UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASS'N OF AM. PHYSICIANS & SURGEONS, INC., et al.,
Plaintiffs,

v.

FOOD & DRUG ADMIN., et al.,
Defendants,

and

DURAMED PHARMACEUTICALS, INC.,
Intervenor-Defendant.

Civil Action No. 07-0668 (JDB)

MEMORANDUM OPINION

In August 2006, the United States Food and Drug Administration ("FDA") approved Barr Pharmaceuticals, Inc.'s ("Barr") supplemental new drug application ("SNDA") for Plan B, an emergency contraceptive drug currently marketed by Duramed Research, Inc. ("Duramed"), a wholly owned subsidiary of Barr. The approval of the SNDA allowed Plan B to be marketed without a prescription to consumers age 18 and over and retained the prescription requirement for consumers under the age of 18. Plaintiffs Association of American Physicians & Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), Family Research Council ("FRC"), and Safe Drugs for Women ("SDW") bring this action challenging the FDA's approval of the SNDA and the procedures the FDA employed as being in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Administrative Procedures Act ("APA"). Plaintiffs assert claims against the FDA and its Commissioner, Dr. Andrew C. von Eschenbach, in his official capacity and in his individual capacity (the "federal defendants").

Currently before the Court are motions to dismiss filed by the federal defendants and Duramed, the intervenor-defendant, pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject-matter jurisdiction and pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. Upon careful consideration of the motions, the parties' memoranda, the arguments advanced at the motions hearing held on February 15, 2008, the applicable law, and the entire record, and for the reasons set forth below, the Court will grant the federal defendants' and Duramed's motions to dismiss.

BACKGROUND

I. Statutory and Regulatory Background

Under the FDCA, a drug's sponsor must first submit a new drug application ("NDA") to the FDA for approval before a new drug may be marketed in the United States. 21 U.S.C. § 355(a)-(b). The new drug application must contain a wealth of information such as investigative reports demonstrating the drug's safety and effectiveness, a statement of the drug's components, and specimens of proposed labeling for the packaging of the new drug. Id. § 355(b)(1). The FDA must reject a NDA if several conditions are not met. For example, a NDA will be rejected if inadequate testing was conducted, if the testing data show that a "drug is unsafe for use under such conditions [as prescribed, recommended, or suggested in the proposed labeling]," if there is "a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," or if "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." Id. § 355(d).

Some NDAs are approved with the restriction that the drug may be dispensed by prescription only ("Rx-only"). The Rx-only requirement applies when, "because of [the drug's] toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." Id. § 353(b)(1)(A). A Rx-only drug may later be approved for over-the-counter ("OTC") use when the agency finds that the prescription requirements "are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and [the agency] finds that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.200(b); see also 21 U.S.C. § 353(b)(3), 355(c)-(d).

II. Factual Background

On July 28, 1999, the FDA approved a new drug application submitted by Women's Capital Corp. ("WCC") -- now a wholly owned subsidiary of Duramed -- for prescription Plan B. Am. Compl. ¶ 66. In April 2003, WCC submitted a supplemental new drug application seeking to make Plan B available to all consumers over the counter in what is commonly referred to as a Rx-to-OTC switch. Id. ¶ 68. Several months later, Barr acquired WCC, and thereafter Barr and Duramed continued to advocate for OTC approval of Plan B. Id.

After the Center for Drug Evaluation and Research ("CDER") completed its review of the application, the Acting Director issued a "not approval" letter to Duramed. Id. ¶ 69. The CDER cited concerns about the ability of consumers under the age of 16 to use Plan B without professional supervision by a practitioner licensed to administer the drug. Id. The Acting Director suggested that Duramed could: (1) provide data to demonstrate that consumers under the

age of 16 could safely use Plan B as an over-the-counter drug, or (2) seek over-the-counter status solely for consumers over the age of 16. Id.

Duramed elected to pursue the second option and submitted an amended SNDA seeking to retain the prescription requirement for consumers under the age of 16 and seeking an OTC switch only for consumers age 16 and older. When the FDA responded on August 26, 2005, the Commissioner informed Duramed that CDER found Plan B to be safe for over-the-counter use for consumers age 17 and older. Id. ¶ 70. Nevertheless, the FDA did not approve this distribution scheme. Instead, the FDA indicated that it would first have to resolve whether it could approve the distribution of the same pharmaceutical drug to different populations for OTC and Rx use, and if so, how to proceed with such an approval. Id. ¶ 70. The FDA thereafter published an Advance Notice of Proposed Rulemaking ("ANPR") seeking public comment on these issues. Id. ¶ 71 (citing 70 Fed. Reg. 52,050 (Sept. 1, 2005)). After receiving approximately 47,000 comments, the FDA determined that it was unnecessary to proceed by rulemaking. Id. ¶¶ 72, 74.

In August 2006, Duramed submitted yet another amended SNDA -- this time requesting OTC availability of Plan B for consumers age 18 and older. Fed. Defs.' Exs. 9 & 10. In its application, Duramed proposed a single package for Plan B to be used for the Rx and OTC populations. Duramed also indicated that it would only make Plan B available for purchase at licensed pharmacies and health care clinics and would direct pharmacies to keep the product "behind the counter." Fed. Defs.' Exs. 9 at 4-7 & 10 at 36-46; see also Am. Compl. ¶ 78. In August 2006, the FDA approved this amended SNDA. Am. Compl. ¶ 78. As approved by the FDA, Plan B's current labeling contains the legend "Rx only for age 17 and younger." Id. ¶ 79.

