UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 07-668 (JDB)
FOOD & DRUG ADMINISTRATION, *et. al.*,	)	
Defendants,	)	
and	)	
DURAMED PHARMACEUTICALS, INC.	)	
Intervenor-Defendant.	)	

DEFENDANTS' MOTION TO DISMISS

Defendants, the United States Food and Drug Administration, Andrew C. von Eschenbach, Commissioner of Food and Drugs, and the United States of America, respectfully move to dismiss this case pursuant to Rules 12(b)(1) and (6) of the Federal Rules of Civil Procedure. In short, plaintiffs lack standing to bring any claim, and the claims are otherwise without merit. The grounds for this motion are set forth fully in the accompanying Defendants' Memorandum of Points and Authorities in Support of Motion to Dismiss. The exhibits may be found at Docket Entry No. 14.

Undersigned counsel did not consult with counsel for plaintiffs because this is a potentially dispositive motion. See Local Civil Rule 7(m).

Dated: September 21, 2007.

Respectfully submitted,

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DURAMED PHARMACEUTICALS, INC.	)	
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DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS

In July 1999, the United States Food and Drug Administration ("FDA") approved a new drug application ("NDA") for prescription marketing of "Plan B," an emergency contraceptive drug product currently marketed by Duramed Research, Inc. ("Duramed"), a wholly owned subsidiary of Barr Pharmaceuticals, Inc ("Barr"). In August 2006, FDA approved Barr's supplemental new drug application ("SNDA"), which requested permission to market Plan B without a prescription ("non-℞" or "OTC") to consumers age 18 and over while remaining prescription only ("℞-only") for consumers under the age of 18. Plaintiffs, four organizations concerned about health care and reproductive issues, seek to vacate FDA's August 2006 decision so that Plan B will again be available only by prescription for all age groups. They allege that FDA's SNDA approval decision and the procedures FDA employed in making it violated the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Administrative Procedure Act ("APA").

The FDCA provides authority to FDA to approve drug applications when the data submitted to the agency show, *inter alia*, the drug product is safe and effective for use under the conditions described in the proposed labeling. 21 U.S.C. § 355(c), (d). It further provides that a drug product should be dispensed by prescription if it is safe for use only under the supervision of a licensed healthcare professional. 21 U.S.C. § 353(b)(1). FDA applied these standards and its expertise to determine that the data Barr submitted to the agency demonstrated that Plan B is safe for use, without the supervision of a licensed healthcare professional, by women 18 years of age and older, and therefore the option of obtaining Plan B non-Rx should be available to consumers in that age group.

FDA's approval decision means only that adult women have the option of purchasing Plan B without a prescription from pharmacies that stock it. Nothing in the FDCA either compels a woman to forego the opportunity to consult with a health care professional before purchasing Plan B, or compels any pharmacist to stock and sell Plan B. Because the non-Rx purchase of Plan B is a voluntary act, plaintiffs essentially are seeking to eliminate the availability of Plan B non-Rx as an option for women who want to purchase it from pharmacies that want to sell it – individuals and entities that are likely not members of plaintiffs' organizations and not before this Court.

Plaintiffs, however, cannot establish standing to seek such relief. Although plaintiffs have alleged numerous standing theories on behalf of women, physicians, and pharmacists within their membership, and the organizations themselves, their allegations are insufficient to establish the elements of standing on behalf of any of these subgroups or individuals. Similarly, plaintiffs have failed to allege a cause of action within the Court's jurisdiction. There is no right under the FDCA or APA for members of the general public to challenge or participate in a drug application

proceeding. Plaintiffs have also failed to exhaust administrative remedies as required by FDA regulations, and, contrary to the allegations in Count VIII, that exhaustion requirement is lawful.

Even if plaintiffs were properly before the Court, the claims themselves lack merit. In Counts II and IV, plaintiffs claim that FDA was barred under the FDCA from approving the SNDA application because 1) FDA was not permitted to approve Rx and OTC versions of the drug to be marketed simultaneously, and 2) FDA was not permitted to approve a "third class" of drug. In Counts V and VI, plaintiffs claim that FDA was required, under the APA and FDCA respectively, to undertake rulemaking to approve Barr's SNDA. Plaintiffs' theories underlying these claims are wrong as a matter of law, and these claims should be dismissed. With regard to the remainder of the Complaint, Counts I, III, and VII fail because FDA's actions were consistent with the governing statutory provisions, well-supported, soundly reasoned, and procedurally proper.[1/]

Finally, plaintiffs have improperly named the Commissioner of Food and Drugs, Andrew C. von Eschenbach, in his individual capacity. *See* Am. Compl. ¶¶ 7, 34. Because plaintiffs do not seek any relief against the Commissioner in his individual capacity, that aspect of the complaint should be dismissed.

BACKGROUND

I. Statutory and Regulatory Scheme

Under the FDCA, a new drug product cannot be marketed in the United States until the drug's sponsor submits an NDA to FDA and obtains the agency's approval. 21 U.S.C. § 355(a), (b).

[1/] The government does not further address these claims in this motion because it has not produced the administrative record in this case. Portions of the record contain Barr's confidential commercial information, and thus their production should be subject to a protective order to be negotiated among the parties. Moreover, production of the record before the Court determines that subject matter exists would be unwarranted.

FDA approval of an NDA requires the sponsor to establish to FDA's satisfaction that the drug is safe and effective for its intended uses. Thus, FDA is required to reject an NDA if, *inter alia*, the data fail to show that the product is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," and "that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d).

A drug product will be approved for prescription only dispensing when, "because of its 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 licensed health care professional. 21 U.S.C. § 353(b)(1). Some drugs are initially approved as Rx-only, but are later "switched" to OTC status when the agency finds that dispensing the drug by prescription is

> 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. Statement of Facts

On July 28, 1999, FDA approved an NDA for Plan B. *See* Am. Compl. ¶ 66. Plan B contains levonorgestrel, a synthetic progestin. *See id*. ¶ 58. It is an "emergency contraceptive," to be taken "as soon as possible . . .after unprotected sex." *See* Def. Ex. 1.[2/]

[2/] When subject matter jurisdiction is challenged under Fed. R. Civ. P. 12(b)(1), the Court may consider evidentiary material outside of the pleadings without treating the motion as one for summary judgment. *Land v. Dollar*, 330 U.S. 731, 735 n.4 (1947); *Coalition for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003); *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197-98 (D.C. Cir. 1992); *Bonterra America, Inc. v. Bestmann*, 907 F. Supp. 4, 5 n.1 (D.D.C. 1995). In addition, the exhibits hereto were filed on the public record in another lawsuit regarding Plan B filed in the U.S. District Court for the Eastern District of New York, *Tummino v. von Eschenbach*, No. 05-CV-366 (ERK/VVP) docket no. 248, and many are available on FDA's website: http://www.fda.gov/cder/drug/infopage/planB/default.htm.

The sponsor of Plan B began discussing a potential Rx-OTC switch application with FDA in 2001. Early in that process, the drug sponsor explained that "in most pharmacies, the OTC version of Plan B may eventually be kept behind-the-counter in part out of respect for community values and in part to avoid losses through shoplifting." Def. Ex. 2 at 1. In April 2003, the sponsor of Plan B submitted an SNDA to FDA requesting the Rx-OTC switch. Am. Compl. ¶ 68.

On December 16, 2003, FDA convened a one-day joint public meeting of its Non-Prescription Drugs Advisory Committee and its Advisory Committee for Reproductive Health Drugs–two panels of medical and scientific experts–to make recommendations to agency decision-makers as to the safety and effectiveness of nonprescription use of Plan B. *See* 68 Fed. Reg. 66113 (Nov. 25, 2003). The joint advisory committee voted to recommend to FDA that Plan B be allowed to be sold without a prescription. Def. Ex. 3.

After FDA communicated to Barr some concerns about the adequacy of the data on OTC use by younger women, Barr submitted to FDA, on March 11, 2004, a proposal to market Plan B as a non-Rx product only to consumers age 16 and over, while maintaining the Rx status for younger women. Def. Ex. 4. Under this proposal, both Rx and non-Rx Plan B would be marketed in the same package and would be distributed from behind pharmacy counters with proof of age required. *Id*.

By letter dated May 6, 2004, Dr. Steven Galson, then the Acting Director (now the Director) of FDA's Center for Drug Evaluation and Research ("CDER"), informed Barr that the SNDA was "not approvable at this time" because Barr had not provided adequate data to show that Plan B was safe for OTC use by young adolescent women, and because Barr's March 11, 2004, proposal seeking to limit the OTC switch to women 16 and older was too preliminary to permit FDA review. Def. Ex. 5 at 1-2; Am. Compl. ¶ 69. Dr. Galson advised Barr that, before its SNDA for Plan B could be

approved, Barr would have to either: (1) submit data demonstrating that the product could be used safely by girls under 16 years of age without professional supervision by a licensed practitioner, or (2) provide information in support of its dual-marketing proposal. Def. Ex. 5 at 2; Am. Compl. ¶ 69.

Barr opted for the second of the two choices, and, on July 21, 2004, Barr filed an amended SNDA, formally proposing to market Plan B as a non-℞ product for consumers age 16 and older and as an ℞ product for girls under age 16. Def. Ex. 6 at 1; Am. Compl. ¶ 70. On August 26, 2005, Dr. Galson completed an internal memorandum regarding Barr's amended SNDA. Def. Ex. 6. He concluded that the studies and other data Barr provided with its SNDA showed that consumers age 17 and older could use Plan B safely and effectively for emergency contraception in a non-℞ setting. Def. Ex. 6 at 2, 12. Specifically, he concluded:

> Plan B provided pursuant to a prescription has previously been proven to be effective for emergency contraception and had a well-documented safety profile. In a label comprehension study and in an actual use study submitted with the supplemental NDA, the sponsor has demonstrated that women of childbearing-potential age 17 and older can use Plan B safely and effectively for emergency contraception in the OTC setting. The data submitted by Barr demonstrate that Plan B is safe and effective without the supervision of a practitioner licensed by law for women age 17 and older in self-medication as directed in the proposed labeling.
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> * * *
>
> In conclusion, I find that as a matter of science, Barr's July 21, 2004 proposal to switch Plan B to OTC status meets the statutory standards for approval of an NDA supplement set forth in 21 U.S.C. 355(d) for women age 17 and older.

