent and minimize accidental chemical burn injuries.").[4] Moreover, as FDA explains, "[t]he primary intended purpose must be something other than a method of action; otherwise, the exclusionary clause would not specify that the primary intended purpose could be achieved by a method of action." FDA Mem. [Dkt. 17] at 9 n.8. Accordingly, given this newly-

[4] FDA explains that part of its initial confusion about DSW's primary purpose stemmed from Prevor's "Proposed Use or Indications" statement, where it advanced several possible intended uses. Prevor wrote that: "DSW is intended to: (1) remove splashes of acidic or basic substances off the skin by physically and mechanically washing the chemicals away from the skin, and (2) neutralize and dilute acids and bases. The first is a physical/mechanical mode of action (comprises approximately 90% of DSW's overall effect), while the second one is a chemical mode of action (comprises approximately 10% of DSW's overall effect). DSW is intended to be used in the industrial setting as a 'first response' method. Its purpose is to help prevent and minimize accidental chemical burn injuries. DSW would offer an alternative to water showers at the workplace as a first-response method." *Id.* Prevor ascribes primary action (approximately 90%) to washing the skin and secondary action (10%) to neutralizing and diluting acids, but it only identifies a single "purpose." Thus, it cannot convincingly argue that the proposed use statement adopted by FDA is not a description of how the product works to achieve its stated purpose. (FDA disagreed with Prevor's 90%/10% analysis, finding it "wholly unsupported by the evidence that Prevor submitted." A.R. at 852.)

defined primary purpose, whether DSW should be regulated as a drug hinges on whether its chemical action achieves the intended goal of preventing and minimizing chemical burns.[5]

B. 21 U.S.C. § 321(h) is Unambiguous: "Meaningfully Contributes To" Does Not Mean "Achieve"

After defining DSW's primary purpose in its Remand Decision, FDA analyzed how DSW appears to work. Because the parties do not dispute that the canister is a device, FDA focused on the DSW solution. A.R. at 843-44. FDA concluded:

> The available scientific evidence indicates that the solution achieves its primary intended purpose, to help prevent and minimize accidental burn injuries, through chemical action on the body of man, by reacting with chemicals to neutralize them (owing to its amphoteric property) and by drawing chemicals that have penetrated the skin to the surface of the skin (owing to its hypertonic property), where the chemicals can then be neutralized or displaced. Although the solution may also work through some degree of physical displacement, the evidence indicates that its chemical action *meaningfully contributes to* its primary intended purpose.

Id. at 840 (emphasis added).

This analysis purports to comply with the statutory command that excludes a product from the device definition if, as relevant, it "achieve[s] its primary intended purposes through chemical action within or on the body of man." 21 U.S.C. § 321(h). But "achieve" means "to carry out successfully;" to "accomplish;" "to attain a desired end or aim;" or "to get or attain as the result of exertion." Merriam-Webster Dictionary Online, http://merriam-webster.com/dictionary/achieve (last visited Aug. 14, 2014). "Contribute" connotes a lesser

[5] Washington Legal Foundation's (WLF) Amicus Brief [Dkt. 25] argues that FDA's approach in redefining DSW's singular primary purpose at the highest level of generality is contrary to the statutory language recognizing that a product can have multiple primary purposes, and that such an interpretation will result in most products having one intended purpose. *Id.* at 8. However, *in this case*, FDA advanced a broader primary purpose on remand by adopting Prevor's own purpose description. Moreover, FDA did not find that DSW has no other purposes, but that it has only one *primary* intended purpose. On this record, the Court cannot fault FDA for its interpretation and cannot rule on how FDA may analyze future products.

involvement: it means only "to help to cause something to happen;" "to give or supply in common with others;" or "to play a significant part in bringing about an end or result." *Id.* at http://www.merriam-webster.com/dictionary/contribute (last visited Aug. 14, 2014). FDA's new definition of "achieves" is not saved by the modifier "meaningful," which is defined as "having real importance or value" or "significant." *Id.* at http://www.merriam-webster.com/dictionary/meaningful (last visited Aug. 14, 2014). Chemical action that helps or plays a significant part in bringing about a specific result is more than *de minimis* involvement, but it does not fulfill the congressional directive that the chemical action must *achieve, i.e.*, accomplish or attain, the primary purpose. Simply put, in plain English, "achieves" and "meaningfully contributes" are not synonymous. Congress used the former and not the latter and, critically, FDA provides no analytical basis for equating the two.

