UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., *et al.*, *Plaintiffs*, *v.* FOOD & DRUG ADMINISTRATION, *et al.*, *Defendants*. DURAMED PHARMACEUTICALS, INC., *Defendant Intervenor*.	Civil Action No. 07:0668 (JDB) ORAL ARGUMENT REQUESTED

MOTION BY DURAMED PHARMACEUTICALS, INC.
TO DISMISS FIRST AMENDED COMPLAINT

Defendant intervenor Duramed Pharmaceuticals, Inc. ("Duramed") hereby moves that this Court dismiss with prejudice plaintiffs' First Amended Complaint under Fed. R. Civ. P. 12(b)(1) for lack of subject-matter jurisdiction and for failure to exhaust an administrative remedy, and that it dismiss Counts II and IV-VI under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

A Memorandum of Points and Authorities and Proposed Order are filed herewith. Oral argument is respectfully requested.

Respectfully submitted,

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Dated: September 21, 2007

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DURAMED PHARMACEUTICALS, INC.'S MOTION TO DISMISS FIRST AMENDED COMPLAINT

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TABLE OF ABBREVIATIONS

AAPS	Association of American Physicians and Surgeons, Inc.
AIPAC	American Israel Public Affairs Committee
ANPRM	Advance Notice of Proposed Rulemaking
APA	Administrative Procedure Act
Barr Pharma	Barr Pharmaceuticals, Inc.
CDER	FDA's Center for Drug Evaluation and Research
CWA	Concerned Women for America
Duramed	Duramed Pharmaceuticals, Inc.
EC	Emergency contraceptive
FAC	First Amended Complaint
FDA	The Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FEC	Federal Election Commission
FRC	Family Research Council
NDA	New drug application
OTC	Over-the-counter
Rx	Prescription or by prescription
SDW	Safe Drugs for Women
sNDA	Supplemental new drug application
Stewart	Holly Stewart *et al*., The Impact of Using Emergency Contraception on Reproductive Health Outcomes: A Retrospective Review in an Urban Adolescent Clinic, J. Pediatric Adolescent Gynecology, 2003 Oct. 16(5).
WCC	Women's Capital Corporation

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INTRODUCTION

Plan B (levonorgestrel) is an emergency contraceptive ("EC"), which reduces the chance of pregnancy after unprotected intercourse (*i.e.*, if another birth control method fails or if none was used). More than thirty countries – including Britain, France, Australia, and Sweden – permit emergency contraceptives to be sold without a doctor's prescription ("Rx").[1] The Food and Drug Administration ("FDA") has found that Plan B is safe and effective for over-the-counter ("OTC"), *i.e.*, non-prescription, use by women age 18 and older.

Plaintiffs, Association of American Physicians & Surgeons, Inc. ("AAPS"), *et al.* (together, "plaintiffs"), disagree. Eight months after FDA permitted OTC sale of Plan B, they brought suit and asked this Court to reject the medical and scientific expertise of FDA, and to find, instead, that Plan B is not safe and effective for OTC use by any woman at any age. In their original Complaint, plaintiffs did not allege that using Plan B directly causes harm, and they did not identify a single user of Plan B harmed by its OTC availability. In August, plaintiffs filed their First Amended Complaint ("FAC") – an attempt to cure the fatal standing problems present in the original Complaint. The attempt fails. Plaintiffs still do not allege that Plan B directly causes harm, and still have not identified a single user of Plan B harmed by its OTC availability.

This Court should dismiss the FAC pursuant to Fed. R. Civ. P. 12(b)(1) because it fails to allege subject-matter jurisdiction, and because plaintiffs have failed to exhaust an available administrative remedy. The Court should also dismiss Counts II and IV-VI of the FAC pursuant to Rule 12(b)(6) because they fail to state a claim upon which relief can be granted.

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[1] Ctr. for Reproductive Rights, Governments Worldwide Put Emergency Contraception into Women's Hands, 7 (Sept. 2004), *available at* http://www.reproductiverights.org/pdf/pub_bp_govtswwec.pdf.

BACKGROUND[2]

Plan B is an FDA-approved EC. *See* FAC ¶ 58. It is manufactured and marketed by Duramed Pharmaceuticals, Inc. ("Duramed"), a wholly-owned subsidiary of Barr Pharmaceuticals, Inc. ("Barr Pharma"). *Id.* ¶ 8.

On January 29, 1999, Women's Capital Corporation ("WCC") – now a wholly owned subsidiary of Duramed – submitted to FDA a new drug application ("NDA") for approval of Plan B as a prescription drug. *Id.* ¶ 66. FDA approved the NDA on July 28, 1999. *Id.*

In April 2003, WCC submitted to FDA a supplemental NDA ("sNDA") to switch Plan B from Rx to OTC availability for all consumers. *Id.* ¶ 68. WCC sought what, in food and drug practice, is commonly called an "Rx-to-OTC switch."[3] On or about February 26, 2004, Barr Pharma acquired WCC. *Id.*

By correspondence dated May 6, 2004, FDA issued a Not Approvable Letter in response to the Plan B sNDA. *Id.* ¶ 69. FDA cited an alleged failure to demonstrate that adolescents under age 16 could use Plan B without professional supervision by a licensed medical practitioner. *Id*. In response, Duramed submitted an amended sNDA to retain Rx status for women under age 16, and to permit OTC availability for those age 16 and over. *Id.* ¶ 70. (Duramed maintains that Plan B is safe and effective OTC for all women who would use it.)

By letter dated August 26, 2005, FDA informed Duramed that FDA's Center for Drug Evaluation and Research ("CDER") had completed its review of Duramed's amended sNDA and had found that "the scientific data [are] sufficient to support safe use" of Plan B as an OTC product for women age 17 years and older. *Id.* Notwithstanding this scientific finding, FDA, in

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[2] Duramed Pharmaceuticals, Inc. contests many allegations in the FAC, but, pursuant to Rules 12(b)(1) and (6), takes those allegations as true (solely) for purposes of the present motion.