Id. Dr. Galson also concluded, however, that Barr's data were insufficient to demonstrate that the population under age 17 could use this product safely without a prescription. Def. Ex. 6 at 4, 12.

Also on August 26, 2005, then-FDA Commissioner Dr. Lester Crawford wrote to Barr and, while he acknowledged and adopted Dr. Galson's findings regarding the scientific data, he explained that the agency had not yet resolved all outstanding issues regarding the application. Def. Ex. 7; Am.

Compl. ¶ 70. On the same day, FDA announced its intention to issue an advance notice of proposed rulemaking ("the ANPRM") soliciting public comment on whether rulemaking was necessary to resolve and clarify certain Rx-only to non-Rx switch issues. 70 Fed. Reg. 52050 (Sept. 1, 2005); Am. Compl. ¶ 71.

After FDA reviewed the comments on the ANPRM, FDA informed Barr, on July 31, 2006, that it was proceeding with further evaluation of its SNDA without first engaging in rulemaking, and invited Barr to further discuss its application. Def. Ex. 8. In August 2006, Barr filed an amended SNDA which sought non-prescription availability of Plan B only for consumers age 18 and older. *See* Def. Exs. 9 & 10. In its application, Barr explained that, given that Plan B will have both Rx-only and non-Rx labeling, Barr would only distribute the product to licensed pharmacies and health care clinics and would not make it available for purchase at convenience stores, gas stations, and the like. Similarly, because it would be inappropriate to place a product with Rx labeling on open store shelves, it would direct the pharmacies that retail the drug to keep it "behind the counter." *See* Def. Ex. 9 at 4-7, & Def. Ex. 10 at 36-46.

On August 24, 2006, FDA approved the amended SNDA, thereby permitting non-Rx access to Plan B for consumers 18 years of age and older. Def. Ex. 10; Am. Compl. ¶ 78. In separate memoranda, then Acting Commissioner von Eschenbach and CDER Director Dr. Galson reaffirmed Dr. Galson's earlier conclusions that Plan B may be safely used without a prescription by women age 17 and older, but that the data were insufficient to demonstrate safety in non-Rx use by children under age 17. Def. Exs. 9 & 11. Dr. von Eschenbach found that age 18 (rather than 17) was the appropriate age cut-off to "help ensure safe and effective use of the product." Def. Ex. 11. Dr.

Galson, in a separate memorandum to the file, concurred in that conclusion and otherwise found that all requirements for approval of the amended SNDA were met. Def. Ex. 9.

III. The Amended Complaint

Plaintiffs, Association of American Physicians and Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), Family Research Council, and Safe Drugs for Women, seek to vacate FDA's August 2006 SNDA approval decision. In their amended complaint, they raise the following claims: 1) FDA's approval decision was unlawful because the data in the SNDA were insufficient to show safety and effectiveness for adult OTC use; 2) FDA's approval decision violated the FDCA in allowing Plan B to be marketed as both ℞ and non-℞; 3) FDA's age-based decision violated the FDCA; 4) FDA violated the FDCA in creating a "third class" of drug; 5) FDA violated the APA by not engaging in rulemaking ; 6) FDA violated the FDCA by not engaging in rulemaking; 7) FDA was improperly influenced by political pressure; and 8) FDA's exhaustion requirement is unlawful. Am. Compl. ¶¶ 96-136. They seek only declaratory and injunctive relief. *Id*. ¶ 137.

ARGUMENT

Plaintiffs bear the burden of establishing subject matter jurisdiction, including the elements of standing. *Northeastern Fla. Chapter, Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 663 (1993); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Standing cannot be "inferred argumentatively from averments in the pleading," but, rather, plaintiffs "must allege facts essential to show jurisdiction." *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (citations omitted). Where, as here, "the parties invoking federal jurisdiction are not 'the object of the government action or inaction' they challenge,"

"standing is 'substantially more difficult to establish.'" *Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1289 (D.C. Cir. 2007) (quoting *Lujan*, 504 U.S. at 562).

On the merits, the "[f]actual allegations must be enough to raise a right to relief above the speculative level," and that a plaintiff must make "a 'showing,' rather than a blanket assertion, of entitlement to relief.'" *Bell Atlantic Corp. v. Twombly*, — U.S. —, 127 S. Ct. 1955, 1965 & n.3 (2007). Thus, "the complaint must set forth sufficient information to suggest that there exists *some* recognized legal theory upon which relief can be granted." *Gregg v. Barnett*, 771 F.2d 539, 547 (D.C. Cir. 1985) (emphasis in original and citation omitted).

I. PLAINTIFFS LACK STANDING TO CHALLENGE FDA'S AUGUST 2006 SNDA APPROVAL DECISION.

In their amended complaint, plaintiffs have revised their standing allegations in response to the earlier motions, but none of their numerous standing claims are legally sustainable.

A. Requirements for Standing.

To invoke federal subject matter jurisdiction, a party must establish as a threshold matter the existence of a "justiciable controversy" with the defendant – one that is "definite and concrete, touching the legal relations of parties having adverse legal interests." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). To establish constitutional standing, a plaintiff must satisfy three requirements: First, a plaintiff must show an "injury-in-fact," which is defined as "an invasion of a legally protected interest that is (a) concrete and particularized [meaning that the injury must affect the plaintiff in a personal and individual way], and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 & n.1(citations and quotation marks omitted); *see also Warth v. Seldin*, 422 U.S. 490, 508 (1975). Second, the plaintiff must

demonstrate a "causal connection between the injury and the conduct complained of." *Lujan*, 504 U.S. at 560. This means that the injury has to be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result[] [of] the independent action of some third party not before the court." *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976). Third, the injury in question must be redressable by the relief sought by the complaint. This means that it "must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan*, 504 U.S. at 561 (quoting *Simon*, 426 U.S. at 38); *see also Allen v. Wright*, 468 U.S. 737, 750-51 (1984).

In addition to the constitutional requirements for standing, the Court must consider whether any prudential limitations should restrain it from exercising its judicial power. *See Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91, 99 (1979). Among the prudential limitations identified by the Supreme Court are the doctrines that (1) a plaintiff cannot rest his claim to standing on the rights and interests of third-parties, *Lujan*, 504 U.S. at 562; *Simon*, 426 U.S. at 44-45; *Warth*, 422 U.S. at 499; (2) the plaintiff must be in the zone of interests meant to be protected by the statute in question, in order to have standing to challenge the government's application of the statute, *Office of Workers' Compensation Programs v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 127 (1995); and (3) a plaintiff cannot rely on a generalized grievance shared by a large segment of the populace, *Gladstone Realtors*, 441 U.S. at 100; *Warth*, 422 U.S. at 499. *See also McKinney v. United States Dep't of Treasury*, 799 F.2d 1544, 1550-51 (Fed. Cir. 1986).

There are two ways for an organization to establish standing to bring suit. First, to have organizational standing, plaintiff organizations must satisfy the same standing requirements that

apply to individuals: injury-in-fact, that is fairly traceable to the challenged action, and that will likely be redressed by a favorable decision. *See American Legal Found. v. FCC*, 808 F.2d 84, 89 (D.C. Cir. 1987) (citing *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378-79 (1982)). However, "[c]onflict between a defendant's conduct and an organization's mission is alone insufficient to establish Article III standing." *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005) (citations and quotation marks omitted). Second, to have representational standing, an organizational plaintiff must demonstrate that its "members would otherwise have standing to sue in their own right, [that] the interests at stake are germane to the organization's purpose, and [that] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *See Friends of the Earth, Inc. v. Laidlaw Envt'l Servs., Inc.*, 528 U.S. 167, 180-81 (2000).[3/]

B. Plaintiffs Cannot Establish Standing Based on Alleged Injuries from Plan B's Labeling.

Plaintiffs' first standing theory is based on their contention that the Plan B labeling contains false and misleading information. *See* Am. Compl. ¶¶ 17, 85-89. They allege that members of plaintiffs' organizations who are "prospective consumers of Plan B," physicians and their patients, pharmacists and their customers, have a "FFDCA-granted right" to certain drug labeling information. *Id.* ¶ 17. Plaintiffs claim that these individuals "will not receive the

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[3/] *Accord American Legal Found. v. FCC*, 808 F.2d 84, 89 (D.C. Cir. 1987) (quoting *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977)). Thus, at least one member must be able to personally demonstrate all of the elements of Article III standing: (1) an injury-in-fact; (2) traceable to the challenged action of the defendant; and (3) redressable by a favorable decision. *Friends of the Earth, Inc.*, 528 U.S. at 180-81; *see also Hunt*, 432 U.S. at 343; *Warth*, 422 U.S. at 511. *See also Colwell v. HHS*, No. 04CV1748 BTM (RBB), 2005 U.S. Dist. LEXIS 6556, at *21-22 (S.D. Cal. Mar. 7, 2005) (holding that AAPS lacked representational standing to sue on behalf of physicians who had themselves failed to establish standing to challenge an HHS guidance document relating to providing interpretive services).

FFDCA-required warning label statements and run the risk of using Plan B without an appreciation of the limitations of Plan B's safety and efficacy and its comparability with analogous drugs." *Id.*

This theory is untenable for several reasons. First, this standing theory consists of two mutually exclusive propositions: (1) a member currently believes that the Plan B labeling is false and misleading; and (2) she risks a future injury from her continued reliance on the accuracy and completeness of the Plan B labeling (even though she has already determined that the labeling is misleading). No individual member could establish standing on this theory because it would be impossible simultaneously to attest to those contradictory propositions.[4/] Because plaintiffs cannot demonstrate that, if a member herself attempted to make these allegations, she would be able to establish "standing to sue in [her] own right," *see Friends of the Earth*, 528 U.S. at 180-81, the organizational plaintiffs cannot rely on these allegations to establish representational standing.[5/]

Second, plaintiffs' allegation that they "run the risk of using Plan B without an appreciation of the limitations in Plan B's safety and efficacy and its comparability with analogous drugs," Am. Compl. ¶ 17, is far too speculative to constitute injury-in-fact. Plaintiffs do not allege that they have suffered injuries in the past; only that they are "at risk" of some

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[4/] These allegations are also highly implausible. Although the plaintiff organizations have been quite vocal in their positions on emergency contraception and other reproductive issues, plaintiffs maintain here that their members are unaware of those positions. Indeed, on its website, plaintiff CWA describes its view that the Plan B's labeling is misleading. *See* http://www.cwfa.org/articledisplay.asp?id=12788&department=MEDIA&categoryid=life.

