IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Case No. 1:11-cv-01187 (RMC)

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

I. Introduction

Prevor challenges the United States Food and Drug Administration's ("FDA") decision that Diphoterine Skin Wash ("DSW") is a combination product, consisting of a drug and a device, that should be regulated by FDA's Center for Drug Evaluation and Research ("CDER"). In its effort to avoid filing a new drug application, Prevor seeks to have this Court set aside FDA's decision so that Prevor can avail itself of the less-onerous pre-market clearance process for devices.

DSW is comprised of a pressurized liquid solution within a dispensing canister. It is intended for use in mitigating accidental burn injuries caused by acids or bases. Prevor concedes that the canister is a "device" under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Prevor also concedes that the solution prevents or minimizes chemical burns in two ways: (1) by physically washing the chemicals off the skin; and, (2) by neutralizing chemicals on the skin. However, Prevor disagrees with FDA's determination that the solution is not a device.

Despite the statute's plain language, Prevor contends that only one of the intended purposes of the DSW solution can be its "primary intended purpose." Prevor asserts that the solution's physical action is more important than its chemical action and FDA must therefore regulate DSW as a device in the agency's Center for Devices and Radiological Health ("CDRH"). Prevor's argument is without merit for two reasons. First, the FDCA's definition of "device" excludes an article from its coverage if the article "achieve[s] its primary intended purposes through chemical action within or on the body." 21 U.S.C. § 321(h) (emphasis added). Applying the plain language in the device definition, FDA concluded that DSW has more than one primary intended purpose; that is, physically washing toxic chemicals off the skin and neutralizing toxic chemicals on the skin are both "primary intended purposes" of DSW's solution. Second, the neutralizing effect of the solution is achieved "through chemical action within or on the body." Therefore, FDA properly determined that DSW's solution is not a device.

Prevor also challenges FDA's decision that DSW is a combination product consisting of a drug and a device. But the statute is clear on this point: a combination product is one that "constitute[s] a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1). Prevor incorrectly concluded that the solution in DSW is not a drug under the FDCA, and therefore that DSW does not have two regulated components. FDA properly determined that DSW has two constituent parts, a drug and a device, and is therefore a combination product.

Finally, Prevor challenges FDA's decision to designate CDER as the lead agency center responsible for regulating DSW. The assignment of a combination product to a particular FDA center is dependent on the product's primary mode of action, or "PMOA" (e.g., a product with a

drug PMOA would be assigned to CDER). To determine a combination product's PMOA, FDA must first identify the "mode of action" of each constituent part (e.g., "drug mode of action" or "device mode of action," 21 C.F.R. § 3.2(k)), and then determine which "mode of action" "provides the most important therapeutic action of the combination product" (i.e., the PMOA). 21 C.F.R. § 3.2(m). FDA properly determined that DSW's solution provides the PMOA of the product and, in accordance with the FDCA, assigned DSW to CDER. Because Prevor incorrectly asserts that DSW is not a combination product, Prevor failed to conduct the correct regulatory analysis to assess DSW's PMOA. Rather than comparing DSW's drug constituent (the solution) to DSW's device constituent (the canister), as the regulations require, Prevor compared the solution's chemical and physical actions against each other.

The agency's decision here is based on the clear language of the FDCA's device definition and the proper application of FDA's product-jurisdiction regulations. The agency's actions are reasonable and not arbitrary or capricious. Prevor is not entitled to the relief it seeks. The government is entitled to summary judgment based on the administrative record in this case.

II. Statutory and Regulatory Background

A. Statutory Framework

21 U.S.C. § 321(g)(1) defines "drug," in pertinent part, as:

> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified [above].

21 U.S.C. § 321(h) defines "device" as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is–
>
> ***
>
> (2) 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
>
> (3) 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.

(Emphasis added.)

When Congress enacted the Safe Medical Devices Act of 1990, it required FDA to designate lead agency centers to regulate "products that constitute a combination of a drug, device, or biological product" ("combination products"). Pub. L. No. 101-629, 104 Stat. 4511, 4526 (1990) (codified at 21 U.S.C. § 353(g)). The statute further provides, in relevant part:

> The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of–
>
> (A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction; [or]
>
> (B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction[.]
>
> ***

21 U.S.C. § 353(g)(1). The statute also required FDA to enact regulations to implement these center designations. 21 U.S.C. § 353(g)(3).

B. Product-Jurisdiction Regulations

FDA's product-jurisdiction regulations define "combination product," in relevant part, 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) (emphasis added); see 56 Fed. Reg. 58754 (Nov. 21, 1991). The regulations set forth FDA's process for determining which agency center has primary jurisdiction for regulating combination products, based on the product's PMOA. 21 C.F.R. Part 3; see 70 Fed. Reg. 49848 (Aug. 25, 2005).

Under the regulations, each constituent part of a combination product contributes a "mode of action" to the product. 21 C.F.R. § 3.2(k); see 70 Fed. Reg. at 49850. The regulations define "mode of action" as the "means by which a product achieves an intended therapeutic effect or action." 21 C.F.R. 3.2(k). The regulations provide: "A constituent part has a device mode of action if it meets the [FDCA] definition of device . . . and it does not achieve its primary intended purposes through chemical action within or on the body of man or other animals . . . ." 21 C.F.R. § 3.2(k)(2). Similarly, a constituent part has "a drug mode of action if it meets the [FDCA] definition of drug . . . and it does not have a . . . device mode of action [i.e., it does not meet the definition of device]." 21 C.F.R. § 3.2(k)(3).

In turn, "PMOA" is defined 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). Under the regulations, a combination product with a drug PMOA is assigned to CDER. 21 C.F.R. § 3.4(a)(1). Similarly, a combination product with a device PMOA is assigned to CDRH. 21 C.F.R. § 3.4(a)(2).

A sponsor of a product application may submit a request for designation ("RFD") to FDA's Office of Combination Products ("OCP") for any product when it believes the lead agency center is unclear or in dispute.[1] 21 C.F.R. § 3.7. OCP's designation of a lead agency center can be changed only (a) with the written consent of the sponsor, or (b) with concurrence of FDA's Principal Associate Commissioner, to protect the public health or for other compelling reasons. 21 C.F.R. § 3.9.

III. Factual Background

A. Prevor's 510(k) Submission to CDRH

Prevor, a French company, seeks to market DSW in the United States. In September 2008, Prevor submitted a pre-market notification (called a "510(k)" submission) to CDRH to have DSW cleared for distribution. A.R. 002. Prevor's 510(k) described DSW as an alternative to water for preventing or mitigating chemical burn injuries. A.R. 148-149. The 510(k) stated, in part:

> One of the disadvantages of using water . . . is that it does not neutralize the chemical; therefore any chemical left on the skin, even if diluted by water, can still penetrate and react with the tissue and cause burns.
>
> A safe and effective alternative to water is [DSW]. . . . [DSW] binds to, or reacts with, the chemical to neutralize it, thereby reducing the potency and reactivity of

[1] The FDCA and FDA's regulations make clear that FDA's designation of one center as the lead agency component for the premarket review and regulation of a combination product does not preclude consultations by that center with other agency centers or, in appropriate cases, FDA requiring separate applications. See 21 U.S.C. § 353(g)(2), (g)(4)(H); 21 C.F.R. § 3.4(c).