[3] *See, e.g.*, FDA, CDER, Manual of Policies and Procedures (MaPP 6020.5) 2 (Jan. 15, 1997), *available at* http://www.fda.gov/cder/mapp/6020-5.pdf.

the letter, refused to take final action on Duramed's sNDA, *id.*, and, indeed, delayed final action indefinitely. FDA stated that the sNDA presented the agency with the question whether and, if so, how to permit the distribution of one and the same pharmaceutical product to different populations for OTC and Rx use, and indicated that it would seek public comment on whether to initiate rulemaking to resolve those issues. *Id.*

On September 1, 2005, FDA published in the *Federal Register* an Advance Notice of Proposed Rulemaking ("ANPRM") (Docket No. 2005N-0345), which sought public comment on whether to initiate rulemaking regarding dual OTC/Rx labeling. 70 Fed. Reg. 52,050 (Sept. 1, 2005). FDA received approximately 47,000 comments in response. FAC ¶ 72.

On July 31, 2006, FDA sent to Duramed a letter stating that the agency had determined that it was unnecessary to engage in rulemaking to approve the sNDA. *Id.* ¶ 74. Finally, on August 24, 2006, more than three years after the filing of the initial sNDA, FDA approved OTC access to Plan B for use by women age 18 and older, and retained the prescription requirement for women age 17 and younger. *Id.* ¶ 76; Exhibit ("Ex.") 1 (the "FDA Decision").[4]

Currently, Plan B is sold in a single package containing labeling that describes the OTC use by women age 18 and older, and the Rx use by women age 17 and younger. Ex. 2.

On April 12, 2007 – more than eight months after FDA approved the sNDA – plaintiffs filed the present lawsuit. In response, FDA and Duramed filed motions to dismiss, which argued, *inter alia*, that plaintiffs did not allege sufficient facts to establish their standing to sue. On August 17, 2007, plaintiffs amended their Complaint in an attempt to cure those deficiencies. They did not succeed. Plaintiffs still do not allege that Plan B causes any direct harm to women or girls. FAC *passim*. Instead, plaintiffs allege that the availability of Plan B OTC will lead

[4] All exhibits are copies of materials incorporated in the FAC. In ruling on a motion to dismiss, the court may consider documents "attached to or incorporated in the complaint." *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997).

women age 18 and older to make ill-considered decisions regarding their health care, and that those decisions may, in turn, lead to harm; that younger women may obtain Plan B without a prescription illicitly; that the Plan B labeling is misleading; that physicians may lose money; and that pharmacists may be inconvenienced. FAC ¶¶ 18-26.

For the reasons set forth below, the FAC should be dismissed.

ARGUMENT

I. PLAINTIFFS LACK STANDING.

A. The Requirements for Standing.

Plaintiffs must establish that they have Article III standing. *See Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 472, 475 (1982). Plaintiffs must show that they have suffered "injury in fact" that is "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (internal quotations omitted). Plaintiffs must also establish "a causal connection between the injury and the conduct complained of," and that it is "'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Id.* (internal quotations omitted).[5] Where, as here, the parties invoking federal jurisdiction are not the object of the governmental action they challenge, standing is "substantially more difficult to establish." *Id.* at 562 (internal quotations omitted).

Plaintiffs must also establish that no "prudential" limitation prevents the Court from hearing their claims. *See Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11-12 (2004). In

[5] To the extent that plaintiffs allege procedural injury, "the normal standards for redressability and immediacy" are relaxed. *Lujan*, 504 U.S. at 572 n.7. However, "[t]he mere violation of a procedural requirement . . . does not permit any and all persons to sue to enforce the requirement." *Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996) (*citing Lujan*, 504 U.S. at 572-73). Plaintiffs alleging a procedural violation must have a concrete injury apart from an interest in having the procedure observed. *See Lujan*, 504 U.S. at 573 n.8.

the ordinary course, plaintiffs must sue on their own behalf, not on behalf of the interests of third parties. *Lujan*, 504 U.S. at 562. Plaintiffs cannot rely on general grievances of the population. *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Plaintiffs who seek to challenge an agency action under a statute, such as the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353(b) (2000) (as amended 2003), must be within "the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Valley Forge*, 454 U.S. at 475.

To establish organizational standing, a plaintiff organization must satisfy the standing requirements that apply to individuals. *See American Legal Found. v. FCC*, 808 F.2d 84, 89 (D.C. Cir. 1987). An organization suing not in its own right but on behalf of its members must demonstrate that: "(1) at least one of its members would have standing to sue in his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires that an individual member of the association participate in the lawsuit." *National Wrestling Coaches Ass'n v. Department of Educ.*, 366 F.3d 930, 937 (D.C. Cir. 2004). An organization challenging an agency action on that basis "must show . . . that at least one member has suffered injury in fact." *Public Citizen, Inc. v. National Highway Traffic Safety Admin.*, 489 F.3d 1279, 1289 (D.C. Cir. 2007).

The party invoking a court's subject-matter jurisdiction has the burden of establishing the elements required for standing, and "courts must accept as true all material allegations of the complaint." *Warth*, 422 U.S. at 501; *Lujan*, 504 U.S. at 560-61. Plaintiffs must "'allege . . . facts essential to show jurisdiction. If [they] fai[l] to make the necessary allegations, [they have] no standing.'" *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (internal quotations omitted) (alteration in original) (emphasis added), *modified in part on other grounds*, *City of Littleton v. Z.J. Gifts D-4, LLC*, 541 U.S. 774 (2004); *Lujan*, 504 U.S. at 560-61.