[5/] Plaintiffs also attempt to allege this injury on behalf of individuals who are not members of plaintiff organizations, namely patients of physicians and customers of pharmacists. However, a plaintiff cannot rest a claim to standing on the rights and interests of third-parties. *Lujan*, 504 U.S. at 562. Although a party *with standing* may sometimes assert the substantive claims of a third party, plaintiffs have failed to satisfy the stringent requirements for that exception. *See infra* at 19-21.

unspecified injury in the future. "[H]ypothesized 'increased risk' has never been deemed sufficient 'injury.'" *Ctr. for Law & Educ.*, 396 F.3d at 1161.

Third, plaintiffs are incorrect in suggesting that the FDCA "grant[s]" them a "right" to labeling information that alone provides a basis for standing. *See* Am. Compl. ¶ 17. "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 Def. Fund, Inc. v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994)).[6/] The FDCA, however, "does *not* confer a broad, legally enforceable right to information," and therefore does *not* "creat[e] a basis for informational standing." *American Farm Bureau*, 121 F. Supp. 2d at 99 (emphasis added).[7/]

C. Plaintiffs Cannot Establish Standing Based on Women Members' Option of Foregoing a Doctor's Appointment.

Plaintiffs next assert that members who are potential Plan B consumers will be injured in purchasing Plan B without a prescription because they will "forego[] the office visit associated with obtaining contraceptive prescriptions." Am. Compl. ¶ 18.[8/] After FDA's SNDA approval

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[6/] *See also Havens Realty Corp. v. Coleman*, 455 U.S. 363, 373 (1982) ("The actual or threatened injury required by Art. III may exist solely by virtue of statutes creating legal rights, the invasion of which creates standing. Section 804(d) [of the Fair Housing Act], which . . . established an enforceable right to truthful information concerning the availability of housing, is such an enactment.")(citations and quotation marks omitted); *Public Citizen v. FTC*, 869 F.2d 1541, 1546, 1549 (D.C. Cir. 1989).

[7/] The statutes and regulations governing the labeling of drug products require the manufacturer to submit proposed labeling to FDA for approval, but nothing in the statute provides the public with a right of action for disclosure against FDA. *See* 21 U.S.C. § 355(b)(1)(F) & (d)(7); 21 C.F.R. part 201; 21 C.F.R. § 314.50(e)(2)(ii) & (l)(i); 21 C.F.R. § 314.125(b)(6).

[8/] Plaintiffs allege that, if these women are required to see a physician, they will receive (1) "direct medical advice about [Plan B's] drug interactions . . . and medical screening for medical contraindications;" (2) "counseling about the various health risks associated with sexual activity;" and (3) "medical screening (*e.g.* pap smear; breast-cancer screening; mammograms for women over 40; sexually transmitted diseases; cervical cancer; human papilloma virus prevention; cholesterol, blood pressure, and other cardiovascular screening)." Am. Compl. ¶ 18.

decision, adult women now have the *option* of purchasing Plan B without first obtaining a prescription. However, there is nothing in FDA's OTC approval decision that prevents these women from choosing to speak to a medical doctor before purchasing Plan B. Any woman who is concerned about her health care or who desires counseling can consult a physician for those purposes, just as she might choose to consult a physician regarding other conditions for which there are OTC treatments, such as arthritis or acid reflux. And there is certainly no reason to conclude that women will be hampered in their ability to obtain cholesterol and blood pressure screening by having the option of purchasing Plan B without a prescription. Thus, plaintiffs cannot show that the alleged injury of foregoing medical screening and consultation is "fairly traceable" to FDA's Plan B decision and "not the result of the independent action" of women making health care choices. *See Ctr. for Law & Educ.*, 396 F.3d at 1161 (citing *Lujan*, 504 U.S. at 560).[9/]

D. Plaintiffs Cannot Establish Standing Based on Member Physicians' Competitive and Economic Injuries.

Plaintiffs allege that member physicians will suffer economic injury in the form of increased competition from pharmacists because potential patients can now obtain Plan B directly from pharmacies and will not need to seek a medical appointment to obtain Plan B. Am. Compl. ¶¶ 19-20. As a result of those skipped appointments, physicians will lose the "non-nominal financial benefit" from the amount charged for such visits. *Id.* ¶ 20.

[9/] Because girls under 18 must obtain a prescription to purchase Plan B, as before FDA's August 2006 SNDA approval decision, these girls will presumably obtain the same health care, drug-labeling information, and counseling that they received before the August 2006 decision. Plaintiffs allege incorrectly (as a matter of law) that the FDCA "does not prohibit someone 18 or older from purchasing Plan B and giving it to someone younger than 18." Am Compl. ¶ 95. FDA considers the act of providing Plan B to a minor under such circumstances to be dispensing a prescription drug without a prescription in violation of 21 U.S.C. § 353(b)(1).

It is well established that "the economic injury which results from lawful competition cannot, in and of itself, confer standing on the injured business." *Hardin v. Kentucky Utilities Co.*, 390 U.S. 1, 5-6 (1968). Plaintiffs must also be within the "zone of interests" to be protected or regulated by the statute to establish standing. *Investment Co. Inst. v. FDIC*, 815 F.2d 1540, 1543-44 (D.C. Cir. 1987). The D.C. Circuit has explained that "the essential inquiry" for zone of interests test is "whether Congress intended for a particular class of plaintiffs to be relied upon to challenge agency disregard of the law." *Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855, 870-71 (D.C. Cir. 2001) (citations omitted). The test "will deny standing" when "plaintiff's 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." *Id.*

Here, physicians fail the zone of interest test because their alleged interest in generating fees from unnecessary doctor visits is antithetical to the purposes of the FDCA. The core objective of the FDCA's drug regulation provisions is to promote public health by regulating drugs for safety and effectiveness.[10/] Specifically, the provisions governing Rx-OTC switches, 21 U.S.C. § 353(b)(1); *see also* 21 U.S.C. § 355; 21 C.F.R. § 310.200(b),[11/] provide that a drug may

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[10/] *See* 21 U.S.C. § 393(b)(2) (defining the FDA's mission as including "ensuring that . . . drugs are safe and effective"); *United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (The FDCA's "overriding purpose is to protect the public health."); *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 50 (D.D.C. 2003) ("There is no question that the legislative intent behind enactment of the original FDCA was to protect the public from unsafe drugs.") (citing *United States v. Undetermined Quantities of Veterinary Drug*, 22 F.3d 235, 238 (10th Cir. 1994)), *aff'd*, 353 F.3d 947 (D.C. Cir. 2004), *cert. denied*, 543 U.S. 925 (2004); *In re Establishment Inspection of Wedgewood Vill. Pharmacy, Inc.*, 270 F. Supp. 2d 525, 549 (D.N.J. 2003) ("Congress intended that the FDCA . . . allow the FDA broad enforcement powers to fulfill its mandate that it protect the public from unsafe medication."), *aff'd sub nom. Wedgewood Village Pharmacy, Inc. v. United States*, 421 F.3d 263 (3d Cir. 2005).

[11/] "A court must conduct the 'zone of interests' inquiry with 'reference to the particular provision of law upon which the plaintiff relies.'" *See Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 55 (D.D.C. 2003) (quoting *Grand Council of the Crees (of Quebec) v. FERC*, 198 F.3d 950, 956 (D.C. Cir. 2000)), *aff'd*, 362 F.3d 817 (D.C. Cir. 2004).

be made available OTC (which generally provides quicker and easier access for consumers) when the agency finds that the product is safe and effective for use without medical supervision. Congress' "two-fold objective" in enacting the provisions governing the Rx/OTC distinction was: "(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." S. Rep. No. 82-946, at 1 (1951).

Nothing in Congress' "two-fold objective" relates to the competitive and financial interests of doctors. Even under the relaxed standard that there be "some indicia" that the litigant was intended to be "protected, benefitted or regulated by the statute under which suit is brought," *Liquid Carbonic Indus. Corp. v. FERC*, 29 F.3d 697, 704 (D.C. Cir. 1994), plaintiffs cannot establish that Congress intended to protect or benefit physicians' earnings from medical appointments made to obtain drug prescriptions. Accordingly, a physician's economic interest is not an intended beneficiary of the Rx-OTC provisions of the statute.

Indeed, in their opposition to Barr's intervention motion (in which plaintiffs defended their competitive injury standing claim), plaintiffs did not assert that the alleged competitive injury falls within the zone of interests of the FDCA. *See* Opposition to Motion to Intervene, Doc. # 19 (July 13, 2007) ("Pl. Int. Opp.") at 5-9. Instead, plaintiffs relied on a different alleged interest: that physicians should be considered "intended beneficiaries" of the OTC switch provisions of the FDCA because the clarification of the Rx and OTC distinction facilitates the physicians' performance of their jobs. *See* Am. Compl. ¶¶ 30, 46. Plaintiffs are not permitted,

however, to rely on one interest or injury for purposes of establishing injury-in-fact and a different interest or injury for the zone-of-interest test. As the D.C. Circuit has explained:

> [O]n any given claim the injury that supplies constitutional standing must be the same as the injury within the requisite "zone of interests" for purposes of prudential standing. For example, if plaintiffs established an interest sufficiently aligned with the purposes of the [statute] for prudential standing, but failed to show (for example) an adequate causal relation between the agency decision attacked and any injury to that interest, we could not adjudicate the claim--even if plaintiffs had constitutional standing with respect to some other interest that was outside the requisite "zone."

Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1232 (D.C. Cir. 1996).[12/] Accordingly, plaintiffs are not permitted to rely on their alleged competitive injury in establishing injury-in-fact, and their interest in the accurate labeling to establish zone-of-interest.

Furthermore, the physicians' purported interest in "labeling . . . requirements" that "facilitat[e] their performance of their jobs," Am. Compl. ¶ 30, is too attenuated to fall within the zone-of- interest of the FDCA.[13/] The D.C. Circuit has explained that the zone of interest test would be meaningless if it included "all incidental beneficiaries" of a statutory provision. *Liquid Carbonic Indus. Corp.*, 29 F.3d at 704. Because physicians are, at most, "incidental beneficiaries" of FDA's decisions on prescription-OTC switch applications, they cannot be considered "intended beneficiaries" of the statute.