> the chemical, as well as the chemical's ability to penetrate and damage skin tissue.

A.R. 148. The 510(k) noted that Prevor "has evaluated [DSW] against more than 600 chemicals/chemical groups" and that the product "is effective against acids, bases, oxidizing agents, reducing agents, and chelating agents." A.R. 150. After evaluating Prevor's 510(k) submission, CDRH notified Prevor by letter dated October 30, 2008, that it believed DSW to be a drug that should be regulated by CDER. See A.R. 002.

B. Prevor's Request for Designation to the Office of Combination Products

1. Prevor's Request for Designation

On August 13, 2009, Prevor submitted a request for designation, requesting that OCP either "confirm that DSW is a device to be regulated by [CDRH]" or, alternatively, if OCP believes DSW to be a combination product, "confirm that it should be regulated as a device by [CDRH]." A.R. 001. Prevor described DSW as a liquid solution in a canister propelled by pressurized gas, designed "to help prevent and minimize accidental chemical burn injuries." A.R. 001, 002. According to Prevor, DSW's solution is intended "to physically and mechanically remove splashes of acids and bases off the skin by washing them away" and "to neutralize acids and bases. . . ." A.R. 001 (emphasis added). The proposed labeling for DSW similarly states that the solution is "intended to remove splashes of acidic and basic substances off the skin by mechanically washing the chemicals away from the skin, and to neutralize and dilute acids and bases." A.R. 002 (emphasis added).

The request for designation attempted to show that DSW is appropriately regulated as a device. However, the request compared the physical and chemical actions that achieve the solution's intended purposes in order to identify which action is "primary and the most

predominant" in achieving them. A.R. 001. Prevor described two studies conducted to "compare and quantify the relative contributions of the physical/mechanical effect and the chemical effect" of the solution. A.R. 005; A.R. 005-007. The studies were not conducted under actual use conditions. According to Prevor, however, they showed that the physical/mechanical action and the chemical action account, respectively, for about ninety percent and ten percent of the solution's overall effect. A.R. 007. Prevor concluded that the physical "mode of action" is the "primary mode of action," A.R. 003, and, therefore, the product should be regulated as a device by CDRH. A.R. 002.

Prevor also asserted that DSW is similar to other products, namely Silvaklenz, Reactive Skin Decontamination Lotion ("RSDL"), blow fly larvae ("medical maggots"), and Dermacyn Wound Cleanser, all of which are regulated by CDRH. A.R. 008-009. Prevor alleged that the similarity among the products indicated that DSW should be assigned to CDRH. A.R. 008-010.

2. Office of Combination Products' Decision

Shortly after the request for designation was submitted, and in response to OCP's request for clarification, Prevor provided additional information. A.R. 011-014. OCP also requested and received recommendations from product jurisdiction officers in CDRH and CDER regarding the assignment of DSW to a lead center. A.R. 053-059, 060-066. OCP requested its own staff to conduct a technical review of Prevor's request for designation. A.R. 039-052. CDRH's and CDER's product jurisdiction officers and OCP's technical review all recommended that DSW should be assigned to CDER. A.R. 051-052, 053, 060-061.

On October 16, 2009, OCP issued its designation letter and assigned DSW to CDER for regulation. A.R. 0675-0677. Noting that Prevor's request for designation acknowledged that

the solution "'has a chemical effect on acids and bases,'" OCP determined that DSW's solution has two "primary intended purposes," which are (1) to wash harmful chemicals off the skin, and (2) to neutralize harmful chemicals on the skin. A.R. 676. Accordingly, OCP concluded that DSW's solution was excluded from the device definition because it "achieves it primary intended purposes, at least in part, through chemical action." Id.

OCP next concluded that DSW is a combination product, because it consists of two different regulated components: the solution, which meets the drug definition; and, the canister, which meets the device definition. Id.

Finally, applying the regulations governing assignment of combination products to agency centers, OCP determined that the solution, not the canister, "provides the greater contribution to the overall therapeutic effect of the combination product." Id. In other words, OCP compared the two constituent parts of the product, and determined that the PMOA is provided by the drug constituent, i.e., the solution. Accordingly, OCP assigned DSW to CDER as the lead agency center for regulation. Id. OCP's letter also noted that the other products described in the request for designation were significantly different from DSW and do not support regulation by CDRH. Id.

Prevor did not submit a request for reconsideration to OCP. In a letter dated February 25, 2010, Prevor sought review of OCP's decision by FDA's Office of the Chief Counsel. A.R. 678-723. The Chief Counsel's response, dated March 17, 2010, stated that the time frame for seeking reconsideration by OCP under FDA's product-jurisdiction regulations had passed and suggested that Prevor consider filing a request for review under FDA's procedures established in 21 C.F.R. § 10.75 for internal agency review of decisions of FDA employees. See A.R. 724.

C. Prevor's Request for Review to the Office of Special Medical Programs

1. Prevor's Request for Review

On March 24, 2010, Prevor submitted a request under 21 C.F.R. § 10.75 to have FDA's Office of Special Medical Programs ("OSMP") review OCP's determination.[2] A.R. 725. In the request for review, Prevor reiterated its belief that DSW should be regulated by CDRH because the product is a device or, if OSMP determines that DSW is a combination product, that DSW should still be regulated as a device. A.R. 727.

Despite the unequivocal claims in Prevor's 510(k) submission regarding the critical role played by DSW solution's chemical action, Prevor asserted that the device definition does not exclude DSW's solution because the solution does not achieve its "primary intended purpose" through chemical action but that "physical removal is *the primary intended purpose*" and it is "achieved through mechanical means." A.R. 735 (underscore in original, italics added). Prevor also continued to assert that the chemical "mode of action" of the solution is secondary to its physical "primary mode of action." A.R. 726-729. The request relied on the same two studies described in Prevor's request for designation to compare the solution's relative contributions of its physical/mechanical action and its chemical action against each other. A.R. 730-731. Prevor also argued that the products it first identified in its request for designation as comparable to DSW should serve as precedents for determining which center has primary jurisdiction over DSW. A.R. 731-733, 741-742. After a meeting with OSMP, Prevor submitted two follow-up letters, dated December 2, 2010, and March 24, 2011, in which Prevor reiterated its position and

[2] Under 21 C.F.R. § 10.75, OSMP is the appropriate office within FDA to review decisions of OCP.

described additional products that it believed should serve as precedents for DSW. A.R. 771-780, 781-783.

2. Office of Special Medical Programs' Decision

By letter dated April 25, 2011, OSMP responded to Prevor's request for review. A.R. 784-789. OSMP affirmed OCP's determination that DSW is a "combination product to be assigned to CDER as the lead agency center for premarket review and regulation based on the product's PMOA." A.R. 785.