III. Procedural Background

Almost eight months later, on April 12, 2007, plaintiffs AAPS, CWA, FRC and SDW filed this action seeking to vacate the FDA's August 2006 SNDA approval decision for Plan B. Plaintiff AAPS is a not-for-profit membership organization of physicians who practice in all areas and specialities. Id. ¶ 3. Plaintiff CWA is a nonprofit corporation that represents approximately 500,000 men and women across the nation advancing their interests before Congress and other governmental bodies. Id. ¶ 4. Plaintiff FRC is a nonprofit corporation dedicated to "valuing human life from conception until natural death and upholding the institution of the family, including parental oversight of children's health care." Id. ¶ 5. And Plaintiff SDW is a nonprofit corporation whose members consist of physicians and pharmacists. Id. ¶ 6.

After the federal defendants and Duramed filed motions to dismiss arguing that plaintiffs lacked standing to sue, plaintiffs filed an amended complaint in an attempt to cure any pleading deficiencies. In their amended complaint, plaintiffs allege: (1) that the FDA's approval was unlawful because the SNDA failed to demonstrate that Plan B was safe for OTC use by consumers age 18 and older, (2) that the FDA's approval violated the FDCA by allowing Plan B to be marketed as both a prescription and an OTC drug, (3) that the FDA's age-based decision violated the FDCA, (4) that the FDA has created a "third class" of drugs in violation of the FDCA, (5) that the FDA violated the APA by failing to conduct a rulemaking, (6) that the FDA violated the FDCA by failing to conduct a rulemaking, (7) that the federal defendants were improperly influenced by political pressure, and (8) that the FDA is not authorized to impose administrative exhaustion requirements.

In response to the amended complaint, the federal defendants and Duramed (collectively the defendants) again filed motions to dismiss arguing that plaintiffs' allegations are insufficient to establish the elements of standing and that plaintiffs have failed to exhaust their administrative remedies. Defendants also argue that plaintiffs' theories underlying Counts II, IV, V, and VI are incorrect as a matter of law. Finding the jurisdictional argument of defendants persuasive, the Court will grant the motions to dismiss.

STANDARD OF REVIEW

"[I]n passing on a motion to dismiss, whether on the ground of lack of jurisdiction over the subject matter or for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974); see Leatherman v. Tarrant Cty. Narcotics and Coordination Unit, 507 U.S. 163, 164 (1993); Phillips v. Bureau of Prisons, 591 F.2d 966, 968 (D.C. Cir. 1979). Therefore, the factual allegations must be presumed true, and plaintiff must be given every favorable inference that may be drawn from the allegations of fact. Scheuer, 416 U.S. at 236; Sparrow v. United Air Lines, Inc., 216 F.3d 1111, 1113 (D.C. Cir. 2000). However, the Court need not accept as true "a legal conclusion couched as a factual allegation," nor inferences that are unsupported by the facts set out in the complaint. Trudeau v. Federal Trade Comm'n, 456 F.3d 178, 193 (D.C. Cir. 2006) (quoting Papasan v. Allain, 478 U.S. 265, 286 (1986)).

Under Rule 12(b)(1), the parties seeking to invoke the jurisdiction of a federal court -- plaintiffs here -- bear the burden of establishing that the court has jurisdiction. See US Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000); see also Grand Lodge of Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13 (D.D.C. 2001) (a court has an "affirmative

obligation to ensure that it is acting within the scope of its jurisdictional authority."); Pitney Bowes, Inc. v. United States Postal Serv., 27 F. Supp. 2d 15, 19 (D.D.C. 1998). "'[P]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Grand Lodge, 185 F. Supp. 2d at 13-14 (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1987)). Additionally, a court may consider material other than the allegations of the complaint in determining whether it has jurisdiction to hear the case, as long as it still accepts the factual allegations in the complaint as true. See Jerome Stevens Pharmaceuticals, Inc. v. FDA, 402 F.3d 1249, 1253-54 (D.C. Cir. 2005); EEOC v. St. Francis Xavier Parochial Sch., 117 F.3d 621, 624-25 n.3 (D.C. Cir. 1997); Herbert v. Nat'l Acad. of Scis., 974 F.2d 192, 197 (D.C. Cir.1992).

In reviewing a motion to dismiss pursuant to Rule 12(b)(6), the Court is mindful that all that the Federal Rules of Civil Procedure require of a complaint is that it contain "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Bell Atl. Corp. v. Twombly, 550 U.S. ___, 127 S. Ct. 1955, 1964 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)); accord Erickson v. Pardus, 551 U.S. ___, 127 S. Ct. 2197, 2200 (2007) (per curiam). "A Rule 12(b)(6) motion tests the legal sufficiency of a complaint." Browning v. Clinton, 292 F.3d 235, 242 (D.C. Cir. 2002). Thus, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Bell Atl. Corp., 127 S. Ct. at 1965 (citations omitted).

DISCUSSION

The defendants' motions raise threshold justiciability issues before specifically addressing Counts II, IV, V, and VI of the amended complaint. A matter may be rendered nonjusticiable for a variety of reasons, frequently blending constitutional and prudential considerations. See Flast v. Cohen, 392 U.S. 83, 95 (1968) ("no justiciable controversy is presented . . . when the question sought to be adjudicated has been mooted by subsequent developments, and when there is no standing to maintain the action"). In this case, the absence of standing deprives this Court of jurisdiction to grant the relief plaintiffs request, and the failure to exhaust administrative remedies further renders the action nonjusticiable.