[12/] *See also United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 686 (1973) (alleged injury-in-fact must be within zone of interests); *Reytblatt v. United States NRC*, 105 F.3d 715, 721 (D.C. Cir. 1997) ("The relevant inquiry in this context is whether the *injury* is arguably within the zone of interests to be protected or regulated by the statute in question.") (emphasis added); *FEC v. Akins*, 524 U.S. 11, 20 (1998) ("prudential standing is satisfied when the *injury* asserted by a plaintiff arguably falls within the zone of interests to be protected or regulated by the statute in question") (emphasis added, citation and internal punctuation omitted).

[13/] The physicians' other purported interest in "their patients' interest in safe and effective drugs," Pl. Int. Opp. at 8, relates to third-party standing, which is discussed separately below.

Alternatively, plaintiffs contend that they are within the zone of interest because they are "suitable challengers," Am. Compl. ¶ 32, whose interests are "sufficiently congruent with the intended beneficiaries that they are not more likely to frustrate than further the statutory objectives." Pl. Int. Opp. at 8. They assert that their interest in safe and accurately labeled drugs furthers the statutory objectives. *Id.* Here again, plaintiffs are impermissibly attempting to bifurcate "the injury that supplies constitutional standing" and "the injury within the requisite 'zone of interests.'" *See Mountain States Legal Found.*, 92 F.3d at 1232. Plaintiffs must instead reconcile their alleged Article III injury, that increased competition from pharmacists dispensing Plan B without a prescription will cause plaintiff member physicians to lose money charged for office visits to obtain or renew a contaceptive prescription, Am Compl. ¶ 20, with the statutory objective of "reliev[ing] . . . the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." S. Rep. No. 82-946, at 1. Those are not "congruent" interests and they cannot be logically reconciled.[14/]

As yet another alternative, plaintiffs argue that they need not satisfy the zone-of-interest test "to the extent that" FDA's actions were "ultra vires." Am. Compl. ¶ 32; Pl. Int. Opp. at 9. They rely on authority that holds that, where the government is acting outside of its authority, it would be illogical to limit eligible plaintiffs to those intended beneficiaries of the statutes within

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[14/] In an analogous case, the D.C. Circuit declined to find "suitable challenger" standing where the plaintiff had an economic interest in a particular regulatory scheme and the governing statute was designed to protect the public health: "there is not the slightest reason to think that [plaintiffs'] interest in getting more revenue by increasing the demand for their particular . . . services will serve [the statute's] purpose of protecting health." *Hazardous Waste Treatment Council v. Thomas*, 885 F.2d 918, 924 (D.C. Cir. 1989); *see also Grand Council of the Crees (of Quebec)*, 198 F.3d at 957 (petitioners were not suitable challengers where their objective was outside the agency's view of relevant considerations under the statute). The same is true here: the pursuit of greater physicians' fees is more likely to frustrate than to further the statutory purpose of relieving the public of the burden and expense of obtaining a prescription when medical supervision is unnecessary.

its authority. *See Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 811 n.14 (D.C. Cir. 1987). However, "an 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." *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 102 n.11 (1984) (citation and quotation marks omitted).[15/] Here, plaintiffs do not allege that FDA lacks authority to approve an Rx-OTC switch for drug products; instead, they allege that, in this particular instance, FDA employed the wrong procedures and standards in concluding that approval of Barr's amended application was warranted. These allegations fail to support a claim of ultra vires acts.

E. Plaintiffs Cannot Establish Standing Based on Member Physicians' Assertion of Third-Party Standing on Behalf of Their Patients.

Plaintiffs also allege that the member physicians have third-party standing to "protect the patient-physician relationship and their patients' FFDCA-granted rights to adequate health care, drug-labeling information, safe and effective drugs, and counseling on Rx drugs." Am. Compl. ¶ 21. However, alleging third-party standing is not an alternative to establishing first-party standing: the first party is not relieved of the obligation to satisfy the core requirements for constitutional standing in his own right. *See Powers v. Ohio*, 499 U.S. 400, 411 (1991); *American Immigration Lawyers Ass'n v. Reno*, 199 F.3d 1352, 1361 n.13 (D.C. Cir. 2000) (If any litigant, including those asserting third-party standing, "has not suffered injury[,] there is no constitutional standing."). Instead, third-party standing is a means for a plaintiff with proper standing to assert the substantive claims of another party. *Singleton v. Wulff*, 428 U.S. 106, 112-

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[15/] In *Haitian Refugee Ctr.*, the D.C. Circuit provided, as an example, the facts of *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952), where "the steel mill owners would not be required to show that their interests fell within the zone of interests of the President's war powers in order to establish their standing to challenge the seizure of their mills as beyond the scope of those powers." 809 F.2d at 811 n.14. The amended complaint does not allege any acts by FDA that are akin to the seizure of steel mills.

13 (1976). Thus, plaintiffs cannot cure their inability to establish first-party standing through third-party standing.

Nevertheless, even were the Court to consider third-party standing, plaintiffs have failed to establish its other required elements. Because an injured party is normally the best proponent of her own rights, there must be a hindrance to the third party bringing the claim herself. *See Powers v. Ohio*, 499 U.S. at 411. The Supreme Court has permitted third party standing when these obstacles are "genuine," *Singleton*, 428 U.S. at 116, and "daunting," *Miller v. Albright*, 523 U.S. 420, 449 (1998) (O'Connor, concurring) (quoting *Powers*, 499 U.S. at 414), such that "the third party's absence from court loses its tendency to suggest that [her] right is not truly at stake, or truly important to [her]." *Singleton*, 428 U.S. at 116.

Plaintiffs' own allegations belie any attempt to satisfy this standard. Because plaintiffs have alleged that prospective Plan B customers are members of plaintiff organizations and plaintiffs purport to bring this case on their behalf, Am. Compl. ¶ 15, at least some women patients are already before the Court. Plaintiffs therefore cannot maintain that all women patients are hindered in protecting their own interests. Plaintiffs nevertheless contend that women patients and parents of patients are hindered in bringing suit because they are unaware of the risks involved in OTC use of Plan B and, "if they recognize Plan B's various limitations, their typical response is simply to refrain prospectively from purchasing Plan B or relying on its label information, . . . [and they] will have little incentive to sue." Am. Compl. ¶ 22. With these allegations, plaintiffs have essentially conceded that "the third party's absence from court . . . suggest[s] that [her] right is not truly at stake, or truly important to [her]." *Singleton*, 428 U.S. at 116.

Similarly, plaintiffs have failed to allege any injury-in-fact suffered by women patients. The third-party standing doctrine is based on third-party legal "rights," *see, e.g., Singleton*, 428 U.S. at 114-16, and presupposes that the third party would have standing if before the court. If the third-party herself lacks standing, there are no rights for the first-party to assert. These women patients, as a consequence of FDA's SNDA approval decision, simply have the option of purchasing Plan B without consulting with a physician, and plaintiffs have failed to allege that they have incurred any injury. *See* Am. Compl. ¶¶ 21-22.[16/]

F. Plaintiffs Cannot Establish Standing Based on Member Pharmacists' Assertions of Injury.

Plaintiffs allege that their membership includes practicing pharmacists who are subject to the following injuries: (1) FDA's SNDA approval "subjects . . . pharmacists to liability for holding for sale and selling a misbranded drug," Am. Compl. ¶ 23; (2) they "face expanded legal liability from the removal of the otherwise-applicable protections afforded to pharmacists who dispense an ℞ drug," *id*. ¶ 24; (3) they "face added expense and administrative burdens . . . via requirement not applicable to either OTC or ℞ drugs," *id*. ¶ 25; and (4) they "are subject to compelled speech to further a customer's use of Plan B in violation of these pharmacists' conscience-based objections to Plan B," *id*. ¶ 26.

[16/] Furthermore, the D.C. Circuit has found that the application of third party standing is appropriate where the "government has directly interfered with the litigant's ability to engage in conduct together with the third party, for example, by putting the litigant under a legal disability with criminal penalties." *American Immigration Lawyers Ass'n*, 199 F.3d at 1360 (quoting *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 808 (D.C. Cir. 1987)). Where, however, plaintiff organizations faced no legal sanction from the government's action, and the harm claimed was an "indirect effect" of that action, there was no standing. *Id*. at 1361. Otherwise, "allowing standing for unintended side effects of programs would involve the court in the continual supervision of more governmental activities than separation of powers concerns should permit." *Id*. (quoting *Haitian Refugee Ctr.*, 809 F.2d at 809-10). Here, the government did not directly interfere with the doctor/patient relationship by placing any legal sanction on that relationship; it merely permitted the option of foregoing a doctor's appointment before making a drug purchase. Thus, plaintiffs are unable to satisfy the *Haitian Refugee Ctr.* test for third party standing.

The speculative nature of these allegations fail to "clearly demonstrate" an "injury in fact" that is "concrete in both a qualitative and temporal sense," and "distinct and palpable." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). There is no allegation that any pharmacist member has in fact experienced "expanded legal liability" from FDA's SNDA approval, only that they allegedly "face" such a possibility. It is particularly farfetched that they would be prosecuted for distributing a misbranded drug on the theory that FDA's SNDA approval will some day be found unlawful and they somehow should have foreseen that. "Allegations of possible future injury do not satisfy the requirements of [Article] III. A threatened injury must be 'certainly impending' to constitute injury in fact." *Whitmore*, 495 U.S. at 158 (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). If the injury has not already occurred, plaintiffs must demonstrate a "credible threat" of imminent future injury, *see, e.g., Presbyterian Church (USA) v. United States*, 870 F.2d 518, 528-29 (9th Cir. 1989), and it must be real and immediate. *See Golden v. Zwickler*, 394 U.S. 103, 109 (1969). Similarly, plaintiffs have failed to specify the added expense, administrative burdens, and compelled speech that have been the direct result of FDA's SNDA approval. Admittedly, pharmacists will have to request proof of age to sell Plan B OTC, but this requirement is a *de minimis* burden at most. In the absence of the OTC approval, pharmacists would be processing prescriptions for every Plan B purchase, so that requesting proof of age simply replaces one administrative task with another.

Plaintiffs also cannot establish a causal connection between defendants' conduct and these alleged injuries. Plaintiffs cannot maintain standing to sue the government based on injuries caused by the conduct of third parties. *See Lujan*, 504 U.S. at 560; *Simon*, 426 U.S. at 41-42; *Ctr. for Law & Educ.*, 396 F.3d at 1160-61. For certain alleged injuries, the chain of events would require a lawsuit filed by a third party: after FDA approved sales of Plan B without a prescription to adults,

a pharmacist sold Plan B to a customer, and a governmental entity (other than FDA) sought to prosecute the pharmacist for selling a misbranded drug, or a customer was injured by Plan B and decided to sue the pharmacist who dispensed the drugs. "There is an obvious causal disconnect . . . where . . . [a plaintiff] argue[s] that manufacturers of [a] product should be more heavily regulated so as to prevent claims against [the plaintiff]." *Public Citizen, Inc.*, 489 F.3d at 1290.