B. CWA and FRC Do Not Have Standing To Sue on Behalf of Women, and Parents of Girls.

1. CWA And FRC Do Not Allege Any Imminent Harm.

Plaintiffs Concerned Women for America ("CWA") and Family Research Council ("FRC") each sue on behalf of women and parents of girls. FAC ¶¶ 4, 5, 15.[6] They must allege facts showing that such individuals would have standing to sue. The FAC however, fails to make any specific allegation that any woman or parent of a girl has been or will be harmed. Instead, the FAC avers merely that Plan B's OTC availability may increase the risk that: (1) women will not obtain certain medical services, and will thereby increase the risk that their health will be negatively affected; (2) minor girls will obtain Plan B without a prescription; and (3) women will believe that Plan B should be used as regular birth control. FAC ¶¶ 18, 87. In sum, they allege that OTC availability of Plan B may indirectly increase women's risk of harm.

The D.C. Circuit recently rejected the very proposition CWC and FRA rely on here: that "'increased risk' is *itself* concrete, particularized, and *actual* injury for standing purposes." *National Highway*, 489 F.3d at 1297 (emphasis in original). It held that deeming "all purely speculative increased risks [to be] injurious" would render moot the entire requirement of actual or imminent injury. *Id.* at 1294. The court stated: "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." *Id.* (internal quotations omitted) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)) (standing cannot be premised on possible threat of future injury); *see also Center for Law & Educ. v. Department of Educ.*, 396 F.3d 1152, 1160-61 (D.C. Cir. 2005) ("Outside of increased exposure to environmental harms, hypothesized increased risk has never

[6] The FAC does not allege that CWA or FRC is suing on behalf of girls. If, and to the extent that either does seek to represent girls, it lacks standing for the same reasons that it lacks standing to represent women and parents of girls.

been deemed sufficient injury [to confer standing].").

The D.C. Circuit held that an organization challenging agency action establishes standing only if "the agency action causes an individual or individual members of an organization to face an increase in the risk of harm that is 'substantial,' and the ultimate risk of harm also is 'substantial.'" *National Highway*, 489 F.3d at 1296. "[T]he constitutional requirement of imminence as articulated by the Supreme Court . . . necessarily compels a very strict understanding of what increases in risk and overall risk levels can count as 'substantial.'" *Id.*

CWC and FRA allege neither that women, girls, or parents of girls face an increase in the risk of harm that is substantial, nor that the overall risk levels are also substantial, nor do they allege any facts that would substantiate such allegations, even had they been made.[7] On the basis of one study, plaintiffs allege that OTC access to Plan B causes a decrease in the medical visits, counseling, and screening of women. FAC ¶ 84. The study is Holly Stewart *et al*., The Impact of Using Emergency Contraception on Reproductive Health Outcomes: A Retrospective Review in an Urban Adolescent Clinic, J. Pediatric Adolescent Gynecology, 2003 Oct. 16(5) ("Stewart") (Ex. 3).[8] That study, however, completely fails to support their allegations.

First, although the study found that women receiving an EC at a clinic received additional medical services, the study did not include any women who received an EC OTC. Therefore, it

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[7] In deciding whether to dismiss a complaint for lack of subject matter jurisdiction, this Court need not accept conclusory factual allegations that are not supported by facts alleged in the complaint. *See Primax Recoveries, Inc. v. Lee*, 260 F. Supp. 2d 43, 47 (D.D.C. 2003). Therefore, this Court need not accept Plaintiffs' conclusion, unsupported by the alleged facts, that harm will result – indirectly – from OTC availability of Plan B.

[8] Plaintiffs do not cite the study by name. Instead, they refer to a study that two of them (and two other groups) cited in comments to FDA. FAC ¶ 84. The Stewart study is cited by name in those comments at page 23. *See* http://www.cwfa.org/images/content/planbfiling_CWA_%20FRC_e_%20al_11-01-2005.pdf (The comments incorrectly cite to the study as being published in October 2001. It was published in November 2003). The numbers cited in FAC ¶ 84 are the same as those attributed to the Stewart study in the comments at 23.

did not show that women who receive an EC OTC fail to receive medical care they need or fail to receive, by means other than a clinic visit to obtain an EC, medical care equal to that received by women who obtain an EC at a clinic. Second, the study did not address whether women who receive an EC by prescription (*e.g.*, a telephonic prescription) receive the same medical care as women who receive it at a clinic.[9] Third, there is no reason to believe that women who receive an EC at a clinic are representative of women who use Plan B purchased OTC. Fourth, the study addressed use of ECs by girls and young women ages 13 to 20, with a mean age of 16.8, *id.* at 315-16; and, of course, under the FDA Decision, participants 17 years of age and younger would still have needed a prescription to purchase Plan B. In sum, on its face, the Stewart study is irrelevant to OTC access to Plan B, and provides no support for plaintiffs' claims.

2. Plan B's Labeling Does Not Support Standing for Women or the Parents of Girls.

The FAC alleges that Plan B's labeling is misleading. FAC ¶¶ 85-87. The FAC fails to allege any concrete harm from the labeling, however. Rather, its allegations relate to the effectiveness, not the safety, of Plan B. *Id.* Moreover, the relief the FAC seeks – vacation of FDA's approval – would not redress the alleged deficiency (which would remain in the Rx

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[9] The Stewart study also found that using an EC is not associated with increased risk of future sexually transmitted infections among adolescent girls. Indeed, it found that the control subjects had a higher incidence of Chlamydia. Stewart at 317. Thus, as to the patients at clinics, the Stewart study contradicts the speculations in FAC ¶ 83.