I. Standing

The authority of the judiciary is limited by Article III of the Constitution to the "resolution of 'cases' and 'controversies.'" Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 471 (1982). This principle of limited judicial authority is, in part, manifest by the requirement that a litigant must have standing to bring an action, and thus be "entitled to have the court decide the merits of the dispute or of particular issues." Warth v. Seldin, 422 U.S. 490, 498 (1975). The standing inquiry asks "whether the plaintiff has 'alleged such a personal stake in the outcome of the controversy' as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his behalf." Id. (quoting Baker v. Carr, 369 U.S. 186, 204 (1962)).

Standing is a requirement, therefore, that every litigant -- whether an individual or an organization -- in a federal lawsuit must satisfy. It is a burden borne by the plaintiff and each element of standing "must be supported in the same way as any other matter on which the plaintiff

bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992). At a minimum, a plaintiff must establish three elements: (1) that he "suffered an 'injury in fact' -- an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not 'conjectural' or 'hypothetical' . . . ," (2) "there must be a causal connection between the injury and the conduct complained of," and (3) "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." Id. at 560 (citations and quotations omitted).

Furthermore, to challenge agency action, plaintiffs must satisfy the additional requirement of prudential standing. Litigants have prudential standing to sue if they fall within the zone of interests protected or regulated by the statute at issue, here the FDCA. See Bennett v. Spear, 520 U.S. 154, 162 (1997). The zone-of-interests test is not, however, meant to be especially onerous. Rather, it "is intended to 'exclude only those whose interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.'" Nat'l Ass'n of Home Builders v. United States Army Corps of Eng'rs, 417 F.3d 1272, 1287 (D.C. Cir. 2005) (quoting Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 399 (1987)).

As plaintiffs here are all organizations, they may assert standing in their own capacity by satisfying the above requirements. Additionally, an organization may establish representational standing if: (1) at least one of its members has standing to sue in his or her own right; (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit.

American Library Ass'n v. FCC, 401 F.3d 489, 492 (D.C. Cir. 2005); see also Hunt v. Washington State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977).

In their amended complaint, plaintiffs seek to establish representational standing based upon six alleged injuries that flow from the FDA's approval of the August 2006 SNDA. First, plaintiffs argue that their members were deprived of their FDCA-granted right to information. Am. Compl. ¶ 17. Second, they argue that consumers age 18 and older are now subject to an increased risk of harm from foregoing doctor visits, which are no longer necessary to obtain Plan B. Id. ¶ 18. Third, plaintiffs assert that their member physicians now "face increased competition from pharmacists . . . in the contraceptive area of their medical practice" and that physicians will lose money from lost office visits since consumers age 18 and older can now obtain Plan B OTC. Id. ¶¶ 19-20. Fourth, plaintiffs contend that their member physicians have third-party standing to assert the rights of their patients. Id. ¶¶ 21-22. Fifth, they assert that the FDA's approval of the SNDA subjects their member pharmacists to an increased risk of liability, additional administrative burdens, and compelled speech in violation of conscience-based objections. Id. ¶¶ 23-26. And sixth, plaintiffs assert -- on their own behalf and on behalf of their members -- that the FDA's failure to engage in rulemakings deprived them of procedures to which they were entitled. Id. ¶ 27.

Defendants challenge plaintiffs' ability to satisfy all three requirements for constitutional standing. They argue that plaintiffs' injuries are not concrete and particularized, and actual or imminent. Rather, defendants contend that plaintiffs' injuries are hypothetical and based upon speculation. To support their argument defendants correctly point out that plaintiffs fail to allege that using Plan B causes harm directly and fail to identify a single individual who has been

harmed by Plan B's OTC availability. Defendants also argue that the alleged injuries are not fairly traceable to the FDA's approval decision. Instead, defendants assert that plaintiffs base their standing on purely conjectural claims caused by the independent decisions and actions of third parties. Defendants further contend that plaintiffs are not seeking an appropriate remedy that would redress their alleged injuries. And finally, defendants argue that the FDCA does not grant plaintiffs a right to information to support informational standing.

"For each claim, if constitutional and prudential standing can be shown for at least one plaintiff, [the court] need not consider the standing of the other plaintiffs to raise that claim." Mountain States Legal Foundation v. Glickman, 92 F.3d 1228, 1232 (D.C. Cir. 1996) (citing Watt v. Energy Action Educational Foundation, 454 U.S. 151, 160 (1981)); Village of Arlington Heights v. Metro. Housing Devel. Corp., 429 U.S. 252, 264 n.9 (1977). Relying on this precedent at the motions hearing, plaintiffs' counsel indicated that plaintiffs were no longer putting forward standing claims for CWA and FRC and would instead base their standing upon AAPS and SDW suing on behalf of physicians and pharmacists.[1] See Preliminary Tr., Feb. 15, 2008, at 46-48, 70-

[1]Plaintiffs' decision was motivated by recent D.C. Circuit authority, see Public Citizen, Inc. v. National Highway Traffic Safety Admin. ("NHTSA II"), 2008 WL 169778 (D.C. Cir. Jan. 22, 2008), and Public Citizen, Inc. v. National Highway Traffic Safety Admin. ("NHTSA I"), 489 F.3d 1279 (D.C. Cir. 2007), and this Court's inquiry as to whether CWA and FRC are membership organizations. In at least two cases, the D.C. Circuit has determined that organizations lacked standing for failing to satisfy this requirement. See Fund Democracy, LLC v. SEC, 278 F.3d 21, 25-26 (D.C. Cir. 2002) (no standing for one-person business purporting to represent tens of millions of individual investors, where there was no evidence of any alleged supporter who funded or approved of organization's activities); Am. Legal Found. v. FCC, 808 F.2d 84, 90 (D.C. Cir.1987) (no standing for organization that did not represent a "discrete, stable group of persons with a definable set of common interests" and organization's supporters did not appear to play any role in selecting its leadership or guiding or funding its activities). "In determining whether an organization that has no members in the traditional sense may nonetheless assert associational standing, the question is whether the organization is the functional equivalent of a traditional membership organization." Fund Democracy, LLC, 278 F.3d at 25. Neither the amended