Nor can plaintiffs establish a causal connection between FDA's SNDA approval and the alleged "compelled speech." The FDCA does not require pharmacies to sell particular drug products simply because FDA has approved those products for sale with or without a prescription, and FDA does not compel any speech by pharmacists in connection with the sale of OTC drugs; absent some directive from state law, any pharmacist is at liberty to decide what products to offer for sale.[17/] Thus, any pharmacist who is concerned about any legal liability or compelled speech associated with the OTC sale of Plan B could simply choose not to sell it, and such a decision would not violate the FDCA.

Furthermore, FDA did not dictate the terms of sale of Plan B; the marketing plan to limit distribution of Plan B to retail pharmacies in a "behind the counter" setting was proposed by Barr. The Plan B sponsor advised FDA as early as November 2001 that "in most pharmacies, the OTC version of Plan B may eventually be kept behind-the-counter in part out of respect for community values and in part to avoid losses through shoplifting." Def. Ex. 2 at 1. Barr first submitted a dual-marketing proposal on March 11, 2004; under this proposal, both Rx and non-Rx Plan B would have been marketed in the same package and distributed from behind pharmacy counters with proof of

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[17/] To be sure, there are aspects of the FDCA that apply to pharmacists and pharmacies, such as the prohibition on dispensing a prescription drug without a valid prescription. But states and pharmacy boards have primary responsibility for regulating most aspects of the practice of pharmacy.

age required prior to dispensing the drug without a prescription. Def. Ex. 4. In subsequent filings, Barr elaborated on its marketing plans in its Convenient Access Responsible Education ("CARE") Program, which was designed to limit the availability of Plan B to pharmacies and clinics, to educate healthcare professionals and consumers regarding the safe use of Plan B, and to monitor sales of Plan B to ensure that it is being sold and used in a medically appropriate manner. *See* Def. Ex. 9 at 4-7; *see also* Def. Ex. 10 at 36-46. Because Barr developed and implemented its marketing plan, the "links in the chain of causation between the challenged Government conduct and the asserted injury are far too weak" to establish standing. *Public Citizen, Inc.*, 489 F.3d at 1291 (quoting *Allen*, 468 U.S. at 759). *See also Simon*, 426 U.S. at 41-42; *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 938-40 (D.C. Cir. 2004), *cert. denied*, 545 U.S. 1104 (2005).

Finally, the alleged injuries to pharmacists, and their purported interest in preventing an OTC switch approval, are not within the zone of interests fostered by the FDCA. The factors that FDA considers in approving an OTC switch do not include the alleged economic and administrative burdens placed on pharmacists in selling a particular drug. As with the physicians' allegations, the interests that pharmacists purportedly have in preventing an OTC drug approval are antithetical to the public health purposes of the FDCA, and therefore so "inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Cement Kiln Recycling Coalition*, 255 F.3d at 871.

G. Plaintiffs Cannot Establish Standing Based on Their Alleged Procedural Injuries.

The only injury that plaintiffs allege that they have suffered as organizations is a "procedural injury:" that FDA impermissibly approved Barr's amended SNDA requesting a

partial Rx-OTC switch without conducting rulemaking. Am. Compl. ¶ 27. They allege that this denial of "procedural rights conferred by Congress" constitutes injury-in-fact for standing purposes. *Id.*

This allegation fails to establish standing for several reasons. As an initial matter, its legal premise is faulty. The FDCA authorizes FDA to approve drug applications without rulemaking. As described in greater detail below, *see infra* at 42-43, there are two ways that FDA can approve an Rx-OTC switch – by initiating rulemaking pursuant to 21 U.S.C. § 353(b)(3), or by approving a drug application, pursuant to 21 U.S.C. § 355, that is submitted by the manufacturer of the drug and that requests such a switch. *See* 21 C.F.R. § 310.200(b). FDA's review of a drug application is an informal adjudication and does not require rulemaking. *See* 21 U.S.C. § 355(c), (d) (describing procedures applicable to drug application proceeding); 21 C.F.R. § 314.71 (providing that drug application procedures apply to supplemental drug applications). *See also Apotex, Inc. v. FDA*, No. 06-5060, 2007 U.S. App. LEXIS 4270 at *5 (D.C. Cir. Feb. 23, 2007) (noting that FDA drug application approval letters represent "informal adjudications"); *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001) (FDA consideration of a drug application is an "informal adjudication").

Significantly, nothing in the language of 21 U.S.C. § 353(b)(3) forecloses FDA from approving an Rx-OTC switch in the context of drug application proceedings, and FDA regulations, 21 C.F.R. § 310.200(b), specifically provide for it. In practice, FDA has been approving drug applications, including applications requesting Rx-OTC switches, without rulemaking for decades. Thus, because FDA was not required to conduct rulemaking to approve

an Rx-OTC switch, plaintiffs were not "denied . . . procedural rights conferred by Congress." Am. Compl. ¶ 27.

Furthermore, plaintiffs failed to avail themselves of the procedural right that was available to them: to "petition the Commissioner . . . to take or refrain from taking any . . . form of administrative action." 21 C.F.R. § 10.25. Plaintiffs cannot complain that they have been injured by a lack of opportunity to participate in an administrative proceeding when they failed to partake of the administrative process available to them. *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 525, 543 (1978) (holding that agencies have authority to "fashion their own rules of procedure" for handling and resolving challenges to administrative actions even when a statute does not specify what process to use, and courts have limited power to insist on particular procedures).

Even if plaintiffs had been deprived of a procedural right, their standing allegation still would fail because a procedural injury by itself is insufficient to confer standing. In addition to establishing the procedural violation, plaintiffs must show both that the procedural violation "resulted in an invasion of their concrete and particularized interest." *Ctr. for Law & Educ.*, 396 F.3d at 1159; *see also Fund Democracy, LLC v. SEC*, 278 F.3d 21, 28 (D.C. Cir. 2002) ("The grant of a procedural right cannot serve as the basis for Article III standing unless 'the procedures in question are designed to protect some threatened concrete interest of [plaintiffs'] that is the ultimate basis of his standing.'")(quoting *Lujan*, 504 U.S. at 573 n.8). Here, plaintiffs make no other specific allegations of injury to the organizations as organizations, and instead rely on alleged injuries to groups of their members. *See* Am. Compl. ¶¶ 27-29. As detailed above, however, plaintiffs have failed to show a threatened concrete injury to any legally protected

interest of any of their members, let alone one that was caused by the alleged procedural violation. Thus, without a threatened concrete injury, the plaintiff organizations cannot rely solely on an alleged procedural injury to establish standing. *Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 668 (D.C. Cir. 1996) (*en banc*).

Because plaintiffs "ha[ve] not identified a procedural right sufficient for standing" and "because of the absence of a related, concrete injury," plaintiffs have failed to establish procedural standing. *See AAPS v. HHS*, No. 06-0319 (ESH), 2006 U.S. Dist. LEXIS 73020, at *16-21 (D.D.C. Oct. 6, 2006) (rejecting standing of AAPS, one of the four plaintiffs here, on similar standing claims).

II. THIS COURT LACKS SUBJECT MATTER JURISDICTION TO REVIEW FDA'S APPROVAL OF BARR'S AMENDED SNDA.

Plaintiffs allege federal question jurisdiction under 28 U.S.C. § 1331, which requires that the case "aris[e] under" federal law. *See* Am. Compl. ¶ 9. "A case 'aris[es] under' federal law within the meaning of § 1331 . . . if 'a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.'" *Empire HealthChoice Assur., Inc. v. McVeigh*, 126 S. Ct. 2121, 2131 (2006) (quoting *Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust for Southern Cal.,* 463 U.S. 1, 27-28 (1983)). "The vast majority of cases brought under the general federal-question jurisdiction of the federal courts are those in which federal law creates the cause of action." *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 808

(1986).[18/] Thus, plaintiffs' "well-pleaded" complaint must establish a cause of action under federal law. *See, e.g., Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 830 (2002).

Plaintiffs cannot establish a cause of action under federal law. Plaintiffs allege that their case arises out of "ongoing []FDCA, APA and Due-Process violations." Am. Compl. ¶ 9. It is doubtful that this vague allegation satisfies the rule that a well-pleaded complaint establish the elements of federal question jurisdiction. *See Holmes Group, Inc.*, 535 U.S. at 830. Furthermore, plaintiffs have failed to allege a cause of action under federal law: because there is no cause of action that permits an uninjured member of the public to challenge an FDA decision on a drug application, these plaintiffs cannot obtain judicial review of FDA's decision-making process with regard to Barr's SNDA, and this Court lacks jurisdiction to review this challenge.

A. There is No Private Cause of Action under the FDCA for Members of the General Public to Challenge FDA Review of a Drug Application.

Plaintiffs, who are unaffiliated with Barr, do not have a private right of action to challenge FDA's decision-making on Barr's application. It is well established that there is no express or implied private right of action under the FDCA.[19/] The statutory provisions and regulations that govern the filing of an SNDA provide the drug sponsor, *to the exclusion of the general public,* with particularized rights and procedural remedies. *See* 21 U.S.C. § 355 (providing the administrative procedures by which *sponsors* of drug products apply for approval

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[18/] Courts have recognized a limited exception, not applicable here, to the federal cause of action requirement "where the vindication of a right under state law necessarily turned on some construction of federal law." *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. at 808 (citation omitted).