Even if the study had shown that female patients representative of the general population of users of Plan B visit doctors less frequently when Plan B is available OTC, it would not support the FAC's speculative allegations of possible harm. Information on how many times women visit their doctors does not address (i) the number of such visits that are needed for protection of health, (ii) the quality of the visits that do occur, or (iii) whether during those visits doctors provide information about contraception. To the extent that plaintiffs claim that a reduction in physician visits results in patients obtaining less healthcare information and less healthcare generally, *see* FAC ¶ 82, their claim appears to be that it is unlawful for FDA to fail to use its authority to restrict every drug to Rx-only status to compel consumers to contact doctors so as to be counseled about medical services that might improve their health. Thus, plaintiffs' grievance applies to every drug available OTC, and should be rejected on that ground.

labeling). Indeed, there is no precedent for, and no logic supports, restriction to Rx status of a drug, or a use of a drug, that is otherwise safe and effective when the drug is dispensed OTC but whose labeling is deficient in some way. If Plan B's labeling is deficient, the appropriate remedy is not to vacate the FDA Decision and restrict Plan B to Rx status, but to correct the labeling.[10] To obtain that (or any other) relief, CWA and FRC have an administrative remedy they have not invoked: a citizen petition under 21 C.F.R. §§ 10.25, 10.30 (2007). *See* pp. 19-21, *infra*.

CWA's and FRC's allegations of standing to sue as to the contents of Plan B's labeling apparently are based on *FEC v. Akins*, 524 U.S. 11 (1998), and *Public Citizen v. FTC*, 869 F.2d 1541 (D.C. Cir. 1989), which plaintiffs cited in opposing Duramed's motion to intervene. *See* Opposition to Motion to Intervene 9 (filed July 13, 2007). Both cases are easily distinguishable.

In *Akins*, standing was premised on the fact that the challenged agency decision denied statutorily-mandated information that the plaintiffs could obtain only if the Federal Election Commission ("FEC") ordered a third party, the American Israel Public Affairs Committee ("AIPAC"), to publicly disclose information held only by the AIPAC. *Akins*, 524 U.S. at 20. AIPAC would not provide that information unless ordered by the FEC to do so. Moreover, standing was based on the court's finding – on the basis of an interpretation of the particular statute at issue – that "Congress, intending to protect voters such as respondents from suffering the kind of injury here at issue, intended to authorize this kind of suit." *Id.* (emphasis added).

The plaintiffs' theory in *Akins* was that the statute required the FEC to compel the AIPEC to provide information to the plaintiffs. Here, to the contrary, the plaintiffs' theory is not that section 353(b) requires FDA to compel physicians to provide information to prospective users of

[10] Adopting plaintiffs' position that a need for a labeling change would require revocation of the approval of an sNDA (and, presumably, an NDA), instead of merely an amendment of the labeling, would place enormous burdens on FDA; and consumers would be subject to intermittent availability of needed medicines. For example, over 90 sNDAs for labeling revisions were approved in August 2007 alone. *See http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.Supplements*.

Plan B but, rather, that it requires FDA to compel prospective users of Plan B to seek information from physicians. This entirely different kind of theory – not compulsion exerted on sellers of a product, but compulsion exerted on prospective buyers of a product – finds no support in *Akins*. Moreover, whereas in *Akins* the statute supported compulsion of sellers to provide information, here one of Congress's principal objectives in enacting section 353(b) was to avoid unnecessary compulsion of prospective buyers (through an Rx requirement) where FDA finds that a new drug is safe and effective for OTC use. *See infra* pp. 22-33.

Moreover, the *Akins* plaintiffs could not, on their own, have obtained the information they wanted from the APIAC because the AIPAC would not have given it to them. By contrast, here, even with the FDA Decision, patients contemplating use of Plan B or their parents may, on their own, consult physicians before buying or using Plan B, and may obtain information from them (or from any other source). If a woman who obtains Plan B OTC foregoes consultation with a physician or foregoes an office visit at which she could receive information or medical services, she does so not because the FDA Decision prevents her from doing so but because she chooses not to do so. In sum, the kind of harm that supported standing in *Akins* does not exist here.

CWA and FRC fare no better by relying on *Public Citizen*. There, the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-4408, required producers and distributors of smokeless tobacco products to include specified health warnings on all advertisements for their products. *Public Citizen*, 869 F.2d at 1542. Public Citizen challenged a regulation by the Federal Trade Commission ("FTC") that expressly exempted from the warning requirement "utilitarian objects for personal use . . ." *Id.* The court found standing because the statute expressly provided that a warning was to be placed on smokeless tobacco products, and plaintiffs' action, if successful, would require warnings on utilitarian products. *Id.* at 1547.

Without the warnings, there was "[a]n infringement of an individual's statutory right to receive information . . . " *Id.* at 1548. The FAC here, however, does not identify any statute that entitles CWA or FRC to obtain the type of labeling information – comparison of efficacy for emergency contraceptives for an entire year only – they claim to have been denied.

Moreover, here there is no injury sufficient to confer standing. The information CWA and FRC allege they are entitled to receive is already in Plan B's labeling. The FAC alleges that the labeling misleadingly compares the efficacy rate for perfect use in a single instance with the failure rates of traditional contraceptives for both typical and perfect use over an entire year. FAC ¶ 86. It also alleges that the labeling uses the words "not recommended" and "not intended" instead of "not effective" for routine contraceptive use. It urges that the labeling warn consumers that Plan B is "'not effective for routine use' or words to that effect." *Id.* ¶ 87.