OSMP rejected Prevor's view that DSW's solution is a device, and in doing so rejected Prevor's underlying reasoning that the solution's "chemical action is secondary and the physical action (washing effect) is primary." Id. OSMP explained that Prevor's evaluation of the different modes of action of the solution was not a proper PMOA analysis, which compares two or more constituent parts of a combination product. In this case, a proper PMOA analysis is a comparison between the solution and the canister. However, as OSMP explained, Prevor had conducted an analysis of only a single constituent part, the solution. A.R. 785-786. OSMP further explained that DSW's solution does not meet the definition of a combination product and, as a result, cannot undergo a PMOA analysis. Id.

OSMP also noted that, even if DSW's solution could be evaluated by a PMOA analysis, OSMP found no support for Prevor's conclusion that the solution's "physical action" is the PMOA. A.R. 786 n.1. The review described as "flawed" the two studies submitted by Prevor to support the assertion that the physical/mechanical removal of chemical splashes accounts for approximately ninety percent of the solution's overall effect. Id. OSMP stated that the studies did not simulate the actual conditions of use and that one study lacked a control. Id.

OSMP referred to the device definition's exclusionary language and stated that "an article may have multiple primary intended purposes." A.R. 786. Based on the information in Prevor's request for designation, OSMP found that DSW's solution has two primary intended purposes: (1) washing harmful chemicals off the body; and, (2) neutralizing harmful chemicals on the body. Id. OSMP noted that those purposes are achieved through physical action and chemical action. Id. OSMP concluded that "[b]ecause the solution depends on chemical action within or on the body to achieve one of its primary intended purposes, the solution is not a device within the meaning of [the FDCA]." Id.

OSMP further determined that DSW is a combination product because the solution meets the definition of "drug" and the canister meets the definition of "device." A.R. 787. Finally, to explain its center designation decision, OSMP described its PMOA analysis, which compared DSW's drug constituent to its device constituent to determine which constituent provides the most important therapeutic action of the combination product. Id. OSMP reasoned that DSW's drug constituent provides the product's PMOA because, although the canister sprays the solution onto the skin, "[i]t is the solution that directly acts on the body to help prevent or mitigate chemical burn injuries" and "washes off, neutralizes, and dilutes harmful chemicals that are splashed onto the body." Id. Because of the product's drug PMOA, OSMP concluded that DSW is properly assigned to CDER for premarket review and regulation. Id.

Finally, OSMP disagreed with Prevor's comparisons between DSW and products regulated by CDRH, and stated that the products Prevor identified are inapposite "because they differ from DSW, including with respect to intended use, components, and/or ingredients." A.R. 787; A.R. 787-789. This suit challenges FDA's decision.

IV. Argument

A. Standard of Review

Courts will grant a motion for summary judgment under Rule 56(a) of the Federal Rules of Civil Procedure when the moving party has shown "that there is no genuine dispute as to any material fact and [it] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Moreover, "in ruling on cross-motions for summary judgment, the court shall grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not genuinely disputed." Shays v. Federal Election Comm'n, 424 F. Supp. 2d 100, 109 (D.D.C. 2006). "Summary judgment is an appropriate procedure for resolving a challenge to a federal agency's administrative decision when review is based upon the administrative record." Virginia, Dep't of Med. Assistance Servs. v. Johnson, 609 F. Supp. 2d 1, 6 (D.D.C. 2009) (internal quotations omitted); see Richards v. Immigration & Naturalization Serv., 554 F.2d 1173, 1177 n.29 (D.C. Cir. 1977).

B. FDA Properly Interpreted the Statutory "Device" Definition

Under the exclusionary language in the device definition, an article is not a device if it "achieve[s] its primary intended purposes through chemical action within or on the body of man or other animals." 21 U.S.C. 321(h). FDA has interpreted "primary intended purposes" to allow an article to have more than one primary intended purpose. As discussed below, that interpretation is based on the clear statutory language, has ample support in the case law, and is reasonable and permissible.

When reviewing an agency's construction of a statutory provision, a court's first step is to determine "whether Congress has directly spoken to the precise question at issue. 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." Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984); Barnhart v. Walton, 535 U.S. 212, 218 (2002) (reviewing court must first decide "whether the statute unambiguously forbids" the agency's interpretation). If the court concludes that the language is ambiguous, the court must determine whether the agency's construction is based on a permissible interpretation of the statute. Chevron, 467 U.S. at 843-44 n.11. If the statute does not unambiguously forbid the interpretation, the reviewing court must defer to the agency's construction. Chevron, 467 U.S. at 842-43; Barnhart v. Walton, 535 U.S. at 218.

Here, FDA's interpretation of "primary intended purposes" is contained in an agency decision letter. Chevron deference has been given to an agency's interpretation expressed in informal agency action. See Menkes v. U.S. Dep't of Homeland Security, 637 F.3d 319, 330-332 (D.C. Cir. 2011); Mount Royal Joint Venture v. Kempthorne, 477 F.3d 745, 754 (D.C. Cir. 2007).[3] FDA has received Chevron deference from this Circuit based on decision letters containing the agency's construction of the FDCA. See Mylan Labs. Inc. v. Thompson, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004) (granting Chevron deference to FDA's interpretation of FDCA provisions relating to abbreviated new drug applications that was contained in a tentative-approval letter).

[3] See also Barnhart v. Walton, 535 U.S. at 222 ("the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that Chevron provides the appropriate legal lens through which to view the legality of the Agency interpretation"); United States v. Mead Corp., 533 U.S. 218, 228-30 (2001).

If this Court finds that "primary intended purposes" is ambiguous, and that Chevron deference is not applicable here, FDA's interpretation is still entitled to some deference, in light of the complexity of the FDCA and the specialized experience of the agency in implementing the extensive regulatory framework established by the statute. See Mead Corp., 533 U.S. at 234-35 (describing deference under Skidmore v. Swift & Co., 323 U.S. 134, 139-40 (1944)); Center for Biological Diversity v. Jackson, No. 10-2007, 2011 WL 4498805, *4 (D.D.C. Sept. 29, 2011); Allergan, Inc. v. Crawford, 398 F. Supp. 2d 13, 21-22 (D.D.C. 2005).

1. Under the FDCA's Device Definition, the Term "Primary Intended Purposes" Unambiguously Means That More Than One Purpose Can Be Primary

An analysis of statutory construction begins with an examination of the statutory language. Barnhart v. Sigmon Coal Co., Inc., 534 U.S. 438, 450 (2002). Here, the unambiguous statutory language compels the meaning that FDA gives to "primary intended purposes" – that an article can have more than one primary intended purpose.

A device is defined, in part, as

> an instrument, apparatus, [or] implement . . . which is . . . (2) 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 . . . and [a] which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and [b] which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h). The last two clauses, which describe the articles that are excluded from the device definition, explicitly provide that an article cannot be a device either if it achieves its primary intended purposes through chemical action, or it is dependent upon being metabolized to achieve its primary intended purposes.