Even beyond the plain language of the statute, an analysis of the legislative history and congressional intent further suggests that chemical action which provides a meaningful contribution is an inadequate level of involvement to regulate a product as a drug. As noted by Prevor, when Congress revised the statute, it narrowed the exclusionary clause so that fewer products would be classified as drugs. The earlier version of § 321(h) provided that a product was a device if it did not "achieve *any of* its principal intended purposes through chemical action." Medical Device Amendments of 1976, Pub. L. No. 94-295, § 3, 90 Stat. 539 (1976) (emphasis added). In contrast, the Food and Drug Act now excludes from regulation as a device only those combination products that "achieve [their] primary intended purposes through chemical action." Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 16, 104 Stat. 4511 (1990). By "clarifying the appropriate classification of devices," Congress sought to "avoid[ ] over-regulation and the needless expenditure of FDA resources." Pl. Mem. [Dkt. 16] at 11

(quoting S. Rep. No. 101-513, at 13 (1990)). Specifically, Congress sought to limit the number of combination products to be regulated as drugs, including only those which relied on chemical action to achieve their primary intended purposes. FDA's attempt to substitute "meaningfully contributes to" for "achieves" contradicts this congressional directive. The Agency's expertise cannot re-write the law.

FDA argues that the statute must be ambiguous because it does not state how much chemical action is needed to trigger the exclusionary clause. On remand, FDA stated that the device exclusionary clause—"does not achieve its primary intended purposes through chemical action within or on the body of man"—"does not expressly state how much chemical action suffices for a product to be excluded from the device definition. . . . Certainly some chemical action is necessary for a product to be so excluded; but the statute identifies no minimum threshold . . . ." A.R. at 845. The Court disagrees. The Act unambiguously specifies that the "chemical action" must "achieve" the product's primary purposes. 21 U.S.C. § 321(h). Congress's failure to articulate the exact amount of chemical action required does not render the clause ambiguous. *See, e.g.*, *Natural Res. Def. Council v. Envtl. Prot. Agency*, 489 F.3d 1364, 1373 (D.C. Cir. 2007) ("[T]he absence of a statutory definition does not render a word ambiguous.") (citing *Goldstein v. Sec. Exch. Comm'n*, 451 F.3d 873, 878 (D.C. Cir. 2006)). In classifying a product as a drug based on a vague degree of chemical action, FDA has acted in a manner inconsistent with the statutory language because the Agency has not satisfied the congressional directive that the chemical action of a drug must achieve its primary purposes. *Goldstein*, 451 F.3d at 881 (finding agency interpretation arbitrary where it was at best counterintuitive and came "close to violating the plain language of the statute").

Even if the statute could be deemed ambiguous regarding the precise level of chemical action required to "achieve" a primary purpose, FDA's interpretation would fail under the second prong of *Chevron* because it falls outside the bounds of reasonableness. *See Goldstein*, 451 F.3d at 880-81 (finding that agency's interpretation was unreasonable even if not foreclosed because it was inconsistent with statutory language and purpose). "[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear." *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 229 (1994). Again, "achieves" and "meaningfully contributes to" are not synonymous. FDA cannot return to the pre-amendment language on the pretense of interpreting the current statutory limitation. Accordingly, the Court will not uphold FDA's finding that the solution is a drug because of FDA's erroneous reading of the Food and Drug Act.