Plan B's labeling already addresses both concerns: In the "Drug Facts" box, the section on "Other Information" states: "It does not work as well as most other birth control methods used correctly." Ex. 2, at 2. The section on "Warnings" states: "**Do not use** . . . for regular birth control." *Id.* (emphasis in original). The package insert for patients states: "Emergency contraceptives are not as effective as routine contraception since their failure rate, while low based on a single use, would accumulate over time with repeated use (see Warnings)." *Id.* at 5 (emphases added).[11] The accompanying chart manifestly does not compare Plan B's rate of effectiveness with those of birth control methods for routine use: each of the latter is a line item in the chart, but there is no line item for Plan B. *Id.* at 6. The 75% figure rate cited in FAC ¶ 86 is in a separate box below the chart. Even if the implied failure rate of 25% were compared to the failure rates in the chart, it would be higher than every other one except chance and the cap

[11] The Warnings in the package insert state: "**Plan B is not recommended for routine use as a contraceptive.**" Ex. 2 at 7 (boldface and underlining in original).

for parous women. *Id.* In sum, the labeling uses the words "not as effective," and warns that the efficacy rate for single use should not be compared to that for use of routine contraception over time. Therefore, CWA and FRC cannot premise standing on a denial of information, or a presentation of misleading information, in Plan B's labeling.[12]

3. There Is No Causation.

CWA and FRC also cannot establish the causation element of standing. The FAC is based on the purely conjectural claim that women age 18 and older who obtain Plan B OTC will not seek a physician's advice when needed. Nothing in Plan B's dual OTC/Rx availability and marketing, however, prohibits physicians from addressing with their female patients any topics relevant to their health. Moreover, under the FAC's allegations, if, and to the extent that, women suffer injuries when Plan B is available OTC, those injuries would stem from the women's own decisions regarding health care and contraception, not from the use of Plan B or from the FDA Decision. Such intervening causal events squarely preclude Article III standing. *See, e.g.*, *Brotherhood of Locomotive Eng'rs & Trainmen v. Surface Transp. Bd.*, 457 F.3d 24, 28 (D.C. Cir. 2006) (self-inflicted injury does not support standing).

CWA's and FRC's allegations as to the increased risk to girls age 17 and younger do not support any claim. The legal and medical situation as to them is precisely the same as it was prior to FDA's decision: they can purchase Plan B only by prescription.

The FAC alleges that underage a female who lacks a prescription may obtain Plan B from someone age 18 or older who bought it OTC. FAC ¶ 95. The FAC alleges no facts, however, as

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[12] The Label Comprehension Study, cited at FAC ¶ 88, does not support plaintiffs' claims because: (1) the Plan B labeling was amended after the Label Comprehension Study; and thus the inferences that plaintiffs seek to draw as to the now superseded labeling are irrelevant; and (2) the Study found that the majority of subjects could understand the proposed OTC label with regard to the indication for Plan B, and could recognize common and severe adverse events. *See* Ex. 4 (Plan B OTC Label Comprehension Study) at 348.

to such transfers of Plan B since it became available OTC, or as to studies or foreign experience relating to ECs suggesting that such transfers are likely to occur to any appreciable extent.

Even if such transfers were alleged, they would not be caused by the FDA Decision or by Plan B's OTC availability. Instead, they would be caused by the independent decisions and actions of third parties: the underage users who sought Plan B without a prescription, and the persons age 18 or older who provided it to the underage users. Exactly the same "harm" could occur with no OTC availability if women who obtained Plan B with a prescription provided it to women or girls who had no prescription. Standing cannot be based on these allegations because they are speculations about the actions of third parties, and because those parties' actions breach the causal connection. *Brotherhood of Locomotive Eng'rs & Trainmen*, 457 F.3d at 28.

4. CWA Does Not Meet the Germaneness Requirement for Organizational Standing, and FRC Does Not Allege that It Has Members.

CWA does not allege that the interests it seeks to protect in this case are germane to its organizational purposes. CWA claims merely to represent women and men before governmental bodies on issues of specific interest to women, and that it has been active in reproductive issues. FAC ¶ 4. CWA does not allege its organizational mission or purpose. The allegation that it is involved in reproductive issues fails to indicate whether such involvement is germane to its official mission or purpose. The Court, therefore, has no basis upon which to determine whether standing in this case is consistent with CWA's organizational mission or purpose.

FRC does not even allege that it is a membership organization, that it has any members, or who its members are. *See* FAC ¶ 5. Therefore, the FAC provides no basis for finding that FRC has standing on the basis of the interests of its members (if it has any).

C. AAPS and SDW Do Not Have Standing To Sue on Behalf of Physicians and Pharmacists.

1. AAPS's Members Are Not Within the Zone of Interests Protected by the FDCA.

AAPS represents physicians only. *Id.* ¶ 3. AAPS alleges that doctors will lose revenue if Plan B is made available OTC. *Id.* ¶¶ 19-20. However, a "loss-of-revenue injury" does not create standing here because it fails the "zone of interests" test for prudential standing. *See Calumet Indus., Inc. v. Brock*, 807 F.2d 225, 228 (D.C. Cir. 1986). As the Supreme Court has explained: "In cases where the plaintiff is not itself the subject of the contested regulatory action, the [zone of interests] test denies a right of review if the 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." *Clarke v. Securities Indus. Ass'n*, 479 U.S. 388, 399 (1987). The pecuniary interests of physicians are not among those within the scope of the FDCA's description of FDA's mission under the FDCA, 21 U.S.C. § 393(b). AAPS's asserted interest in profit is not even marginally related to the FDCA, whose "comprehensive scheme of drug regulation is designed to ensure the nation's drug supply is safe and effective." *United States v. Sage Pharms., Inc.*, 210 F.3d 475, 479 (5th Cir. 2000); *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 50 (D.D.C. 2003) ("[T]he legislative intent behind enactment of the original FDCA was to protect the public from unsafe drugs."), *aff'd*, 353 F.3d 947 (D.C. Cir. 2004).[13] Had Congress intended to maximize physicians' profits by maximizing patients' visits to doctors, it would not have provided for OTC availability of drugs at all.