The statute does not confine the primary intended purposes of an article to a single purpose. The plural "purposes" is a clear signal that an article may have more than one primary intended purpose. When determining whether an article is a device within the meaning of the FDCA, FDA is authorized, indeed required, to consider each intended purpose of an article to determine whether that purpose is among the primary intended purposes of the article. Although not all articles must, or will, have more than one primary intended purpose, they can and often do have several primary intended purposes, any one of which can trigger the exclusionary language to bar an article from the device definition.

Interpreting "primary intended purposes" as unambiguously plural is also consistent with congressional intent, as supported by the legislative history of the 1976 and 1990 amendments to the device definition. Initially, "device" was defined as "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(h) (1938). At that time, "device" did not contain the "chemical action" or "being metabolized" language to exclude certain articles from the definition.

In 1976, Congress amended the device definition to add language very similar to the exclusionary language in the current version of the statute:

> an instrument, apparatus . . . , or other or similar or related article, including any component, part, or accessory, which is –
>
> ***
>
> (2) 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

***

> [and] which does not achieve any of its principal 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 any of its principal intended purposes.

Medical Device Amendments of 1976, Pub. L. No. 94-295 § 3(a)(1)(A), 90 Stat. 539, 575 (emphasis added).

Congress added the restrictions in 1976 to "draw a clear distinction between a 'device' and a 'drug'" and "remove[] the gray area that exists between the definitions." H.R. Rep. No. 94-853, at 14 (1976). The House Report explained that the original device definition was

> modified by the proposed legislation to include the distinction that an article is a device if it "does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and [if it] is not dependent upon being metabolized for the achievement of any of its principal intended purposes". This distinction means that articles dependent upon chemical action or being metabolized, and otherwise falling within the definition of "drug" . . . are to be regulated as drugs and not as devices.

H.R. Rep. No. 94-853, at 14.

The language in the 1976 amendments, "any of its principal intended purposes," establishes that an article can have more than one principal intended purpose. Congress' use of the words "any of" conveys that any one principal intended purpose, from among several principal intended purposes, can cause an article to be excluded from the device definition.

In 1990, Congress enacted the Safe Medical Devices Act and amended the device definition's exclusionary language, replacing "any of its principal [intended purposes]" with the current language, "its primary [intended purposes]." See Pub. L. No. 101-629, 104 Stat. 4511, 4526 § 16(b)(1); S. Rep. No. 101-513, at 30-31 (1990). The Senate Report characterized the changes as "editorial to make the device definition compatible with the terminology used in

section 20" of the Safe Medical Devices Act. S. Rep. No. 101-513, at 43 (1990); see also S. Rep. No. 101-513, at 30-31 ("These changes are editorial and conform the device definition to the language in section 20."). In section 20, codified at 21 U.S.C. § 353(g), the phrase "primary mode of action" is used to describe the basis for "determining the appropriate component of the FDA to review premarket submissions for [combination] products." S. Rep. No. 101-513, at 43; 21 U.S.C. § 353(g) (instructing FDA to assign a combination product to an agency center based on the product's "primary mode of action.").

The Senate Report suggests that Congress replaced "any of its principal" in the device definition with "primary" for consistency with its use of the word "primary" in "primary mode of action." The fact that the Senate Report characterized the substitution as "editorial" reveals that Congress did not intend to make a substantive change to the scope of the limiting clauses in the device definition.

The differing contexts in which "primary intended purposes" and "primary mode of action" occur show that Congress intended these terms to be interpreted as they are written. The statutory language governing combination products requires FDA to assign a combination product to one agency center based on the "primary mode of action" of the product, as determined by FDA in accordance with its product-jurisdiction regulations. 21 U.S.C. § 353(g)(1). "Primary mode of action" is singular, and the phrase is used to direct a combination product to one FDA center. See id.

The device definition, in contrast, allows multiple primary intended purposes to inform FDA's determination as to whether an article is excluded from the definition. 21 U.S.C. § 321(h). Giving effect to the plural "purposes" in "primary intended purposes" is fully

compatible with Congress's use of the descriptor "primary." Had Congress intended to say that a device may only have a single primary intended purpose, it could have simply substituted "purpose" for "purposes," but it did not do so.

Nor is FDA's interpretation unique or unusual. In fact, the term "primary purposes" has been used by Congress and the courts in various instances to convey the concept of multiple primary purposes, from two to an undefined maximum. See, e.g., Samantar v. Yousuf, 130 S. Ct. 2278, 2285 (2010) (describing the "two primary purposes" of the Foreign Sovereign Immunities Act); Pub. Citizen Health Research Grp. v. FDA, 740 F.2d 21, 29 (D.C. Cir. 1984) (discussing the "four primary purposes" of the exhaustion doctrine); World Airways, Inc. v. Civil Aeronautics Bd., 547 F.2d 695, 699 (D.C. Cir. 1976) (listing the "three primary purposes" of the 1962 amendments to the Federal Aviation Act of 1958); 42 U.S.C. § 12572(b)(2)(F)(i) (noting specific requirements for one of the "primary purposes" of a national-service demonstration program); 23 U.S.C. § 508(a)(2)(A) (enumerating a minimum of six "primary purposes" for a research and development program within the Department of Transportation).[4]

2. Even if "Primary Intended Purposes" Were Ambiguous, FDA's Interpretation Is Permissible and Merits Deference

If this Court concludes that "primary intended purposes" is ambiguous, FDA's interpretation of that phrase to mean all intended purposes that are "primary," is a permissible – and the most reasonable – reading of the text. This construction does not strain the meaning of "primary," which may mean different things in different contexts. The flexibility of "primary"

[4] Accord Webster's Encyclopedic Unabridged Dictionary of the English Language 1537 (1996) (defining "primary" as, among other things, "**1.** first or highest in rank or importance; chief; principal: *his primary goals in life*. . . syn. **1.** main, prime").

reasonably permits it to be used in "primary intended purposes" (and previously "principal intended purposes") to indicate more than one intended purpose in the device definition's exclusionary language.

There can be no reasonable dispute that, in 1976, when Congress added the exclusionary language using "any of its principal intended purposes," it intended that an article may have more than one principal intended purpose, any one of which could exclude the article from the device definition. Congress added the exclusions to the device definition at that time to require, without qualification, that "articles dependent upon chemical action or being metabolized, and otherwise falling within the definition of 'drug' . . . to be regulated as drugs and not as devices." H.R. Rep. No. 94-853, at 14 (1976).

If Congress had intended that the 1990 amendments, which replaced "any of its principal" with "primary," to restrict the interpretation of "primary" to "one" or to "lone, exclusive of others," the scope of the device definition's exclusions would have been significantly narrowed.[5] In turn, this change could have substantially altered the FDCA's product classification regime and required FDA to regulate an untold number of articles as devices that were regulated as drugs since 1976, substantially reversing the impact of the device definition's exclusions. If Congress had intended such a significant change, it would not have characterized the 1990 amendments as merely "editorial."