71. In response, defendants further contend that physicians and pharmacists lack prudential standing because their alleged grievances do not fall within the zone of interests protected by the FDCA.[2]

A. Informational Injury

"Informational standing arises 'only in very specific statutory contexts' where a statutory provision has 'explicitly created a right to information.'" American Farm Bureau v. EPA, 121 F. Supp. 2d 84, 97 (D.D.C. 2000) (quoting Animal Legal Defense Fund, Inc. v. Espy, 23 F.3d 496, 502 (D.C. Cir. 1994)). For example, in Havens Realty Corp. v. Coleman, 455 U.S. 363, 373 (1982), the Supreme Court determined that the combination of two provisions of the Fair Housing Act of 1968 supported informational standing. First, the Act made it unlawful for entities "[t]o represent to any person because of race, color, religion, sex, or national origin that any dwelling is

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complaint nor the opposition are very forthcoming with information to aid the Court in this analysis.

Furthermore, the amended complaint fails to allege any organizational purpose for CWA. To establish representational standing, an organization must allege that the interests it seeks to protect through the litigation are germane to its purpose. Although the germaneness prong is undemanding, only requiring "that an organization's litigation goals be pertinent to its special expertise and the grounds that bring its membership together," CWA may also not meet this requirement based upon its complete failure to explain what grounds bring its membership together -- if indeed it has members. Humane Soc. of the U.S. v. Hodel, 840 F.2d 45, 56 (D.C. Cir. 1988).

[2]Plaintiffs submitted a notice of supplemental authority on February 12, 2008, attaching an unpublished opinion in Ass'n of Am. Physicians & Surgeons v. FDA, No. 00-2898 (D.D.C. 2001), where the court determined that AAPS had standing to challenge the FDA's regulations regarding pediatric testing of new drugs. In the notice, plaintiffs argued that AAPS must necessarily have standing in the instant action based upon mutual collateral estoppel. At the motions hearing, however, plaintiffs appeared to concede that this was an erroneous assertion. See Preliminary Tr., Feb. 15, 2008, at 51. Plaintiffs' interpretation of the collateral estoppel doctrine would allow AAPS to sue the FDA in any situation merely because one district court previously determined that AAPS had standing in a single case.

not available for inspection, sale, or rental when such dwelling is in fact so available, 42 U.S.C. § 3604(d)." Id. at 373. And second, this prohibition was made enforceable through an explicit cause of action in § 812(a) of the Act, 42 U.S.C. § 3612(a). Id. Based upon these provisions, Congress had "thus conferred on all 'persons' a legal right to truthful information about available housing." Id.

The statutory framework here is unlike the one at issue in Havens Realty. Plaintiffs cannot demonstrate that Congress intended to confer upon them a legal right to the information they seek. Moreover, plaintiffs cite no authority for the proposition that the FDCA can support informational standing. Defendants, on the other hand, point to American Farm Bureau v. EPA, 121 F. Supp. 2d 84 (D.D.C. 2000), in which the court rejected the plaintiff's informational standing theory under the FDCA. Although the court was addressing a provision that is not cited by plaintiffs here, that court clearly stated that the "FFDCA does not confer a broad, legally enforceable right to information." Id. at 99.

Plaintiffs' theory is overly expansive and unsupported by the case law they cite. Public Citizen v. FTC, 869 F.2d 1541, 1543 (D.C. Cir. 1989), is the most helpful case for plaintiffs, but it too is distinguishable. There, the Smokeless Tobacco Act provided that: "It shall be unlawful for any manufacturer . . . of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this chapter, one of the labels required by paragraph (1)." Id. at 1543 (quoting 15 U.S.C. § 4402(a)(2)). The FTC then promulgated a regulation that exempted "utilitarian objects for personal use" from the warning requirement. Id. at 1544. Because the statute required warnings on all forms of

advertising other than outdoor billboards, the court determined that plaintiffs had standing to challenge the deprivation "of valuable warnings to which Congress allegedly determined they were entitled." Id. at 1547.

In focusing on the plaintiffs' injuries in Public Citizen, the D.C. Circuit noted that the injury "resides not in what might be called the 'speculative' chance that members will in fact become snuffdippers, or that their health will suffer as a result; rather, it arises from the more certain charge that they are being deprived of information and warnings that will be of substantial value to them and to which they are legally entitled." Id. at 1546. Here, in contrast, plaintiffs do not put forth sufficient factual allegations to indicate that they have been deprived of information to which they are legally entitled. Instead, plaintiffs focus on the more speculative chance that their members may be misled based upon the efficacy information that is contained on Plan B's labeling.[3]

Moreover, even if plaintiffs were able to establish that the FDCA could support informational standing and that their members had suffered a concrete and particularized injury, plaintiffs would still fail to satisfy the redressability prong for constitutional standing. In Public Citizen, the court noted that the plaintiffs' injury regarding the deprivation of warnings would be

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[3]At the motions hearing on February 15, 2008, plaintiffs vaguely indicated that they could establish informational standing based upon recent amendments to the Pediatric Research Equity Act. Plaintiffs' amended complaint, however, asserts no claims based upon these amendments, and plaintiffs failed to raise this argument in their opposition or in their two supplemental filings. Furthermore, plaintiffs did not point the Court to any specific provision that would support their contention. Upon the Court's review of 21 U.S.C. § 355c, it appears that the amendments apply to drug applications submitted on or after September 27, 2007, and to already approved applications if the Secretary so orders in his discretion. Here, Duramed's SNDA was submitted more than a year before these amendments took effect, and there is no allegation that the Secretary has ordered Duramed to submit such assessments for its already approved application.