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[13] *Calumet* rejected a claim of standing by manufacturers of certain lubricating oils to challenge OSHA's exclusion of competitors' oils from "health hazards" labeling requirements. 807 F.2d at 226. The court held that, because the plaintiffs were not regulated by the agency action they challenged and because "the interest to be protected by the [OSHA] is worker safety and *not* business profits," petitioners' interests, "as entrepreneurs seeking to protect their competitive interests," did not meet the test for prudential standing. *Id.* at 228 (emphasis in original). Similarly here, the FDCA is intended to protect consumers, not physicians' profits.

The claimed pecuniary injury also results from women's own independent decisions to seek or not seek physicians' services. Therefore, AAPS's theory also fails to establish the "causal connection between the injury and the conduct complained of," required by *Lujan*, 504 U.S. at 560, for Article III standing.

2. AAPS and Its Members Cannot Sue on Behalf of Third Parties.

AAPS claims that its members' patients and customers will be harmed by the FDA Decision. FAC ¶¶ 21-22. This claim is not one of harm to AAPS or to its members, but to the members' patients and customers. The claim is thus beyond the ordinary claim of organizational standing to seek redress for harm to an organization's members. AAPS is at two removes from the alleged harm, not just one.

AAPS's claims of harm, in any event, are nonsensical. The FAC asserts that Plan B's OTC status will deny AAPS's members' patients the ability to vindicate their own rights. *Id.* But Plan B's OTC status does not deny any right of any woman. All women potentially affected by the FDA Decision are free to seek a physician's advice (and, indeed, as to women age 18 or older, a physician's unnecessary prescription) whenever they consider buying Plan B. The claim that granting women age 18 and older a right (to obtain Plan B OTC) denies them a right (to be compelled to consult a medical practitioner if they want Plan B) is Orwellian.

Indeed, plaintiffs allege that they have "close and confidential relationships with their patients." FAC ¶ 21. This allegation highlights the illogic of AAPS's theory of standing. AAPS claims, without any supporting particular facts, that its members' patients "lack a formal understanding of the risks posed by foregoing medical screening and by using Plan B without fully understanding the potential complications." *Id.* Yet it is the very "close and confidential relationship" between AAPS's members and their patients that can and should prevent this very "harm." There is, simply put, no harm because, at any visit, an AAPS member can communicate

the need for the broad range of medical services alleged in FAC ¶ 82 to the female patients, with whom the member has the alleged "close and confidential relationship." If AAPS contends that its members cannot communicate that information because the women choose never to consult them, then the members (and AAPS) lack the type of close relationship required under the standing doctrine to sue on behalf of women and the parents of girls, *see Lujan*, 504 U.S. at 562.

AAPS's right to sue on behalf of patients fails for another reason. The FAC alleges, in effect, that physicians have an economic interest in objecting to competition from pharmacists. FAC ¶¶ 19-20. The established understanding is that increased competition benefits consumers. *See, e.g.*, 2B Phillip E. Areeda et al., *Antitrust Law: An Analysis of Antitrust Principles and Their Application* 4–5 (3d ed. 2007). Here, the FAC alleges that, as suppliers of services to consumers, AAPS's members have standing to argue, on behalf of consumers of those services, that competition should be reduced. The patent illogic of that position and the bias that arises from the alleged economic interest of physicians in reducing competition, FAC ¶ 19, to the disadvantage of their patients preclude standing for AAPS on the basis of a finding that its physician members have standing as representatives of the members' patients age 18 and older who want Plan B.[14]

3. No Harm Is Alleged to SDW's Members.

The FAC asserts that the FDA Decision subjects pharmacist members of Safe Drugs for Women ("SDW") to "expanded legal liability." FAC ¶ 24. Although the FAC refers darkly to "selling a misbranded drug," *id.* ¶ 23, and to exposure to "tort liability," *id.* ¶ 24, it alleges no facts that could constitute such liability. In sum, it fails to identify any "expanded liability" –

[14] A number of States permit pharmacy access to emergency contraceptives without the involvement of a medical doctor, without regard to the FDA Decision. *See* http://www.ec-help.org. The alleged "competition" between pharmacist and doctors would not support standing for plaintiffs' members from these States.

because there is none. The only change made by the FDA Decision is that pharmacists may now sell Plan B OTC to customers age 18 and older. If pharmacists take suitable steps to ensure that the customers to whom they sell Plan B OTC are age 18 or over, they face no added liability.

The mere possibility that some pharmacist may improperly sell Plan B OTC to a customer under age 18, and may, as a result, incur liability, does not create standing. "When plaintiffs do not claim that they have ever been threatened with prosecution, that a prosecution is likely, or even that a prosecution is remotely possible, they do not allege a dispute susceptible to resolution by a federal court." *Babbitt v. United Farm Workers Nat'l Union,* 442 U.S. 289, 298-99 (1979) (internal quotations omitted); *see also Takhar v. Kessler*, 76 F.3d 995, 1000 (9th Cir. 1996) (rejecting possibility of future prosecution as basis for standing because plaintiff did not "set forth any [allegations of] concrete or actual threat of prosecution," and rejecting each of his "fear of prosecution" allegations as too speculative to create standing).

Next, SDW's allegation of "added expense and administrative burdens," FAC ¶ 25, is purely conjectural. The FAC does not allege any particular facts that would enable the Court to assess the alleged "added expense and administrative burdens" on pharmacists. No alleged facts show that the cost or burden of dispensing Plan B OTC exceeds the cost or burden of dispensing it Rx. Indeed, for pharmacists, OTC dispensing probably involves less cost and burden. They no longer have to ensure that a customer age 18 or older has a valid prescription for Plan B, and no longer have to maintain such customers' prescriptions on file. They no longer have to take the time to accept and record telephonic prescriptions of Plan B for such customers.[15]

[15] The FAC asserts that the FDA Decision imposes on pharmacists "requirements not applicable to either OTC or Rx drugs. Under Plan B's distribution scheme under the 'CARE' program, such pharmacists must involve themselves directly in sales that cashiers previously could handle." FAC ¶ 25. These conclusory allegations are not supported by any alleged facts. Nothing in the FDA Decision requires any pharmacist to substitute for a cashier, or otherwise imposes on pharmacists any burden that does not already exist as to other OTC and Rx drugs. Pharmacists already are responsible for dispensing age-restricted OTC nicotine-replacement drug

A pharmacist does have to confirm the age of a customer seeking Plan B OTC, but doing so is a simple and quick process, easily accomplished by having a pharmacy clerk ask for valid government-issued identification. Even if doing so were an "added expense and administrative burden" compared to Rx dispensing, the increase plainly would be *de minimis*.