---

[5] Cf. Reconsideration Letter from FDA's Principal Associate Commissioner to Apotex Corp. at 5 (Sept. 8, 2003) (noting that "many products have more than one primary intended purpose"). Available on FDA's website at: http://www.fda.gov/downloads/CombinationProducts/JurisdictionalInformation/RFDJurisdictionalDecisions/RedactedDecisionLetters/UCM113771.pdf.

C. FDA Reasonably Concluded That DSW Is A Combination Product with A Drug Constituent That Provides Its Primary Mode of Action; Therefore, FDA's Designation Of CDER As the Lead Center To Regulate DSW Was Appropriate

Agency decisions reviewed under the Administrative Procedure Act ("APA") may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). When, as here, the agency's decision is based on evaluation of scientific information within its area of technical expertise, its decisions are traditionally accorded great deference. Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 216 (D.D.C. 1996). A court reviews an agency's scientific judgment by "'exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality.'" Troy Corp. v. Browner, 120 F.3d 277, 283 (D.C. Cir. 1997) (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir. 1976)). Such deference to an agency's scientific expertise has been applied in cases under the FDCA. See, e.g., Rempfer v. Sharfstein, 583 F.3d 860, 867-868 (D.C. Cir. 2009); Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1320-21 (D.C. Cir. 1998).

Of course, a reviewing court also "'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. Oregon Natural Res. Council, 490 U.S. 360, 378 (1989) (quoting Overton Park, 401 U.S. at 416). The agency must have articulated an explanation that establishes a "'rational connection between the facts found and the choice made.'" Bowen v. Am. Hosp. Ass'n, 476 U.S. 610, 626 (1986) (quoting Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). When the court can "reasonably . . . discern[]" the agency's path, it will uphold the agency's decision. Pub. Citizen, Inc. v. Fed. Aviation Admin.,

988 F.2d 186, 197 (D.C. Cir. 1993) (internal quotation marks omitted). In applying the arbitrary and capricious standard, the court reviews the administrative record assembled by the agency. Camp v. Pitts, 411 U.S. 138, 142 (1973).

Based on the administrative record in this case, FDA reasonably concluded that DSW's solution is not a device. Citing information Prevor itself submitted in its request for designation, the agency found that the solution relies on both physical and chemical actions on the body to achieve its primary intended purposes. A.R. 786. In light of that finding, FDA properly determined that DSW's solution is excluded from "device" by the definition's chemical-action exclusion. As OSMP explained, "if 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." A.R. 786. OSMP stated that the solution's two primary intended purposes are washing harmful chemicals off the body and neutralizing harmful chemicals on the body, and noted that Prevor acknowledged that the solution's neutralization effect is achieved through chemical action. A.R. 785. OSMP determined that the solution is excluded from the device definition because it "depends on chemical action within or on the body to achieve one of its primary intended purposes." A.R. 786.

OSMP highlighted the following excerpt from Prevor's request for designation when affirming the determination by OCP that DSW's solution is not a "device" because of its chemical action on the body:

> The RFD explains: 'DSW also has a chemical effect on acids and bases. . . . DSW is amphoteric, Lewis type, capable of neutralizing an acid or a base. It forms covalent bonds with both acids and bases. Once the bond is formed, the acid or base becomes a neutral salt. DSW attracts acidic substances to its basic site and vice versa. A bond is formed between DSW and the acid or base, and the offending chemical becomes inactive because it is bonded with DSW.' RFD, pp.

> 3-4 [A.R. 003-004]. The diagram provided in the RFD indicates that this chemical action occurs on the body. RFD, p. 4 [A.R. 004].

A.R. 786.

To further show that "[n]eutralizing the acids and bases in harmful chemicals is one of the solution's primary intended purposes," OSMP emphasized the link between the solution's chemical action and the solution's intended therapeutic effects:

> In addition to washing harmful chemicals off the body, the solution is intended to neutralize harmful chemicals on the body. Exposure to various chemicals can lead to chemical reactions on the body resulting in chemical burn injuries. The solution inhibits such chemical reactions through another chemical action, *i.e.*, by neutralizing the acids and bases in harmful chemicals, and through this chemical action, the solution helps prevent or mitigate chemical burn injuries.

Id.

OSMP also considered and rejected Prevor's arguments asserting that DSW's solution meets the device definition. The record shows that OSMP appropriately (1) discounted Prevor's attempt to show that chemical action is not used to achieve the solution's "primary intended purposes," and (2) declined to rely on Prevor's "mode of action" studies.

OSMP noted that, when determining an article's primary intended purposes, it was not proper to evaluate DSW's solution using a primary mode of action (i.e., PMOA) analysis. A.R. 785-786. As OSMP explained, Prevor made a fundamental mistake by contrasting the solution's chemical action with the solution's physical action, instead of comparing actions of DSW's constituent parts – here, the canister and the solution. See A.R. 785, 787. OSMP stated that both the statutory provision and FDA's regulation prescribe that "a PMOA analysis applies only to combination products." A.R. 785; 21 U.S.C. § 353(g); 21 C.F.R. § 3.4. After noting that DSW's solution does not consist of different regulated components, OSMP stated that "a PMOA

analysis does not apply to the solution because it [i.e., the solution] is not a combination product." A.R. 785.

OSMP found that the two studies Prevor described in its request for designation were unreliable and lent no credibility to the company's view that the chemical action of DSW's solution provides merely a "secondary effect" to the physical/mechanical action. A.R. 786 n.1. In these studies, Prevor attempted to quantify the relative contributions of the chemical and physical/mechanical actions toward achieving the solution's overall effect. A.R. 005-007, 730-731. According to Prevor, the studies showed that approximately ninety percent of the solution's effect was achieved by physical/mechanical action and roughly ten percent was achieved by chemical action. A.R. 007, 731.

OSMP questioned the relevancy of these studies, in light of their objective. Cf. A.R. 786 n.1 (explaining that DSW's solution is not a combination product, and noting that, even if it were, the studies "do not demonstrate that the [solution's] physical action provides the PMOA"). In any event, OSMP's evaluation found the studies to be flawed and not useful for reaching valid conclusions because they "do not simulate the conditions of use and therefore do not appear to measure or reflect the actions of the solution on the body."[6] Id. OSMP also noted that one study omitted a control liquid against which the measurements for DSW's solution could have been compared. Id.

[6] DSW's solution is to be sprayed onto the user's skin from a pressurized canister. In contrast, Prevor's studies attempted to assess the effects of DSW's solution by taking measurements from a laboratory beaker, into which DSW's solution was being added in small increments (1 milliliter at a time), to a chemical, sodium hydroxide. Compare A.R. 002-003 (DSW's operating instructions) with A.R. 005-006 (study methodology).

After affirming that DSW's solution is not a "device," OSMP explained that the solution meets the definition of "drug" because it is intended for use in preventing and minimizing accidental chemical burn injuries. A.R. 787 (citing 21 U.S.C. § 321(g), which provides, in relevant part, that "drug" is an article "intended for use in the . . . mitigation, treatment, or prevention of disease"). After finding that DSW is a combination product because the solution is a "drug" and the canister is a "device," OSMP conducted a PMOA analysis and assigned the product to CDER. A.R. 787; see 21 C.F.R. § 3.4.