redressed by a favorable court decision because a successful challenge would "result in the FTC requiring the inclusion of warnings on utilitarian items." Id. at 1547. Here, plaintiffs have not demonstrated that the remedy they seek would likely redress the labeling deficiencies they allege regarding Plan B. If the SNDA is vacated, Plan B would remain available by prescription, with presumably the same information on the label regarding its efficacy. It would simply no longer be available OTC. As defendants point out, the FDA provides an avenue for plaintiffs to achieve the labeling changes they desire. Plaintiffs may file a citizen petition under 21 C.F.R. §§ 10.25, 10.30. The Court therefore concludes that plaintiffs' alleged informational injuries are inadequate to support constitutional standing here.

B. Increased Risk of Harm

In their amended complaint, plaintiffs argue that the FDA's approval of the SNDA will lead to an increased risk of harm for consumers of Plan B who are age 18 and older. According to plaintiffs, these consumers "will fail to receive critical health-care protection as the result of foregoing doctor visits previously required for contraceptives." Am. Compl. ¶ 18. Although the D.C. Circuit "has not closed the door to all increased-risk-of-harm cases," the door remains only slightly ajar. NHTSA II, 2008 WL 169778, at *3 (quoting NHTSA I, 489 F.3d at 1295). In such cases, the D.C. Circuit has only "allowed standing when there was at least both (i) a substantially increased risk of harm and (ii) a substantial probability of harm with that increase taken into account." Id. (quoting NHTSA I, 489 F.3d at 1295, and citing Natural Resources Defense Council v. EPA, 464 F.3d 1, 6-7 (D.C. Cir. 2006), and Mountain States Legal Found., 92 F.3d at 1234-35). In applying this standard, the courts keep in mind that "'the constitutional requirement of imminence as articulated by the Supreme Court' requires 'a very strict understanding of what

increases in risk and overall risk levels' will support injury in fact." Id. at *6 (quoting NHTSA I, 489 F.3d at 1296). Based upon these D.C. Circuit precedents, plaintiffs have now conceded that they have not demonstrated sufficient injury in fact to support their public safety standing argument. See Preliminary Tr., Feb. 15, 2008, at 46-48, 70-71.

C. Physicians' Competitive and Economic Injuries

Plaintiffs allege that their member physicians will now suffer competitive and economic injuries because "[b]oth existing patients and new patients who otherwise would have come to such physicians to obtain a contraceptive prescription instead now can obtain Plan B directly from pharmacists, without first visiting a physician's office to obtain a prescription." Am. Compl. ¶ 20. Plaintiffs allege that physicians will lose the non-nominal financial benefit from these office visits.

Although Plan B was available OTC for one full year before plaintiffs filed their amended complaint, they fail to allege that any physician has in fact suffered a loss of revenue in this manner. The declaration attached to plaintiffs' opposition also fails to allege any concrete injury in fact. Instead, plaintiffs' claims are purely hypothetical and speculative. Moreover, plaintiffs have not demonstrated that such alleged injuries would be causally connected to the FDA's approval of the SNDA. Causation is substantially more difficult to prove when it "depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." Lujan, 504 U.S. at 562 (quoting ASARCO Inc. v. Kadish, 490 U.S. 605, 615 (1989)). Here, any loss of revenue suffered by physicians would be attributable to the independent choices of women to

forego office visits. Nothing in the FDA's approval of the SNDA forbids a woman from first consulting with her doctor before obtaining Plan B, even if it is sold OTC.

In any event, plaintiffs cannot prevail with this standing argument because their alleged competitive and economic injuries do not fall within the zone of interests of the FDCA for prudential standing. The zone-of-interests test excludes "those whose interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.'" Nat'l Ass'n of Home Builders, 417 F.3d at 1287 (quoting Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 399 (1987)). The relevant zone of interests is determined "not by reference to the overall purpose of the Act in question . . . , but by reference to the particular provision" at issue in the litigation. Grand Council of Crees (of Quebec) v. FERC, 198 F.3d 950, 956 (D.C. Cir. 2000) (quoting Bennett, 520 U.S. at 175-76).

Here, this litigation revolves around the Rx-to-OTC provisions of the FDCA. In enacting these provisions, Congress had "a two-fold objective: (1) to protect the public from abuses in the sale of potent prescription drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." Sen. Report No. 82-946 (1951), 1951 U.S.C.C.A.N. 2454, 2454. Noticeably absent from these objectives is any intent to increase or maintain the revenue physicians generate from office visits when patients seek prescription drugs. In fact, as defendants note, physicians' "alleged interest in generating fees from unnecessary doctor visits is antithetical to the purposes of the FDCA." Fed. Defs.' Mem. at 15. These provisions were enacted to provide consumers with easier access to drugs that do not first require consultation

with a physician, not to maintain the constraints on access inherent in requiring physician visits. Thus, physicians lack prudential standing under the FDCA.[4]

D. Physicians' Third-Party Standing on Behalf of their Patients

A "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." Warth, 422 U.S. at 499. Despite this general prohibition, plaintiffs AAPS and SDW allege that their physician members have third-party standing to sue on behalf of their patients. To establish third-party standing, a litigant must satisfy three requirements: "The litigant must have suffered an 'injury in fact,' thus giving him or her a 'sufficiently concrete interest' in the outcome of the issue in dispute; the litigant must

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[4]Plaintiffs argue that even if they are not intended beneficiaries within the zone of interests they are at least suitable challengers. Courts may deem certain parties to be suitable challengers "if their interests are sufficiently congruent with those of the intended beneficiaries [such] that the litigants are not 'more likely to frustrate than to further the statutory objectives.'" First Nat. Bank and Trust Co. v. National Credit Union Admin., 988 F.2d 1272, 1275 (D.C. Cir. 1993) (quoting Clarke v. Sec. Indus. Ass'n, 479 U.S. at 397). As discussed above, however, it is evident that the asserted interest of physicians to increase their revenue from office visits is incongruent with the interests of consumers to obtain drugs that are safe for over-the-counter use without unnecessary expenses.