The FAC also alleges that, under the "CARE" program, unlike when Plan B was available only Rx, pharmacists must "often" involve themselves directly in the sales of Plan B, *e.g.*, when there is only one pharmacist on duty. This possibility, the FAC alleges, could subject pharmacists to "compelled speech." FAC ¶ 26. These allegations are incoherent. Any pharmacist's conscience-based objections to Plan B would apply whether Plan B is available Rx or OTC . Even if Plan B were Rx only, every unit of it would be dispensed under the supervision of a pharmacist; and, if only one pharmacist were on duty, he or she would dispense it. The FDA Decision does not determine whether more than one pharmacist is on duty at any given time or when a pharmacist, rather than a clerk supervised by a pharmacist, must personally provide the product. Finally, confirming a customer's age is not compelled speech in any legally cognizable

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products. In his memorandum explaining the FDA Decision, Commissioner Von Eschenbach notes: "[R]etail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products. With regard to drug products, for example, the legal age to purchase FDA approved non-prescription nicotine replacement therapy products is 18. Moreover, I also understand that as a matter of state law many products routinely sold by pharmacies, *e.g.*, tobacco products and nonprescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older." Ex. 5 at 1 (Memorandum from Andrew C. Von Eschenbach, M.D., to NDA 21- 45, S-011 (Aug. 23, 2006)) A pharmacist's responsibility for supervising the correct dispensing of Plan B is no more burdensome than the analogous responsibility for supervising the correct dispensing of Rx drugs after they have been prepared and are awaiting customer pick-up. The pharmacist need not personally interact with customers.

sense. If it were, age restrictions on the sale of tobacco products, alcoholic beverages, and OTC nicotine-replacement therapies would be in jeopardy under the First Amendment.[16]

Finally, FAC ¶ 30 alleges, on the basis of FAC ¶ 46, that pharmacists are within the zone of interests protected by 21 U.S.C. § 353(b). The only interest of pharmacists referred to in ¶ 46 is an interest in clarity as to whether a drug is to be dispensed Rx or OTC. The FAC fails to allege any harm to that interest. It fails to allege that the legend "Rx only for women age 17 and younger" is unclear, or has confused any pharmacist. Thus, the FAC fails to allege any harm to the one interest of pharmacists it alleges is protected by section 353(b).

II. PLAINTIFFS HAVE FAILED TO EXHAUST AN AVAILABLE ADMINISTRATIVE REMEDY.

There is an independent basis for dismissal of the FAC: plaintiffs have failed to exhaust an available administrative remedy, *i.e.*, that provided by 21 C.F.R. § 10.25(a) (2007), which provides: "An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." *See also* 21 C.F.R. § 10.30 (2007).[17] Plaintiffs are required to file a citizen petition under those provisions before seeking judicial relief. *See*, *e.g.*, *Garlic v. FDA*, 783 F. Supp. 4 (D.D.C. 1992) (dismissing complaint against FDA for failure to exhaust administrative remedies by filing a citizen's petition); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 6-7 (D.D.C. 1989) (same).[18]

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[16] The FDA Decision does not compel any pharmacy to stock Plan B or any pharmacist, as a matter of professional responsibility, to dispense it. Those are matters for private decision and state law.

[17] Plaintiffs' allegation that "neither FFDCA nor any other provision of law provides an alternate legal remedy for Plaintiffs' injuries," FAC ¶ 36, is, as a matter of law, simply incorrect. *See* 21 C.F.R. §§ 10.25, 10.30. FAC ¶ 37 reflects a lack of understanding of the concept of an adequate administrative remedy: *i.e.*, one that may result in the agency action plaintiffs seek.

[18] These decisions demonstrate that that the *Federal Register* preambles cited in FAC ¶ 31 do not bind the Department of Justice or this Court, and, indeed, have no operative effect.

In *Association of Flight Attendants-CWA v. Chao*, 493 F.3d 155 (D.C. Cir. 2007), the D.C. Circuit recently re-affirmed the requirement of exhaustion of administrative remedies:

> "[N]o one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51, 58 S. Ct. 459, 82 L. Ed. 638 (1938). Broadly speaking, the doctrine of exhaustion of administrative remedies "serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency." *McCarthy v. Madigan*, 503 U.S. 140, 145, 112 S. Ct. 1081, 117 L. Ed. 2d 291 (1992). The exhaustion requirement ensures that agencies-and not the federal courts-take primary responsibility for implementing the regulatory programs assigned by Congress. *Id.*; *see also McKart v. United States*, 395 U.S. 185, 193-95, 89 S. Ct. 1657, 23 L. Ed. 2d 194 (1969).

Id. at 158 (alteration in original). The court dismissed a suit by unions seeking to compel the FAA and OSHA to regulate the airline industry's working conditions because the unions had not exhausted available administrative remedies. *Id.*

In *Garlic*, plaintiffs suffering from Alzheimer's Disease challenged FDA's failure to approve a certain drug to treat the disease. This Court summarily rejected plaintiffs' argument that filing a citizen petition was not mandatory: "The provision for review of the Commissioner's final decision confirms that the procedure is intended to allow the FDA to develop its policy without judicial interference. The procedure also allows the FDA to produce an administrative record for the reviewing court to consider." *Garlic*, 783 F. Supp. at 4-5. The Court further cautioned that permitting "'interested parties' to bypass administrative remedies would undermine the entire regulatory process." *Id.* at 5. That reasoning applies here.