OSMP's PMOA analysis compared DSW's drug constituent to its device constituent and determined that DSW's solution is more important to fulfilling the therapeutic purpose of the product than the canister. A.R. 787 ("It is the solution that directly acts on the body to help prevent or mitigate chemical burn injuries" and "washes off, neutralizes, and dilutes harmful chemicals that are splashed onto the body."). OSMP concluded that DSW is properly assigned to CDER because the combination product's PMOA is provided by its drug constituent. Id.; 21 U.S.C. § 353(g); 21 C.F.R. § 3.4.

OSMP also described the critical differences between DSW and the products cited by Prevor as regulatory precedents for DSW. Prevor contended that classifying DSW's solution as a drug rather than a device is inconsistent with FDA's regulation of several products as devices. A.R. 731-732. In refuting this contention, OSMP found that each of the products Prevor described were inapposite because they differ from DSW in fundamental ways, i.e., in intended use, components, and ingredients. A.R. 787.

Specifically, with respect to the RSDL product, OSMP stated that the functions of the device constituent in RSDL and in DSW are not comparable. A.R. 787-788. As OSMP

explained, RSDL has a device constituent (a sponge applicator) that is used to physically scrub chemical warfare agents and T-2 toxin from the skin, and RSDL's device constituent, not its drug constituent (a lotion), provides the PMOA for the product.[7] A.R. 787-788. OSMP also contrasted DSW's canister with RSDL's sponge applicator, noting that DSW's canister does not directly remove chemicals from the body and Prevor has "not demonstrated that [DSW's] canister provides the PMOA." A.R. 787.

Regarding Silvaklenz Skin and Wound Cleanser Solution (Silvaklenz) and heparin catheter lock flush solutions, OSMP stated, "These products contain a solution but the solution in these products is a combination product because the solution is comprised of different regulated components." A.R. 788. OSMP described these products in detail, stating:

> Silvaklenz Skin and Wound Cleanser Solution consists of cocamidopropyl betaine and silver, which are responsible for providing the chemical mode of action (reducing surface tension and antimicrobial effects), and the other components in the solution are responsible for providing the physical mode of action (mechanically removing debris, tissue, and particles). Likewise, for heparin catheter lock flush solutions, heparin is responsible for providing the chemical mode of action (anticoagulant) and the sterile saline or sterile water in the solution is responsible for providing the physical mode of action (physically occupying space within the catheter and exerting pressure on the patient's circulating blood). Applying a PMOA analysis to these combination products, FDA determined that the PMOA was attributable to the device constituent(s).

A.R. 788.

In distinguishing DSW's solution, OSMP stated that, based on the information submitted by Prevor, DSW's solution lacks individual components with distinct drug and device actions and, therefore, the solution is not comprised of different regulated components and thus is not a

[7] Prevor acknowledged that RSDL's PMOA is provided by its device constituent. A.R. 787.

combination product. Id. OSMP explained that, as described in Prevor's request for designation, "it is not any particular component but the solution as a whole that is responsible for its chemical action." Id. OSMP concluded that the PMOA analysis required for the Silvaklenz solution and the heparin catheter lock flush solution is inapplicable to DSW's solution. Id.

OSMP disposed of the remaining products that Prevor advanced as precedents for DSW, including medical maggots, bone void fillers, Prontosan Wound Irrigation Solution, and NasalCEASE, stating that these products do not alter the facts that DSW's solution does not meet the definition of "device," DSW is a combination product, and the studies described in Prevor's request for designation do not support the assignment of DSW to CDRH.[8] A.R. 788-789.

In sum, the record shows that FDA reasonably concluded that: (1) neutralizing chemicals on the skin is one of DSW solution's "primary intended purposes"; and (2) DSW's solution is excluded from the device definition because neutralizing chemicals on the skin is achieved through chemical action on the body. Moreover, FDA reasonably determined that DSW's drug constituent provides the combination product's PMOA, which required DSW to be assigned to CDER. Because the administrative record shows that FDA considered the necessary factors, that FDA's decisions bear a rational connection to the evidence, and that FDA provided a sufficient explanation of its decision-making, the agency's actions should be upheld by this court.

[8] OSMP also noted that some of the products cited by Prevor were not properly before the office on review. A.R. 789 n.3.

D. Prevor's Arguments Provide No Support for the Relief Sought in this Case

1. Prevor Misunderstands FDA's Interpretation of "Primary Intended Purposes"

Prevor contends that FDA abruptly altered its construction of the device definition, creating a new interpretation that is contrary to the statutory language. Pl.'s Mot. Summ. J. at 14. According to Prevor, "FDA replaced the word 'primary' to read 'all' or 'any,'" allowing every intended purpose to trigger the device definition's exclusionary language, thereby rendering "primary" superfluous. Pl.'s Mot. Summ. J. at 13. This is not so, for two reasons.

First, FDA does not view each of an article's intended purposes to be a primary intended purpose. Under the exclusionary language in the device definition, only an article that achieves its "primary intended purposes" through chemical or metabolic action is excluded from the device definition. Prevor's contention that FDA does not give meaning to the word "primary" in "primary intended purposes" is unfounded.

Relying on OSMP's statement, "if 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 device," Pl.'s Mot. Summ. J. at 10 (emphasis in original), Prevor asserts that the agency's use of "even in part" means that "even a de minimis chemical effect" will prevent a product from being a "device." Pl.'s Mot. Summ. J. at 14. This is incorrect. OSMP concluded that DSW's solution is not a device because it "depends on chemical action within or on the body to achieve one of its primary intended purposes." A.R. 786 (emphasis added). OSMP's interpretation does not exclude an article from being classified as a device based on a de minimis chemical effect.

Second, FDA's interpretation of "primary intended purposes" in the device definition's exclusionary language is not new. In fact, FDA's interpretation is contained in a designation letter sent in 2003 to another company claiming, as Prevor does here, that only one intended purpose of an article can be the article's primary intended purpose. In that letter, FDA stated:

> Apotex's argument that the definition of a device requires a determination of one single primary intended purpose is not persuasive. Like Normocarb, many products have more than one primary intended purpose. Indeed, the use of the plural "purposes" in [21 U.S.C. § 321(h)] expressly recognizes this possibility.

Designation Letter from FDA's Office of the Ombudsman to Apotex Corp. at 3 (May 2, 2003), aff'd in Reconsideration Letter from FDA's Principal Associate Commissioner to Apotex Corp. at 5 (Sept. 8, 2003).[9]

FDA issued a draft guidance relating to product-jurisdiction matters entitled, "Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices & Additional Product Classification Issues," Draft Guidance (June 2011), available at www.fda.gov/combinationproducts/default.htm. Because this document was issued after the agency decision challenged in this action, the government does not rely on it here. In any event, contrary to Prevor's assertion, this guidance document does not evince a new statutory construction. See Pl.'s Mot. Summ. J. at 24-27. FDA's interpretation of the device definition has been consistent. Thus, Prevor's argument that FDA needed to undertake notice-and-comment rulemaking to change its interpretation is moot.