In addition to the fact that "meaningfully contributes to" is an unreasonable interpretation of the statute, it appears to be a significant shift in FDA's practices when classifying products. The language does not appear in the legislative history, in any FDA guidelines, or in any other classification decisions.[6] "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." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 448 n.30 (1987) (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981)). Of course, FDA is not foreclosed from adopting new approaches, but in doing so, it must provide a reasoned analysis

[6] FDA argues that it is generally prohibited from releasing classification decisions because they involve trade secrets or confidential commercial information. However, FDA does not contend that those decisions apply the "meaningfully contributes to" standard. Rather, it states that such decisions demonstrate FDA's practice of refusing to classify products as devices where they work through both chemical and physical action. FDA Mem. at 29; A.R. at 857. Without more, FDA's explanation only adds to the arbitrariness of its handling of DSW.

explaining the rationale motivating the change. *See Council for Urological Interests v. Sebelius*, 946 F. Supp. 2d 91, 108-109 (D.D.C. 2013) (relevant question is whether agency supported new reading of statute with a reasoned analysis sufficient to command deference); *Goldstein*, 451 F.3d at 883 (finding change in agency policy arbitrary absent a justification for departing from prior interpretation).

Here, FDA's reason for concluding that "meaningfully contributes to" can be equated with "achieve" is inadequate. That FDA may need to render classification decisions early and quickly, *see* A.R. at 841, 845-46, does not excuse its failure to comply with clear statutory terms.[7] FDA provides no other rationale for imposing this new standard. While FDA certainly is entitled to give effect to the language of a statute, it cannot enact unprecedented standards without offering cogent reasons for its new approach.

FDA asserts that its new standard is supported by the legislative history. This argument does not present a "reasoned analysis" for its change. Moreover, it is inaccurate. FDA states that Congress's view of the exclusionary clause was that a product with a meaningful contribution of chemical action could be characterized as "dependent upon chemical action." A.R. at 846. First, the phrase "dependent upon" is used in the statute to refer to a metabolizing process, not chemical action. *See* 21 U.S.C. § 321(h) (A product is not a device if it "does not achieve its primary intended purposes through chemical action" *and* "is not dependent upon being metabolized for the achievement of its primary intended purposes."). Second, "meaningfully contributes to" connotes a lesser role of involvement than "dependent upon," just as it does with "achieve."

[7] The statute does not demand that FDA quantify the exact contribution of a chemical to a product's ultimate goal. However, it does require more than simply finding that the product would not work as claimed without chemical action.

C. FDA's Scientific Analysis of the Role of Chemical Action in DSW

Prevor and FDA both argue strenuously about the importance of chemical action relative to physical action in DSW. Prevor submitted two studies and a video demonstrating how DSW is used, in support of its claim that the product does *not* achieve its primary intended purpose through chemical action. *See* A.R. at 005-007, 018. On remand, FDA analyzed Prevor's studies and promotional materials, finding that they ultimately "attribute[d] DSW's claimed success to diphoterine's chemical action." *Id.* at 846. FDA also reviewed other published literature—including clinical observations, case studies, *in vivo* studies, and *in vitro* studies—and concluded that it was the chemical action in the DSW solution that achieves the primary purpose of helping to minimize and prevent burn injuries. *Id.* at 847-49. The studies and published literature, FDA found, did not show that the physical action was predominant (*id.* at 853-56), contrary to Prevor's assertion.[8]

The Court is cognizant of the deference that must be afforded to agency determinations, particularly when FDA has made a scientific finding in its area of expertise. *See, e.g.*, *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009); *A.L. Pharma, Inc. v. Shalala*, 62

[8] Prevor takes issue with FDA's reliance on Prevor's website and inapposite scientific literature. But FDA is entitled to consider Prevor's own promotional materials in determining the intended use of a product. *See, e.g.*, *United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 256-57 (D.D.C. 2012), *aff'd* 741 F.3d 1314 (D.C. Cir. 2014) ("'[I]t is well established that the intended use of a product, within the meaning of the [Food and Drug Act], is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.'" (quoting *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980))). It is not the role of this Court to second-guess FDA's scientific analysis. *See Cytori Therapeutics, Inc. v. Food and Drug Admin.*, 715 F.3d 922, 923 (D.C. Cir. 2013) ("In Administrative Procedure Act cases alleging arbitrary and capricious agency action, courts must be careful not to unduly second-guess an agency's scientific judgments."). FDA correctly states that "the Agency may review published literature about the product or product ingredients if relevant to product classification or assignment, for example, published results from *in vitro* studies, animal testing, clinical testing, and or/case histories." A.R. at 841.