[19/] *See Wander v. Kaus*, 304 F.3d 856, 859 (9th Cir. 2002); *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-30 (Fed. Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000); *American Farm Bureau v. EPA*, 121 F. Supp. 2d 84, 96 (D.D.C. 2000).

from FDA to market new drugs).[20/] These provisions do not provide a right to judicial relief to members of the general public. *See, e.g., Cowan v. United States*, 5 F. Supp. 2d 1235, 1238 (D. Okla. 1998) ("numerous courts have held standing is conferred only upon those involved in the statutory application process"); *Duncan v. United States*, 590 F. Supp. 39, 42 (W.D. Okla. 1984) ("The Plaintiffs have not filed an NDA and do not have standing to seek review of a decision on the NDA of another.").[21/]

Indeed, the FDCA permits judicial review only of a final agency decision "refusing or withdrawing approval" of an SNDA. 21 U.S.C. § 355(h). There is no statutory basis for judicial review of an SNDA which, like Barr's amended SNDA, has been *approved*. *See Bradley,* 483 F.2d at 413 n.1. There is likewise no regulatory basis for a member of the general public to challenge a drug approval outside FDA's citizen petition process. And there is certainly no statutory basis for a member of the public to challenge a manufacturer's distribution and marketing plans that formed part of the application approved by FDA. Now that FDA has issued

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[20/] For example, section (b) describes all of the material that *the applicant* is required to submit with its application and authorizes several different types of meetings that may take place between FDA officials and the applicant at various stages of the process (but which are not open to public participation); section (c) provides *the applicant* with an opportunity for hearing on the approvability of the application; section (d) sets forth the grounds for refusing a drug sponsor's drug application and provides *the applicant* with an opportunity for a hearing; section (h) provides that "[a]n appeal may be taken *by the applicant* from an order of [FDA] refusing or withdrawing approval of an application under this section." (emphasis added).

[21/] Nor can plaintiffs claim to be in the "zone of interests" meant to be protected by the administrative procedures set forth in section 355. Where a statute provides certain rights to an applicant, a third-party is not within the zone of interests. *Cf. Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 11-12 (D.D.C. 1991) ("Members of the public do not have such a right, and neither the regulation nor the Patent Statute confer this procedural right on third-party protestors. . . . Plaintiff's claims are not within the 'zone of interests' protected by 37 C.F.R. § 1.56 because plaintiff is not a patent applicant. Section 1.56 addresses itself to patent applicants, prescribing the manner in which reissue applications will be handled by the PTO and detailing the duty of disclosure imposed on reissue applicants."). The only entity that ever had standing or a cause of action to challenge the legality of FDA's actions on the SNDA was Barr. Barr did not, however, raise any challenge to FDA's action with regard to its SNDA, nor does it purport to do so now.

a final decision approving Barr's amended application, not even Barr could challenge FDA's final decision on its SNDA.

No other provision of the FDCA provides a cause of action for the general public to challenge a drug approval. Accordingly, the FDCA does not provide a jurisdictional basis for this challenge.

B. Plaintiffs Have Failed to Allege Any Other Legitimate Cause of Action

Plaintiffs also cannot establish federal question jurisdiction based on violations of the APA or United States Constitution. The APA provides a cause of action for a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. As this Court recently found:

> The failure to establish Article III standing is separately fatal to plaintiffs' ability to state a claim for review under the APA, which has its own standing requirement. *See* 5 U.S.C. § 702. *See also Sierra Club v. Morton*, 405 U.S. 727, 739-40, 92 S. Ct. 1361, 31 L. Ed. 2d 636 (1972) ("[A] mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization 'adversely affected' or 'aggrieved' within the meaning of the APA. The Sierra Club is a large and long-established organization, with a historic commitment to the cause of protecting our Nation's natural heritage from man's depredations. But if a 'special interest' in this subject were enough to entitle the Sierra Club to commence this litigation, there would appear to be no objective basis upon which to disallow a suit by any other bona fide 'special interest' organization, however small or short-lived. And if any group with a bona fide 'special interest' could initiate such litigation, it is difficult to perceive why any individual citizen with the same bona fide special interest would not also be entitled to do so.").

Friends of the Earth v. United States DOI, 478 F. Supp. 2d 11, 22 n.13 (D.D.C. 2007). Here, defendants have shown that plaintiffs have failed to establish any sufficient injury for standing purposes, *see supra* at 11-27; they likewise cannot establish that agency action has caused them

to "suffer[a] legal wrong" within the meaning of section 702. In addition, plaintiffs cannot rely on their values or political perspective to establish a "legal wrong" because "[d]isagreement with government action or policy, however strongly felt, does not, standing alone, constitute an 'injury' in the Constitutional sense which is cognizable in the federal courts and susceptible of remedy by the judicial branch; it is a matter properly addressed to the Congress or the Executive." *Evans v. Lynn*, 537 F.2d 571, 598 (2d Cir. 1976); *see Norton v. Southern Utah Wilderness Alliance,* 542 U.S. 55, 62-65, 124 S. Ct. 2373, 2379-80 (2004) (APA limits claims to agency action required by law and may not be used to mount broad programmatic attacks).

Nor can plaintiffs establish that they have been "adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. "[T]o be 'adversely affected or aggrieved . . . within the meaning' of a statute, the plaintiff must establish that the injury he complains of (*his* aggrievement, or the adverse effect *upon him*) falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 883 (1990) (emphasis in original). Here again, as demonstrated above, plaintiffs cannot claim to be adversely affected or aggrieved within the meaning of the FDCA, because the FDCA does not provide any right to members of the general public to participate in or challenge the approval of a drug application, and because plaintiffs have failed to demonstrate any injury from the approval of the OTC option for adults. Accordingly, plaintiffs have failed to state a claim under the APA.

Plaintiffs' vague allegations of "Due-Process violations," without identifying any particular right or interest which has been impaired, do not establish a cause of action. *See* Am. Compl. ¶¶ 9, 39, 122, 126. Plaintiffs' "federal constitutional claim depends on their having had a

property right. . .”; only if plaintiffs can identify a cognizable property or liberty interest need the Court even address the question of “how much process is due.” *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538, 541 (1985)(citations omitted). Plaintiffs do not have any cognizable right to have the approval status of Plan B changed, or to require the agency to conduct rulemaking in connection with its review of a drug application. *Cf. Board of Regents v. Roth*, 408 U.S. 564, 577 (1972) (“[t]o have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it.”). Because plaintiffs have failed to identify any cognizable right that has been violated, the “Due-Process” allegation fails to comply with the well-pleaded complaint rule. *See* Fed. R. Civ. P. 8(a).

Accordingly, this Court lacks jurisdiction over plaintiffs’ challenge and the amended complaint should be dismissed.

III. PLAINTIFFS HAVE FAILED TO EXHAUST ADMINISTRATIVE REMEDIES.

Plaintiffs failed to exhaust the administrative remedy available to them under FDA regulations: filing a citizen petition with FDA pursuant to 21 C.F.R. § 10.25. FDA regulations require that a party first use the citizen petition process to “request that the Commissioner take or refrain from taking any form of administrative action,” and that request must “be the subject of a final administrative decision based on [the citizen petition] . . . before any legal action is filed in a court.” 21 C.F.R. § 10.45(b).[22/]

[22/] Section 10.45(e) further provides “[a]n 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.” 21 C.F.R. § 10.45(e). Taken together, 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.

"The [exhaustion of administrative remedies] doctrine provides 'that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.'" *McKart v. United States*, 395 U.S. 185, 193 (1969) (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1938)). The purpose of the exhaustion requirement is to "avoid[] [the] premature interruption of the administrative process . . . to let the agency develop the necessary factual background upon which decisions should be based, [a]nd 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." *McKart*, 395 U.S. at 193-94; *Burt Lake Band of Ottawa & Chippewa Indians v. Norton*, 217 F. Supp. 2d 76, 78 (D.D.C. 2002) ("In cases where Congress has allocated decision-making responsibility to the Executive branch, petitioning parties are required to exhaust all available administrative remedies before seeking judicial relief.") (citation omitted), *appeal dismissed*, No. 02-5341, 2002 WL 31778064 (D.C. Cir. Dec. 4, 2002). The exhaustion requirement also promotes judicial efficiency because the agency may decide the matter in favor of the plaintiff and obviate the need for judicial review. *McKart*, 395 U.S. at 195.[23/]

This Court has applied the exhaustion requirement mandated by FDA regulations. For example, in *National Gay Rights Advocates v. HHS*, the Court dismissed the complaint as premature for failure to file a citizen petition where, as here, plaintiffs "have chosen to ignore the administrative processes available to them by making no attempt to seek relief in this manner."

[23/] This regulatory exhaustion requirement is not jurisdictional, and courts decline to apply it in certain circumstances. *See McCarthy v. Madigan*, 503 U.S. 140, 144-49 (1992); *Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155 (D.C. Cir. 2007). None of those circumstances, however, are presented here.

No. 87-1735, 1988 U.S. Dist. LEXIS 17283, at *1-7 (D.D.C. 1988). *See also Garlic v. FDA*, 783 F. Supp. 4 (D.D.C. 1992), *appeal dismissed*, 986 F.2d 546 (D.C. Cir. 1993).

Plaintiffs cannot evade the exhaustion requirement by asserting that the citizen petition process is less desirable than direct judicial review. *See* Am. Compl. ¶ 36-37. The APA "does not require an equally effective remedy, only an adequate one." *American Disabled For Attendant Programs Today v. HUD*, 170 F.3d 381, 390 (3d Cir. 1999). Nor can plaintiffs evade the exhaustion requirement by challenging a final agency action on another party's application. *See* Am. Compl. ¶¶ 133-135. FDA regulations require plaintiffs to file their *own* petition to bring their *own* arguments and evidence first to the agency. 21 C.F.R. § 10.45(b). Because plaintiffs raise arguments in this lawsuit that were not raised by Barr in its SNDA proceeding, *see, e.g.,* Am Compl. ¶¶ 60-65, 82-94, the purposes of the exhaustion requirement – to first allow the agency to evaluate and respond to these arguments, and if necessary, create a record – would be undermined by waiving the requirement here.

IV. PLAINTIFFS HAVE FAILED TO STATE A CLAIM THAT FDA UNLAWFULLY APPROVED Rx AND OTC VERSIONS OF PLAN B AND UNLAWFULLY CREATED A THIRD CLASS OF DRUGS.

Because plaintiffs lack standing and have failed to establish that this Court has jurisdiction to review their claims, the Court need not reach the substance of plaintiffs' claims. Were the Court nevertheless to reach them, Counts II and IV should be dismissed as a matter of law. Plaintiffs allege in Court II that FDA exceeded its statutory authority when it approved Barr's proposal, in its amended SNDA, to have Plan B available without a prescription to consumers in one age group while retaining the prescription requirement for another age group. They allege that the FDCA prohibits the simultaneous distribution of the same drug as both Rx

and OTC, so that FDA's approval of Barr's SNDA violated the FDCA. Am. Compl. ¶¶ 102-104. Similarly, or perhaps alternatively, plaintiffs allege in Count IV that FDA unlawfully created a "third class of drugs," in addition to the ℞ and OTC "classes of drugs." Am. Compl. ¶¶ 115-119. Because FDA reasonably construed the FDCA consistent with the structure and purpose of the statute, plaintiffs' arguments regarding FDA's statutory authority are without merit, and Counts II and IV should be dismissed for failure to state a claim.