[9] The letter to Apotex Corp. is available on FDA's website at: http://www.fda.gov/downloads/CombinationProducts/JurisdictionalInformation/RFDJurisdictionalDecisions/RedactedDecisionLetters/UCM113771.pdf.

Prevor also states that FDA's interpretation of "primary intended purposes" as applied to DSW is "more consistent with the statutory language in place before 1990, which allowed FDA to consider 'any of its principal' intended purposes in classifying a product." Pl.'s Mot. Summ. J. at 18. Prevor asserts that Congress's intent in enacting the Safe Medical Devices Act of 1990 was to narrow the exclusionary language in the device definition. See Pl.'s Mot. Summ. J. at 18. In other words, Prevor argues that Congress meant to include more articles within the FDCA's device definition, and that the agency's current interpretation disregards that intention. This is incorrect. As noted above, the 1990 change to the device definition was editorial only, and was not enacted so that more articles would be classified as devices. Consistent with Congress' intent not to make a substantive change to the device definition, FDA's interpretation of the definition's exclusionary language has remained constant before and after the 1990 amendment.

2. Prevor's Interpretation of "Primary Intended Purposes" is Erroneous

Prevor believes that it is necessary to rank a product's intended purposes (e.g., a primary purpose, a secondary purpose, and a tertiary purpose) and disregard all purposes after the "primary" purpose.[10] Pl.'s Mot. Summ. J. at 13. In construing the statute in this manner, Prevor ignores the plain language of "primary intended purposes" and makes no attempt to reconcile the plural "purposes" with "primary." Prevor's interpretation of the device definition is at odds with itself and with the cases construing "primary."

[10] Even if the solution's intended purposes were stated as one primary intended purpose, that primary purpose would be to help prevent and minimize accidental chemical burn injuries. Cf. Pl.'s Mot. Summ. J. at 5 ("DSW is intended to prevent and mitigate toxic chemical burns"). The result would be the same. Because the solution achieves that purpose using physical (washing off) and chemical (neutralization) action, the latter excludes the solution from the device definition.

Moreover, DSW's solution cannot be transformed into a "device" just because one of its actions is physical. Under the plain meaning of the device definition, which explicitly excludes an article that "achieve[s] its primary intended purposes through chemical action within or on the body," 21 U.S.C. § 321(h), an article that achieves its primary intended purposes both through physical action and through chemical action cannot be a device. The exclusionary language in the device definition does not contain an exemption for articles that achieve their primary intended purposes in part through chemical action. There is also nothing in the legislative history of the FDCA to support Prevor's claim that the device definition was meant to encompass an article that relied on several actions to achieve its intended purposes, so long as its physical action purportedly could be linked to a greater proportion of the article's effect.[11]

All of Prevor's attempts to downplay the importance of the solution's chemical action (see Pl.'s Mot. Summ. J. at 3-6, 8, 14-15, 29-31) are irrelevant because DSW solution's physical and chemical actions are not to be compared with each other to determine whether the solution meets the device definition. In its 510(k) submission, Prevor unequivocally emphasized the importance of the solution's chemical action in preventing and mitigating burn injuries from accidental chemical spills, noting its advantages over water because of the solution's ability to react with and neutralize chemicals. Prevor's 510(k) listed "acids, such as hydrochloric acid;

[11] Although Prevor argues the solution's dilution action (or "dissolution" (A.R. 001, 004)) is part of the solution's "primary intended purpose," see Pl.'s Mot. Summ. J. at 5 ("DSW has only one primary intended purpose: to physically wash away and dilute chemical spills or splashes on the skin to prevent and mitigate chemical burns." (emphasis added)), its submissions to FDA were to the contrary. In its request for review to OSMP, Prevor stated that dilution is a "third and trivial mode of action," purportedly accounting for less than one-half a percent (0.5%) of DSW's overall effect. A.R. 729. The fact that Prevor includes the dilution action with the washing effect as a primary intended purpose is inconsistent because Prevor refuses to accept "primary" to describe the purported 10% contribution of the solution's chemical action.

bases, such as sodium hydroxide; oxidizing agents, such as hydrogen peroxide, reducing agents, such as sodium thiosulfate, and chelating agents, such as fluoride ions" as examples of "the different chemicals/chemical groups to which [DSW] can bind and neutralize." A.R. 150. The proposed labeling for DSW informs the user that DSW is intended to neutralize acids and bases, in addition to mechanically removing chemicals from the skin. A.R. 002. Prevor asserted, in a letter to OSMP, that "the benefit provided by the chemical action of DSW is valuable, by neutralizing the pH of any remaining offending chemical on the skin surface." A.R. 774. Prevor cannot backpedal from these statements nor expect FDA to ignore them.

3. Prevor Incorrectly Claims That DSW's Solution Has A "Device Mode of Action"

Alternatively, even when Prevor assumes arguendo that DSW is a combination product, it continues to incorrectly interpret the device definition and conclude that DSW's solution is a device. Pl.'s Mot. Summ. J. at 29. Prevor claims that, because the solution is a device, it "also has a device mode of action under the regulatory definition." Id. But, under FDA's regulations, unless a constituent part of a combination product meets the device definition, it cannot have a "device mode of action." See 21 C.F.R. § 3.2(k)(2). Here, the device definition's chemical action exclusion precludes DSW's solution from being a device. See A.R. 786. DSW's solution, therefore, does not have a "device mode of action." A.R. 787.

Prevor also claims that "FDA's decision did not explain why between the nozzle and the liquid, the liquid provided the primary mode of action." See Pl.'s Mot. Summ. J. at 30. If Prevor believed that the canister makes the greatest contribution to DSW's overall intended therapeutic effects, the burden was on Prevor to provide sufficient evidence to prove that point. Prevor did not meet that burden. Moreover, OSMP provided the explanation that Prevor claims

is lacking. OSMP explained that DSW's solution is more important to fulfilling the therapeutic purpose of the product than the canister because, although the canister sprays the solution onto the skin, "[i]t is the solution that directly acts on the body to help prevent or mitigate chemical burn injuries" and "washes off, neutralizes, and dilutes harmful chemicals that are splashed onto the body." A.R. 787.

4. Prevor's Claim of Disparate Treatment Has No Merit

FDA fully complied with the APA by explaining the significant distinctions between DSW and the products identified by Prevor and, why, as a result, FDA came to the conclusion it did with respect to DSW. Cf. Sanofi-Aventis U.S. LLC v. FDA, 733 F. Supp. 2d 162, 172 (D.D.C. 2010) (holding that "this is not a case in which the FDA treated drugs that were 'identical in all material respects' differently" and "FDA provided 'legitimate reasons[s]' for deciding that enoxaparin should be treated differently than the drugs cited by [the company]") (quoting Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 28 (D.D.C. 1997)). FDA followed the law, including the FDCA and the agency's regulations, in reaching its decisions. Although Prevor argues that "FDA's decision represents disparate treatment of similar products," Pl.'s Mot. Summ. J. at 23, it is Prevor that evaluates DSW by a self-created analysis not supported by the law.[12] Prevor's attempt to drive the outcome by altering the analysis should be rejected.