Plaintiffs' argument that they may evade the prudential standing analysis altogether by labeling the FDA's approval of the SNDA ultra vires is equally unavailing. "[A]n ultra vires claim rests on 'the officer's lack of delegated power. A claim of error in the exercise of that power is therefore not sufficient.'" Pennhurst State School & Hosp. v. Halderman, 465 U.S. 89, 102 (1984) (quoting Larson v. Domestic & Foreign Commerce Corp., 337 U.S. 682, 690 (1949)). Here, it is undisputed that the FDA has the authority to approve Rx-to-OTC switches. Plaintiffs simply argue that the FDA made substantive and procedural errors in approving the SNDA for the Rx-to-OTC switch of Plan B. In any event, plaintiffs have failed to satisfy the Article III requirements for standing, so the prudential analysis is not outcome determinative.

have a close relation to the third party; and there must exist some hindrance to the third party's ability to protect his or her own interests." Powers v. Ohio, 499 U.S. 400, 411 (1991) (citing Singleton v. Wulff, 428 U.S. 106 (1976)) (internal citations omitted).

As discussed above, neither AAPS, SDW, nor their members have alleged a redressable concrete injury sufficient to establish standing on their own behalf. Hence, plaintiffs cannot rely on the legal rights and interests of potential or current patients to substitute for their own lack of standing. Additionally, plaintiffs have not established that a genuine hindrance prevents patients from protecting their own interests. In fact, some consumers were already before this Court in this lawsuit since CWA alleged representational standing on behalf of "women and parents of girls who would consider taking (or having their minor girl take) Plan B." Am. Compl. ¶ 15. In any event, plaintiffs' allegations indicate that the alleged rights of their patients may not truly be at stake because, according to plaintiffs, even if patients "recognize Plan B's various limitations, their typical response is simply to refrain prospectively from purchasing Plan B or relying on its label information." Id. ¶ 22. Plaintiffs' concession further undermines their argument that a genuine obstacle is preventing patients from asserting their own rights. For these reasons, plaintiffs have not established third-party standing based on their member physicians' patients.

E. Pharmacists' Injuries

Plaintiffs assert that the FDA's approval of the SNDA subjects their member pharmacists to an increased risk of liability, additional administrative burdens, and compelled speech in violation of conscience-based objections. Am. Compl. ¶¶ 23-26. As to the claims of increased risk of liability, plaintiffs assert that their member pharmacists: (1) may be prosecuted for selling a misbranded drug and (2) may face "expanded legal liability from the removal of the otherwise-

applicable protections afforded to pharmacists who dispense an Rx drug pursuant to a physician's prescription." Id. ¶¶ 23-24. Plaintiffs' allegations are purely speculative, however. No pharmacist has alleged that he has been prosecuted or subjected to liability in either manner.

Indeed, it is a stretch to say that a pharmacist could be prosecuted for selling a misbranded drug when there has been no determination that Plan B is misbranded. "When plaintiffs 'do not claim that they have ever been threatened with prosecution, that a prosecution is likely, or even that a prosecution is remotely possible,' they do not allege a dispute susceptible to resolution by a federal court." Babbitt v. United Farm Workers Nat. Union, 442 U.S. 289, 299 (1979) (quoting Younger v. Harris, 401 U.S. 37, 42 (1971)). Because the pharmacists' fears of prosecution here "are imaginary or speculative, [they] are not to be accepted as appropriate plaintiffs.'" Babbitt, 442 U.S. at 298 (quoting Younger, 401 U.S. at 42).

Plaintiffs' second argument regarding an increased risk of liability fares no better. They explain that pharmacists are often immune from malpractice suits when they correctly fill a physician's prescription. Pls.' Opp. at 11. But while Plan B is now available OTC for consumers age 18 and older, that does not prevent pharmacists from correctly dispensing Plan B to limit their exposure to any form of legal liability. Again, no facts to support an assertion of increased risk have been presented by plaintiffs. Their claim that their risk of legal liability has increased, then, is speculative and lacking in any causal connection to the FDA's approval of the SNDA.

Plaintiffs next allege that pharmacists face added administrative burdens in OTC dispensing of Plan B. Neither the amended complaint, the opposition, nor the exhibits, however, specify what these alleged administrative burdens are. Although the manner and degree of evidence required to support the elements of standing vary at the successive stages of litigation, on

a motion to dismiss a plaintiff must still provide sufficient factual allegations to support the alleged injury. Lujan, 504 U.S. at 561. Here, plaintiffs' pleadings are devoid of such factual allegations. Logically, it seems as though the administrative burdens of pharmacists would have decreased after the FDA approved the SNDA. To sell Plan B over the counter to the correct age population, a clerk would have to check a consumer's identification. Prior to the SNDA, when Plan B was prescription only, pharmacists would presumably have to receive, verify, file, and maintain all consumers' prescriptions.