A. The Court Should Defer to FDA's Reasonable Construction of the Statute.

Where, as here, the Court is reviewing an agency's construction of statutory provisions, the two-step analysis of *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), governs. First, the Court must inquire "whether Congress has directly spoken to the precise question at issue;" if Congress's intent is clear, the Court "must give effect to [such] unambiguously expressed intent." *Id*. at 842-43. Second, if Congress has not "directly" addressed "the precise question at issue," the Court may not "impose its own construction on the statute." *Chevron*, 467 U.S. at 843. Rather, it must determine if the agency's interpretation is based on "a permissible construction of the statute." *Id*.

Chevron deference applies where, as here, "Congress delegated authority to the agency generally to make rules carrying the force of law." *Gonzales v. Oregon*, 546 U.S. 243, 244 (2006) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001)).[24/] Accordingly, the

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[24/] "Delegation of such authority may be shown in a variety of ways." *Mead Corp*., 533 U.S. at 227. With the FDCA, Congress has authorized and directed FDA to decide what drugs may lawfully enter the marketplace, and when and how they may enter. *See, e.g.*, 21 U.S.C. §§ 353, 355, 355c. Further, *Chevron* deference is appropriate when "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 here at issue." *Barnhart v. Walton*, 535 U.S. 212, 222 (2002). Thus, deference is appropriate in the drug approval context because of "the complexity of the statutory

D.C. Circuit has repeatedly given *Chevron* deference to FDA's interpretation of the FDCA, as well as the agency's own implementing regulations. *See, e.g., Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006); *Mylan Labs., Inc. v. Thompson*, 389 F.3d at 1281; *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883 (D.C. Cir. 2004); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319, 1320 (D.C. Cir. 1998) (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).[25/] Furthermore, *Chevron* deference extends to administrative determinations that are not embodied in rulemaking or formal adjudication, including, as in this case, the documents supporting a drug application approval decision. *See Apotex, Inc. v. FDA*, No. 06-5060, 2007 U.S. App. LEXIS 4270, at *5 (D.C. Cir. Feb. 23, 2007) ("the district judge's opinion, which grants Chevron deference to the FDA's statutory interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) embodied in FDA approval letters (*i.e.*, informal adjudications), is supported by the Supreme Court's post-*Mead* decision in *Barnhart v. Walton*, 535 U.S. 212, 222 (2002), as well as our own decision in *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004)").

B. FDA Reasonably Found Dual-Marketing Permissible Under the FDCA.

FDA has reasonably construed the FDCA to permit approval of both an Rx-only version and a non-Rx version of a product with the same active ingredient when there is a material distinction between the two versions of the drugs. The FDCA does not explicitly address simultaneous approval of Rx-only and non-Rx versions of the same product. The relevant provision of the statute provides that a drug product will be approved for prescription only

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regime"and "FDA's expertise." *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004).

[25/] *See also Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1352 (Fed. Cir. 2003) ("Deference is due to an administrative agency's regulations particularly when the subject matter of the regulatory authority is a 'highly detailed' regulatory program to which the agency has brought its 'specialized expertise,' . . . a characterization that aptly describes the FDA's role.") (quoting *Mead*, 533 U.S. at 235, 121 S. Ct. at 2175).

dispensing when, "because of its 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 licensed health care professional. 21 U.S.C. § 353(b)(1). FDA has construed that provision to mean that there can be simultaneous marketing of Rx-only and non-Rx versions of the same drug so long as one version requires the supervision of a licensed health care professional and the other version does not. Thus, as long as there is a distinction between the two versions – *e.g.* intended use, strength, route of administration, dosage form, or patient population – that requires professional supervision for one version of the drug, but does not require such supervision for the other version, the simultaneous existence of Rx and non-Rx versions of the drug product is permissible.[26/]

Here, FDA approved Barr's request for both an Rx version and a non-Rx version of Plan B after Dr. Galson found that adult women could safely use Plan B without a prescription, while the Rx restrictions should remain for safe use of the drug by minor women. This distinction in FDA's conclusions on the safety data justifies classifying Plan B for adults as non-Rx, while classifying Plan B for persons under 18 years of age as Rx-only. FDA's approval of the two versions is consistent with the language of 21 U.S.C. § 353(b)(1), which distinguishes between Rx and non-Rx use based primarily on a determination of safe use under professional supervision.

[26/] For example, FDA has approved Rx and non-Rx versions of the following active ingredients or drug products: loperamide (Rx for chronic diarrhea/non-Rx for acute diarrhea); ibuprofen (Rx at a higher dose for the relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis; non-Rx at a lower does for temporary relief of minor aches and pain and temporary reduction of fever); H2 blockers (Rx at a higher dose for peptic ulcer disease; non-Rx at a lower dose for heartburn); nicotine products (Rx when administered through inhalers and nasal sprays; non-Rx when administered through gums, lozenges, and patches); orlistat (Rx at 120 mg three times a day for obesity; non-Rx at 60 mg three times a day for weight loss); omeprazole (Rx for erosive esophagitis, active benign gastric ulcer, and for the treatment of heartburn and other symptoms associated with GERD; non-Rx for frequent heartburn); terbinafine (Rx for tinea veriscolor; non-Rx for athlete's foot, ring worm, jock itch). *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

Contrary to plaintiffs' suggestion, Am. Compl. ¶ 50, the FDCA does not prohibit the marketing of the Rx version and the non-Rx version of Plan B in the same box. FDA's SNDA approval decision requires Plan B to bear labeling that "Rx only for age 17 and younger." Am. Compl. ¶ 79. This labeling does not violate 21 U.S.C. § 353(b)(4)(A), which prohibits the dispensing of a prescription drug without the "Rx only" legend on its label, because the Plan B label contains those words. Nor does the labeling violate 21 U.S.C. § 353(b)(4)(B), which prohibits a product that is sold only as an OTC product from falsely containing the "Rx only" legend on its label, because Plan B is not solely OTC and the labeling is not false. Nothing in section 353(b)(4) prohibits a product that is being sold *both* as an Rx and OTC product from bearing labeling that accurately reflects its approval status.[27/]

Moreover, FDA's Plan B approval decision is consistent with Congress' overall purpose in enacting the Durham Humphrey Amendments to the FDCA in 1951: "to deal more directly and realistically with the labeling and dispensing of drugs." S. Rep. No. 82-946, at 1 (1951). Prior to the enactment of these amendments, manufacturers made the determination regarding whether a prescription was necessary for the products they manufactured. H.R. Rep. No. 82-700, at 3-6 (1951). The lack of uniformity in the application of these standards led to confusion and the inadequate protection of the public health. *Id*. The purpose of the labeling requirements was to "eliminate confusion," "by requiring that drugs be so labeled [prescription or OTC] as to indicate to the retail druggist and to the general public into which of these two classes they fall."

[27/] Indeed, by its literal terms, the prohibition on an OTC product having the "Rx only" legend on its label does not apply to Plan B. 21 U.S.C. § 353(b)(4)(B). Subsection (B) of section 353(b)(4) states that it applies only to drug products that are not subject to paragraph (1) of section 353(b). Paragraph (1) of section 353(b) defines the prescription requirement. Because Plan B is a prescription drug in part, it is subject to paragraph (1). Accordingly, subsection (B) of 353(b)(4) does not apply to Plan B.

Id. at 3. Nothing in the legislative history indicates that Congress contemplated dual-status packaging in discussing the distinct labeling requirements for separate Rx and OTC products, or intended to bar a dual-marketing arrangement. Rather, Congress intended to create a uniform standard that was clearly and accurately reflected in the labeling. Because FDA's SNDA approval decision requires Plan B to bear labeling that accurately describes its approval status, "Rx only for age 17 and younger," Am. Compl. ¶ 79, the decision is consistent with the overall purposes of the Durham-Humphrey Amendments of providing clear notice of the drug approval status in the labeling of the product.

At the very least, FDA's approval of the dual marketing of Plan B, and the marketing of both versions of the product in a single box containing the labeling required for both versions, reflects a permissible construction of the FDCA. The agency found that Barr's proposal was in the interests of the public health and permissible under the FDCA. This Court should defer to that conclusion. *See e.g., Novartis Pharms. Corp.*, 435 F.3d at 349 ("FDA interpretations of the FDCA receive deference"); *Purepac Pharm. Co. v. Thompson*, 354 F.3d at 883 (same); *Mylan Labs, Inc. v. Thompson*, 389 F.3d at 1281 (FDA's construction of FDCA was "permissible . . . and therefore satisfies *Chevron*).

C. FDA Did Not Create a Third Class of Drugs.

Plaintiffs appear to be alleging in Count IV that FDA created a third class of drug by approving Barr's CARE program. *See* Am. Compl. ¶¶ 115-119. Plaintiffs' contention is incorrect: FDA approved an Rx-only version of Plan B and a non-Rx version of Plan B; it did not approve a "third class" of drug. As explained above, FDA has reasonably construed the FDCA

to permit approval of both an Rx-only version and a non-Rx version of a product with the same active ingredient when there is a material distinction between the two versions of the drugs.

To the extent plaintiffs are alleging that FDA lacks authority to approve marketing restrictions on drug products, they are incorrect. As noted above, *see supra* at 23-24, FDA did not mandate specific distribution channels for Plan B or direct the specific conditions under which it would be sold: it was *Barr* that developed the CARE proposal, and it is *Barr* that is implementing it. Nothing in the FDCA prohibits a sponsor from voluntarily limiting distribution of a product it manufactures to certain types of retail outlets, or from directing other marketing conditions of the type contained in the CARE program, with or without notice to FDA.[28/]

Because FDA did not create a "third class" of drug as a matter of law, Count IV should be dismissed.

V. PLAINTIFFS HAVE FAILED TO STATE A CLAIM THAT FDA VIOLATED THE APA AND FDCA IN APPROVING BARR'S SNDA WITHOUT CONVENING RULEMAKING.