Prevor cites to several CDRH-regulated products - RSDL, medical maggots, Dermacyn Wound Cleanser, and NasalCEASE - to support its contention that FDA departed from the agency's long-standing interpretation of "device" when evaluating DSW. Pl.'s Mot. Summ. J.

[12] Because Prevor's evaluation of its own product is deficient, any product comparison that Prevor makes would be flawed.

at 19-24. None of these products advances Prevor's argument. The disparity is among the products, not FDA's statutory construction. See A.R. 787-789. For example, the device constituents in RSDL and in DSW do not function similarly to achieve their therapeutic effects. As explained by OSMP, RSDL's device constituent provides the product's PMOA. Because the PMOA of DSW is provided by a drug constituent, FDA was required to assign DSW to CDER, not CDRH.

In the course of describing how FDA allegedly modified its interpretation of "primary intended purposes," Prevor claims that two FDA reviewers opined that "RSDL, and its predecessor product, M291, should have been classified and would be classified differently . . . today." Pl.'s Mot. Summ. J. at 20. But, neither RSDL's nor M291's classification was at issue in the CDRH reviewer's internal memo. Prevor has conflated the classification of a product (e.g., as a drug, device, or drug-device combination product) with the PMOA analysis for combination products. The CDRH reviewer was describing the PMOA analyses of RSDL and M291, not its product classification under the FDCA. A.R. 057-058. Moreover, the OCP technical review memo raised a hypothetical issue regarding M291, which was unrelated to FDA's interpretation of "primary intended purposes." See A.R. 049.

Additionally, medical maggots may be an eye-catching reference, but it is misguided to analogize them to DSW. The differences between the products are many. Medical maggots are animate and DSW is not. Medical maggots are intended to debride wounds (A.R. 098), whereas DSW is intended to prevent and mitigate chemical burns. Medical maggots act by rasping and tearing necrotic tissue, id., but DSW is intended to remove and neutralize chemicals spilled on

the skin. Although the behavior of medical maggots may not be fully understood, see id., there is no doubt that DSW's solution acts chemically and physically to achieve its therapeutic effects.

Furthermore, Dermacyn Wound Cleanser is indicated for use to cleanse, debride, and remove foreign material from wounds "through the physical force of the solution sprayed on the wound." A.R. 102-103. There does not appear to be any claim or intended use involving chemical action.[13]

Prevor also argues that DSW should be regulated in the same way as heparin catheter lock flush solutions and Silvaklenz.[14] Pl.'s Mot. Summ. J. at 32-34. The solutions in these products are combination products. A.R. 788. DSW's solution is not a combination product. This distinction alone reveals that Prevor's product examples are not relevant to FDA's determinations here.

5. Prevor's Scattershot Approach Fails to Identify Errors in FDA's Decision-Making

Prevor's numerous complaints about FDA's decision-making process are, at best, unpersuasive. See Pl.'s Mot. Summ. J. at 36-41. Only one is worth highlighting. Prevor finds

---

[13] NasalCEASE is not part of the administrative record. It was not cleared for marketing as a device until after OCP ruled on Prevor's RFD. See Pl.'s Mot. Summ. J. at 21.

[14] In making this argument, Prevor contends, "Even FDA's internal review acknowledges that DSW is similar to these other products, determined to be devices outright, or combination products with a device PMOA." Pl.'s Mot. Summ. J. at 33. In support, Prevor cites to the OCP reviewer's internal memo. Id. The cited pages discussed Dermacyn Wound Cleanser, Silvaklenz, RSDL, medical maggots, and M291, and contained the following conclusions: (a) "the primary intended purposes for the Dermacyn and Diphoterine-containing products are different"; (b) "this intended use [of Silvaklenz] would differ from the Diphoterine product"; (c) "this reviewer does not recommend that this [medical maggots] decision be used as a basis for the classification and jurisdictional assignment of [DSW]"; and (d) "this reviewer cannot conclusively comment regarding M291's similarity to RSDL or the DSW solution." In short, there was no acknowledgment of DSW's similarities to any of the products.

fault with OCP and OSMP's failure to reconcile their "opposite finding" with the recommendation made by the CDER reviewer for assigning DSW to a lead agency center. Pl.'s Mot. Summ. J. 37. The reason for the lack of reconciliation was the absence of anything to reconcile. CDER's product jurisdiction officer recommended to OCP that DSW "is a combination product that belongs in CDER." A.R. 060. That is precisely the same decision reached by OCP and OSMP.

Prevor noted that one reviewer agreed that DSW's PMOA was the physical removal of the acid or base. Pl.'s Mot. Summ. J. at 36-37. However, Prevor failed to distinguish between CDER's first-line reviewer and the center's decision-maker, its product jurisdiction officer, who is responsible for responding to an OCP request to recommend an assignment of a combination product. Here, although a first-line reviewer in CDER recommended to that center's product jurisdiction officer that CDRH take the lead in regulating DSW, the product jurisdiction officer, i.e., the decision-maker for the center, disagreed. The CDER product jurisdiction officer recommended to OCP that DSW be assigned to CDER. A.R. 060-061. That recommendation is consistent with the recommendation of CDRH's product jurisdiction officer as well as the OCP staff's technical review of Prevor's request for designation. A.R. 051-052, 053, 060.

V. Conclusion

FDA's determination that DSW is a drug-device combination product to be regulated by CDER is fully supported by the record in this case. In stark contrast, Prevor applied an incorrect interpretation of the device definition, relied on an inappropriate analysis to assign DSW to a lead agency center, and thereby arrived at the wrong conclusion. For these and all of the

foregoing reasons, this court should grant the government's motion for summary judgment and deny Prevor's motion for summary judgment.

Respectfully submitted,

RONALD C. MACHEN JR.
United States Attorney

TONY WEST
Assistant Attorney General
Civil Division

MAAME EWUSI-MENSAH FRIMPONG
Acting Deputy Assistant Attorney General

MICHAEL S. BLUME
Director

MARK L. JOSEPHS
Assistant Director

By: /s/ JOHN W. M. CLAUD
JOHN W. M. CLAUD
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
202-307-5747

Dated: December 22, 2011

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel
Food and Drug Division
Office of General Counsel
U.S. Dep't of Health and Human Services

ELIZABETH H. DICKINSON
Acting Chief Counsel

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation

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

ATTACHMENT

Glossary of Relevant Abbreviations

DSW - Diphoterine Skin Wash

CDER - Center for Drug Evaluation and Research

CDRH - Center for Devices and Radiological Health

FDCA - Federal Food, Drug, and Cosmetic Act

OCP - Office of Combination Products

OSMP - Office of Special Medical Programs

PMOA- Primary Mode of Action (21 U.S.C. § 353(g)(1); 21 C.F.R. § 3.2(m))

RFD - Request for Designation (21 C.F.R. § 3.7)

RSDL - Reactive Skin Decontamination Lotion