Finally, the Court need not linger long on plaintiffs' compelled speech argument. The FDA's approval of the SNDA does not force or require any pharmacist to sell Plan B -- whether or not he or she has conscience-based objections to the drug itself. Moreover, pharmacists dispense Plan B whether by Rx or OTC, and hence approval of the SNDA has not really impacted their speech. Thus, plaintiffs cannot show that this alleged injury is fairly traceable to the challenged action of the defendants.

F. Procedural Injury

Plaintiffs assert procedural injury on their own behalf and on behalf of their members as their last basis for standing. "The mere violation of a procedural requirement [however] does not permit any and all persons to sue to enforce the requirement." Florida Audubon Soc. v. Bentsen, 94 F.3d 658, 664 (D.C. Cir. 1996). The D.C. Circuit has held that, to demonstrate injury sufficient for standing in a procedural rights case, the plaintiff must show that the omission or insufficiency of the procedure has "demonstrably increased [the] risk of serious . . . harm" that "actually threatens the plaintiff's particular interests." Id. at 667; see also Commonwealth of Massachusetts v. EPA, 415 F.3d 50, 60 (D.C. Cir. 2005) (Sentelle, J., concurring) (applying

"demonstrably increased risk" standard in cases outside of NEPA). A plaintiff may not establish standing based on a procedural injury unless the plaintiff alleges that the procedural violation "has resulted in an invasion of their concrete and particularized interest." Center for Law and Educ. v. Department of Educ., 396 F.3d 1152, 1159 (D.C. Cir. 2005). Moreover, on the causation prong, "a procedural-rights plaintiff must show . . . that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest." Florida Audubon Soc'y, 94 F.3d at 664-65. Thus, "the primary focus of the standing inquiry is not the imminence or redressability of the injury to the plaintiff, but whether a plaintiff who has suffered personal and particularized injury has sued a defendant who has caused that injury." Id. at 664.

Here, plaintiffs argue that they were denied the opportunity to participate in notice and comment rulemakings for the Rx-to-OTC switch for Plan B. Plaintiffs have not, however, identified a legally protected interest that has been infringed by these alleged procedural shortcomings. Plaintiffs advance no allegations of injury suffered by the organizations themselves, and as explained above, plaintiffs have not demonstrated a concrete injury in relation to their members. Moreover, the Supreme Court "has never freed a plaintiff alleging a procedural violation from showing a causal connection between the government action that supposedly required the disregarded procedure and some reasonably increased risk of injury to its particularized interest," and here, plaintiffs have not demonstrated a sufficient causal connection between a procedural violation and an alleged injury. Id.; California Forestry Assoc. v. Thomas, 936 F.Supp. 13, 19-20 (D.D.C. 1996). The allegations in plaintiffs' amended complaint, then, are insufficient to support procedural standing.

II. Exhaustion

Plaintiffs have failed to establish standing because they lack a sufficient personal stake in the outcome of the litigation so as to warrant the invocation of federal-court jurisdiction. Nonetheless, defendants present a second argument for the dismissal of the amended complaint, namely plaintiffs' failure to exhaust their administrative remedies. This threshold issue presents a more difficult question, but the Court ultimately finds defendants' argument persuasive.

It is undisputed that the FDA's approval of a SNDA is a relatively closed process. The FDA does however provide an opportunity for interested parties, such as plaintiffs, to participate in the regulatory process through the submission of a citizen petition. See 21 C.F.R. § 10.25(a) (providing that "[a]n interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action"); see also 21 C.F.R. § 10.30. In fact, the FDA's regulations under the FDCA require that a request that the "Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act." Id. § 10.45(b). Although plaintiffs claim to have submitted comments during the agency's general ANPR, they in no way participated in the SNDA approval process for Plan B.[5] Thus, the agency

[5]To the extent that plaintiffs are now arguing that their participation in the ANPR process satisfied FDA exhaustion requirements, the Court has no evidence to support this contention. Plaintiffs failed to attach any such evidence to their opposition, failed to present any such evidence at the motions hearing, and failed to submit any such evidence after the motions hearing despite two supplemental notices, which indicated plaintiffs' intent to do so. Because plaintiffs were on notice of defendants' exhaustion argument and had ample time to oppose the motions to dismiss, the Court will take the record as it currently stands.

was never provided with an opportunity to address plaintiffs' requests that the FDA take certain actions, such as amending the labeling of Plan B.

Nevertheless, plaintiffs present two arguments to support their contention that the amended complaint should not be dismissed for failure to exhaust administrative remedies. First, plaintiffs rely on Darby v. Cisneros, 509 U.S. 137, 147 (1993), in which the Supreme Court held that federal courts cannot require plaintiffs seeking judicial review under the APA to exhaust optional administrative remedies. The administrative remedy here is mandated by regulation, however, and Darby explicitly stated that "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." Id. at 153 (emphasis added).

Plaintiffs' second argument is more appealing, yet it cannot stand when the regulations are read in context together. Plaintiffs rely on 21 C.F.R. § 10.45(e) divorced from the FDA's other regulatory provisions. Section 10.45(e) states that: "An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court." Plaintiffs argue that they are "interested persons" and that the approval of the SNDA is a final agency action. Thus, they argue that § 10.45(e) allows them to proceed to court without first presenting their arguments to the agency.