F.3d 1484, 1490 (D.C. Cir. 1995). On remand, FDA could find that DSW should be classified as a drug-device combination product with a drug mode of action if it also adopts a plausible construction of the relevant statutory language. However, as the record now stands, the Court cannot affirm FDA's classification decision because it was based on an erroneous and unreasonable interpretation of the law. *See Chevron*, 467 U.S. at 843 n.9 ("The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent.").

Prevor argues against a second remand and asks the Court to order FDA to regulate DSW as a device. Such relief is not warranted. *See, e.g., Wedgewood Vill. Pharm. v. DEA*, 509 F.3d 541, 549-51, 553 (D.C. Cir. 2007) (finding unreasonable agency's interpretation of statutory phrase that did not comport with ordinary meaning of words and remanding to agency for clarification); *A.L. Pharma*, 62 F.3d at 1492 (concluding that FDA decision may have been arbitrary and capricious but finding remand proper so FDA could reconsider or provide adequate explanation for determination). Although much of the Remand Decision falls squarely in the realm of agency expertise, FDA's classification decision on DSW relied on an erroneous interpretation of the Food and Drug Act and applied a vague new standard without appropriate analysis. The case must be remanded for reconsideration by FDA.[9]

In support of its request that the Court order DSW to be deemed a device, Prevor cites *United States v. Regenerative Scis., LLC*, arguing that this Court "made a product

[9] Prevor also disputes that, on remand, FDA made logical distinctions between DSW and analogous products. However, FDA's analysis of the differences between products is not so unreasonable as to require rejection and a ruling that DSW must be classified as a device. *See Am. Forest Res. Council v. Ashe*, 946 F. Supp. 2d 1, 19 (D.D.C. 2013) (finding that while record might support more than one conclusion, the conclusion drawn by agency after changing its approach did not have to be only, or even best, conclusion—only had to be rational because decision was scientific determination to which Court owed particular deference).

classification on its own." Prevor Reply [Dkt. 22] at 25. But *Regenerative* is distinguishable from this case. There, FDA maintained that the defendant's product constituted a drug (or biologic product) and was in violation of various FDA regulations; the defendant argued it was an intrastate method of medical practice subject only to state law. 878 F. Supp. 2d 248, 254 (D.D.C. 2012). The Court analyzed the relevant statute and the defendant's intended uses for the product. *Id.* at 255-57. Ultimately, the Court deferred to FDA's conclusion that the product should be regulated as a drug. *Id.* at 258 (finding that FDA determination was entitled to substantial deference and noting that "[t]he rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise") (internal quotations omitted). Here, Prevor is asking the Court (1) to reject FDA's expert findings, and (2) to make a classification directly contrary to those findings. That second step is not one this Court is willing to take. The case will be remanded to FDA to determine a standard that complies with the statutory requirements and to classify DSW accordingly.[10]

[10] Prevor cites various other cases in support of its argument that the Court should require FDA to regulate DSW as a device. Prevor Reply at 24-25 (citing *United States v. W. Serum Co., Inc.*, 666 F.2d 335 (9th Cir. 1982); *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983); *United States v. Undetermined No. of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994)). None of these cases stands for the proposition that a court may overrule FDA's determination that a product is a device or a drug, effectively usurping one of FDA's primary responsibilities. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) also is not to the contrary. There, FDA attempted to regulate cigarettes and smokeless tobacco as drugs, but the Court found FDA lacked jurisdiction because Congress had unambiguously precluded FDA from regulating of any tobacco products. There is no lack of jurisdiction here.

V. CONCLUSION

For the foregoing reasons, FDA's motion for summary judgment [Dkt. 17] will be denied. Prevor's motion for summary judgment [Dkt. 16] will be granted in part and denied in part. FDA's decision to designate DSW as a drug-device combination product with a drug primary mode of action will be vacated, and the case will be remanded to FDA for further action consistent with this Opinion. A memorializing Order accompanies this Opinion.

Date: September 9, 2014

/s/
ROSEMARY M. COLLYER
United States District Judge