Plaintiffs allege that FDA was prohibited, on two grounds, from approving Barr's SNDA without convening rulemaking. First, plaintiffs assert in Count V that, in approving the SNDA, FDA amended a "rule" regarding the criteria for an OTC switch. As such, the APA requires FDA to conduct a rulemaking. Am. Compl. ¶¶ 81, 121-122. Second, plaintiffs assert in Count

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[28/] In addition, although not explicitly relied on here, FDA regulations provide that "[i]f FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product." 21 C.F.R. § 314.520(a). There are several other FDA-approved drugs that are distributed under marketing plans that are far more restrictive than the one proposed by Barr here. For example, Accutane (isotretinoin), which is indicated for the treatment of severe acne, but may cause birth defects if ingested while pregnant, is marketed under a risk management program in which wholesalers, pharmacies, doctors, and patients must be registered in a computer-based system to participate in the distribution, prescribing, and dispensing of the drug, and a female patient must have a negative pregnancy test confirmed in that system before she can obtain the drug. *See* http://www.fda.gov/cder/drug/infopage/accutane/.

VI that, under the FDCA, FDA may approve an OTC switch only through rulemaking. Am. Compl. ¶¶ 124-126. Neither contention is correct as a matter of law, and Counts V and VI should be dismissed.

A. FDA's Decision-Making Did Not Require Notice and Comment Rulemaking under the APA

Plaintiffs allege that FDA amended a "rule" in allowing the age of the patient population to be the distinguishing feature between the Rx and OTC versions of the same product. Am. Compl. ¶ 121. Plaintiffs acknowledge that FDA has previously approved the simultaneous marketing of Rx and OTC versions of drug products with the same active ingredient. Am. Compl. ¶ 53. Plaintiffs allege that the previous approvals were based on five "parameters:" active ingredient, indication, strength, route of administration, and dosage form. *Id*. Plaintiffs maintain that, before FDA added patient population to the list of parameters, it was required to engage in rulemaking. Am. Compl. ¶¶ 53, 121-122.

Plaintiffs are incorrect. Plaintiffs have failed to identify any document or documents issued by the agency that purportedly constitute either the original rule being amended or the amendment itself. As noted above, the agency, in approving Barr's amended SNDA, was not engaged in rulemaking, but rather was evaluating a drug application, which the D.C. Circuit has found to be an informal adjudicatory proceeding. *See Apotex, Inc.*, No. 06-5060, 2007 U.S. App. LEXIS 4270; *Am. Bioscience, Inc.*, 243 F.3d at 582. Thus, the resulting approval decision constitutes an order, not a rule. *See General Motors Corp. v. Ruckleshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc) (agency's characterization of its action is relevant to determining nature of action), *cert. denied*, 471 U.S. 1074 (1985)*; see also Cent. Tex. Tel. Coop. v. FCC*, 402

F.3d 205, 210 (D.C. Cir. 2005) ("It is fair to ask why both sides assume that we are even dealing with the making of a rule, whether of the legislative or interpretive variety. Agencies often have a choice of proceeding by adjudication rather than rulemaking."). Adjudicatory determinations may establish "broad legal principles" that are not considered "rules." *Id.*[29/]

Here, FDA applied the FDCA, in particular 21 U.S.C. §§ 353(b) & 355, to the facts and data presented in the SNDA, and made an adjudicatory determination. Accordingly, there was no requirement that FDA conduct notice-and-comment proceedings.

B. The FDCA Does Not Mandate Rulemaking to Approve a Drug Application Seeking an OTC Switch.

The FDCA authorizes two administrative mechanisms for FDA to switch an Rx-only drug to non-Rx status. First, FDA may promulgate a regulation changing the status of a drug product from Rx-only to non-Rx. *See* 21 U.S.C. § 353(b)(3) ("The Secretary may by regulation remove drugs [approved for Rx-only distribution] from the requirements of [Rx-only restrictions] when such requirements are not necessary for the protection of the public health."). Under this rulemaking mechanism, the Commissioner may *sua sponte* initiate a proceeding to switch a drug product from Rx-only to non-Rx status. 21 C.F.R. § 310.200(b); *see also* 21 U.S.C. § 353(b)(3). A request to initiate rulemaking may also be made by any "interested person" by filing a citizen petition. 21 C.F.R. § 310.200(b).

Second, the FDCA provides FDA with the authority to approve and reject drug applications, 21 U.S.C. § 355(c),(d), which authority FDA has reasonably construed to apply to

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[29/] It should also be noted that not all rules require notice and comment rulemaking under the APA. *See* 5 U.S.C. § 553(b)(3)(A). Agency rules that "clarify or explain existing laws or regulations" do not require rulemaking. *Nat'l Med. Enters., Inc. v. Shalala*, 43 F.3d 691, 697 (D.C. Cir. 1995).

supplements to approved drug applications. 21 C.F.R. § 314.71(c). Furthermore, FDA regulations explicitly provide that an OTC switch may be accomplished through a drug's sponsor's submission of a supplement to its NDA (*i.e.*, an SNDA), requesting the ℞-only to non-℞ switch. 21 C.F.R. § 310.200(b).

Plaintiffs ignore this latter option and instead appear to allege that section 353(b)(3), which provides that "[t]he Secretary may by regulation" remove the ℞-only designation for an approved drug "when such [prescription] requirements are not necessary for the protection of the public health," is the exclusive authority for making an OTC switch. However, nothing in the literal language of the statute requires this result. Section 353(b)(3) does not provide that it is the "only" mechanism for an OTC switch, and it does not in any way preclude the normal operation of drug approvals under section 355. Thus, it is reasonable and permissible for FDA to approve ℞-OTC switches through the approval of supplemental drug applications.

VI. PLAINTIFFS HAVE IMPROPERLY NAMED COMMISSIONER VON ESCHENBACH IN HIS PERSONAL CAPACITY

Plaintiffs have no basis for naming Commissioner von Eschenbach in his personal capacity. All of the substantive claims at issue in this case, and all of the relief sought, relate to official actions by FDA. *See Feit v. Ward*, 886 F.2d 848, 858 (7th Cir. 1989) (claims brought against defendants in individual capacities to challenge actions taken in official capacities were properly dismissed). Dr. von Eschenbach plainly lacks the authority to grant or deny a drug application in his individual capacity. Nor can plaintiffs obtain the requested declaratory or injunctive relief from him in his personal capacity. *See Feit*, 886 F.2d at 858 (individual capacity claims properly dismissed where "the equitable relief [plaintiff] requests -- a declaration that the

policy is unconstitutional and an injunction barring the defendants from implementing the policy in the future -- can be obtained only from the defendants in their official capacities, not as private individuals"); *In re Iraq & Afg. Detainees Litig.*, 479 F. Supp. 2d 85, 93-94 (D.D.C. 2007).

Plaintiffs have not asserted a constitutional tort, which can establish a basis for naming a government official in his or her personal capacity under *Bivens v. Six Unknown Named Agents*, 403 U.S. 388 (1971).[30/] Plaintiffs have affirmatively disavowed any intention to seek monetary damages as a form of relief in the Complaint. Am. Compl. ¶ 7 ("Defendant von Eschenbach is not sued in his individual capacity for monetary or punitive damages."). And even if plaintiffs had alleged a claim for damages against Commissioner von Eschenbach in his personal capacity, he would be entitled to qualified immunity from such claims. *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982) (government officials sued in personal capacity entitled to qualified immunity unless their conduct violates "clearly established statutory or constitutional rights of which a reasonable person would have known."); *see Anderson v. Creighton*, 483 U.S. 635, 640 (1987); *Barham v. Ramsey*, 434 F.3d 565, 572 (D.C. Cir. 2006).[31/] Because, as noted above, plaintiffs have failed to identify a cognizable liberty or property interest or otherwise properly pleaded a

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[30/] In *Bivens*, the Supreme Court recognized an action for money damages against a federal officer in his or her individual capacity who abuses his or her constitutional authority. *See Corr. Servs. Corp. v. Malesko*, 534 U.S. 61, 66 (2001); *Thompson v. Pope*, 397 F. Supp. 2d 28, 32 (D.D.C. 2005). *Bivens* claims are asserted against individual government actors in their personal capacities and allow for the award of monetary damages for violations only of clearly-established constitutional rights. *See Butz v. Economou*, 438 U.S. 478, 504 (1978).

[31/] In deciding whether certain allegations are sufficient to defeat a qualified immunity defense, the Court applies a two-part analysis of (1) whether a constitutional right was violated on the facts alleged; and (2) assuming the violation is established, whether the right was clearly established. *Saucier v. Katz*, 533 U.S. 194, 200 (2001). "The contours of the right" must be sufficiently clear so that a reasonable official would understand that his conduct violated an individual's rights. *Anderson*, 483 U.S. at 640; *Barham*, 434 F.3d at 572. Where plaintiffs fail to demonstrate a clear violation of a constitutional or statutory right, or where the individual official was not on notice that his conduct was unlawful, the qualified immunity defense will be sustained. *See Spagnola v. Mathis*, 809 F.2d 16, 30 (D.C. Cir. 1986); *Briscoe v. Potter*, 355 F. Supp. 2d 30, 47 (D.D.C. 2004).

constitutional violation, plaintiffs cannot even begin to meet the standard for overcoming qualified immunity.

Plaintiffs are apparently under the mistaken belief that the personal capacity claim is necessary to avoid a sovereign immunity defense. *See* Am. Compl. ¶ 34. The APA, 5 U.S.C. § 702, operates as a waiver of sovereign immunity for any suit seeking non-monetary relief against a United States agency or officer acting in an official capacity even if the cause of action is not brought under the APA. *See Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996). Plaintiffs invoke the Court's equity jurisdiction to address what they describe as the Commissioner's *ultra vires* approval of the SNDA, *see* Am. Compl. ¶¶ 34-35, but resort to equity jurisdiction is unnecessary. Assuming *arguendo* that plaintiffs had standing to bring, and the Court had jurisdiction to review, the claims in this case, all the claims here should have been brought under the APA, and the proper defendant under the APA is the United States, the agency, or the head of the agency in his or her official capacity only. 5 U.S.C. § 703; *see Estes v. Federal Bureau of Prisons*, 273 F. Supp. 2d 1301, 1304 (S.D. Ala. 2003) (finding agency head in official capacity and agency were proper defendants under APA). The claims against the Commissioner in his personal capacity should therefore be dismissed.

CONCLUSION

Accordingly, for all the reasons provided above, this case should be dismissed.

Respectfully submitted,

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