Although plaintiffs' interpretation of the regulatory requirements has some surface appeal, it would allow "'interested parties' to bypass the administrative remedies" and "would undermine the entire regulatory process." Garlic v. FDA, 783 F. Supp. 4, 5 (D.D.C. 1992). Courts would

constantly have to address new arguments that were never presented to the agency. The purpose of the exhaustion doctrine is "the avoidance of premature interruption of the administrative process . . . to let the agency develop the necessary factual background upon which decisions should be based." McKart v. United States, 395 U.S. 185, 193-194 (1969). "And since agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise." Id. at 194. As defendants assert here, "no administrative record of the FDA's consideration of [plaintiffs'] arguments exists . . . because plaintiffs have never submitted those challenges to the FDA." Duramed's Reply at 22.

When § 10.45(e) is read together with other applicable provisions, such as § 10.45(b), a different picture is presented that is more in keeping with the rationale underlying the exhaustion doctrine. As noted above, § 10.45(b) requires that an interested person's "request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a)." Together with § 10.45(e), "these provisions require a party to present its request to the agency and to receive a final decision on that request before seeking judicial review, but do not require the party to pursue an administrative appeal of that final decision before filing its lawsuit." Fed. Defs.' Mem. at 32, n.22. The party would need a final agency decision on its challenge to the approval of a SNDA, but consistent with § 10.45(e) would not then have to seek "reconsideration or . . . a stay" before requesting judicial review. The agency would thereby have an opportunity to apply its expertise, and courts would have developed administrative records to review.

The agency's regulations are most relevant for this challenge to the approval of a SNDA, but it is notable that the FDCA itself also "provides for administrative review of orders . . . denying New Drug Applications." Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 30 (D.D.C. 1997) (citing 21 U.S.C. § 355(h)) (emphasis added). Under the statute, "[a]n appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval" of a new drug application by filing a petition "in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit." 21 U.S.C. § 355(h). The ability to appeal the denial is extended only to the applicant itself, not to interested parties such as plaintiffs. Additionally, the court of appeals will not entertain any arguments and objections to the FDA's determination "unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do." Id. If consideration of additional evidence is required, the court of appeals may require the applicant to present the additional evidence to the FDA so that the agency may have the opportunity to modify its order. Id. The citizen petition process is thus parallel to this statutory process that allows the agency to first address any objection to its action prior to judicial review. Indeed, it would be odd if the applicant were so limited in challenging the denial of its SNDA, but, as plaintiffs would have it, other "interested parties" could proceed right to federal court with a challenge to the grant of a SNDA not first raised with the FDA.

Defendants cite two opinions from this district which have discussed the exhaustion issue and have dismissed complaints as non-justiciable for failure to exhaust administrative remedies under the FDCA. In Garlic v. FDA, 783 F. Supp. 4 (D.D.C. 1992), the plaintiffs challenged the

FDA's failure to approve a specific drug as a treatment for Alzheimer's Disease. The court dismissed the plaintiffs' complaint because they had "not exhausted their administrative remedies by filing a 'citizen's petition' as required by 21 C.F.R. § 10.25(b)." Id. at 4. The court noted that if it were to entertain the complaint without an appropriate administrative record addressing plaintiffs' arguments, the court would involve itself in matters "beyond both [its] expertise and its jurisdiction." Id. And in National Gay Rights Advocates v. Dep't of Health & Human Serv., 1988 WL 43833 (D.D.C. Apr. 26, 1988), the court also dismissed the plaintiffs' complaint for failure to exhaust administrative remedies. There, plaintiffs alleged "that the FDA and NIH have engaged in improper conduct with respect to the development and approval of drugs used to treat and cure AIDS." Id. at *1. In dismissing the complaint, the court noted that it "should not interfere with the agency's decisionmaking by denying FDA and NIH the first opportunity to decide what action is warranted." Id. at *2.

The federal defendants recognize, however, that courts "have the discretion to decline to apply regulatory exhaustion in certain circumstances, such as where the plaintiff demonstrates that it would be irreparably harmed by delay, that the agency is not empowered to grant effective relief, or that the exhaustion effort would be futile." Fed. Defs.' Response to Pls.' Notice of Supp. Authority at 2 (citing McCarthy v. Madigan, 503 U.S. 140, 144-49 (1992)); see, e.g., Bracco Diagnostics, Inc., 963 F. Supp. at 31 ("Lacking a specific congressional mandate as to the plaintiffs' administrative remedy and finding plaintiffs faced with irreparable harm, the Court concludes that exhaustion of administrative remedies in the circumstances of this case is not required."). In fact, the federal defendants asset that they often do not raise the exhaustion defense when such circumstances are present. As an example of such a situation, defendants point to

Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 130 (D.D.C. 1997), aff'd in part and rev'd in part, 140 F.3d 1060 (D.C. Cir. 1998), where a pharmaceutical company sued to compel the FDA to withdraw or change the effective date of its approval of a competitor's abbreviated new drug application.

Here, there are no circumstances that should lead this Court to decline to require exhaustion. Plaintiffs would not be irreparably harmed by delay. The agency is in fact empowered to grant the relief plaintiffs seek. And there is no indication that the administrative process would be futile because the agency has not yet had the opportunity to address all of plaintiffs' arguments. On the other hand, the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed. Because the plaintiffs have failed to exhaust the administrative process mandated by regulation, dismissal of plaintiffs' amended complaint is warranted.

CONCLUSION

For the foregoing reasons, the Court concludes that plaintiffs have not demonstrated their standing to assert the claims in the amended complaint. Hence, the Court has no jurisdiction to entertain the amended complaint. Plaintiffs have also failed to exhaust their administrative remedies and have therefore failed to state a claim upon which relief can be granted. Accordingly, the Court will grant defendants' motions to dismiss. A separate order accompanies this memorandum opinion.

/s/
JOHN D. BATES
United States District Judge

Dated: March 4, 2008