Plaintiffs do not allege that they were not required to exhaust the available administrative remedy, or that any of the limited exceptions to the exhaustion requirement, *see Chao*, 493 F.3d

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FAC ¶ 56 asserts that 21 C.F.R. § 10.45(e) "acknowledge[s] that an interested person may seek judicial review without first petitioning the Commissioner." What section 10.45(e) actually states is: "An interested person may request judicial review of a final decision of the Commissioner . . . without first petitioning the Commissioner for reconsideration or for a stay of action . . . ." 21 C.F.R. § 10.45(e) (2007) (emphasis added).

at 158, applies here. Instead, plaintiffs seek a blanket ruling from this Court that FDA lacks authority to impose a "mandatory" administrative process. FAC ¶¶ 28, 136. What makes exhaustion of the remedy provided by sections 10.25 and 10.30 mandatory, however, is not anything FDA has done (beyond providing the remedy) but the judicially-created exhaustion doctrine. In effect, plaintiffs ask this Court to overturn that entire doctrine.

That request is flatly contrary to, *e.g.*, the authorities cited in the passage from *Chao* quoted on page 20, *supra*. *See also Forsham v. Harris*, 445 U.S. 169, 174 n.3 (1980) (noting without disapproval that court of appeals had remanded to FDA for exhaustion of administrative remedies litigation to enjoin proposed labeling); *Public Citizen Health Research Group v. Commissioner, FDA*, 740 F.2d 21, 28 (D.C. Cir. 1984) (applying exhaustion requirement).

This Court should decline to hear plaintiffs' claims until plaintiffs have exhausted the administrative remedy available to them.

III. COUNTS II AND IV-VI FAIL TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED.

Counts II and IV-VI of the FAC should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) for "failure to state a claim upon which relief can be granted."

In *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955 (2007), the Supreme Court recently clarified the pleading standard under Fed. R. Civ. P. 8(a), and its application to motions to dismiss under Rule 12(b)(6). The Court expressly "retire[d]" the "famous observation" that "the accepted rule [is] that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief" *Id.* at 1968-69 (*quoting Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). "The phrase is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Id*. at 1969.

Twombly held, instead, that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1964-65 (alterations in original) (citations omitted). "Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact) . . . ." *Id.* at 1969 (citation and footnote omitted). Thus, the adequacy of a complaint now depends on the sufficiency of "[f]actual allegations," not speculations.

A. Count II Fails To State a Claim Upon Which Relief Can Be Granted Because It Is Based on an Incorrect Statutory Interpretation.

Under the Administrative Procedure Act ("APA"), the Court may vacate the FDA Decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (2000). This standard is very deferential to the agency. *See Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Accordingly, "there is a presumption in favor of the validity of [the] administrative action [in an action challenging FDA's interpretation of the FDCA]." *Teva Pharm., Indus., Ltd. v. FDA*, 355 F. Supp. 2d 111, 116 (D.D.C. 2004) (*quoting Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996)) (first alteration in original), *aff'd sub nom. Teva Pharm. Indus., Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

FDA has interpreted 21 U.S.C. § 353(b) as permitting, in certain circumstances, an active ingredient to be distributed simultaneously in both an Rx drug product and an OTC drug product. *See* 70 Fed. Reg. at 52,051. In Count II, plaintiffs challenge FDA's interpretation of section 353(b). They contend that it "authorizes approval of a drug product for only one of two mutually exclusive modes of distribution and labeling." FAC ¶ 102. Plaintiffs are dead wrong.

Plaintiffs' approach, requiring that all uses of a drug be either OTC or Rx, is wrong as a matter of statutory construction and public policy, because it is contrary to the text (discussed *infra*) and a key objective of section 353: "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." Ex. 6 (S. Rep. No. 82-946, at 1-2 (1951)). By contrast, FDA's interpretation, which permits OTC availability for use of a drug by one patient population, and Rx availability for use by another, is consistent with the statutory text and serves the statutory objectives – to ensure that drugs for which supervision by a doctor is needed for safety and effectiveness are available only by prescription, while also ensuring that drugs that are safe and effective for OTC use are available to the appropriate patient population without a prescription.

FDA's interpretation should be upheld at step one of the analysis under *Chevron U.S.A., Inc. v. National Res. Def. Council*, 467 U.S. 837 (1984), because it is required by the unambiguous statutory text, or, alternatively, at step two, because FDA's interpretation is reasonable and, therefore, must be given deference. The FDA Decision approving the Plan B sNDA was not "arbitrary and capricious, an abuse of discretion, or otherwise contrary to law" under the APA. Accordingly, this Court should dismiss Counts II.

1. Count II Fails Because the Unambiguous Text and Objectives of Section 353(b) Require FDA's Interpretation Permitting a Drug, in Appropriate Circumstances, To Be Dispensed Rx to One Patient Population and OTC to Another.

The text of section 353(b)(1) and (3) and the objectives plainly evident in the text – to require a prescription where necessary (§ 353(b)(1)) and to permit OTC availability where a prescription is unnecessary (§ 353(b)(3)) – require FDA's interpretation permitting a drug to be dispensed Rx to one patient population (for which a prescription is necessary) and OTC to another (for which a prescription is unnecessary). Plaintiffs' contrary interpretation would fail to implement section 353(b)(1) or 353(b)(3), and so is contrary to the statutory text and objectives.

Section 353(b)(3), which plaintiffs allege does not support FDA's approval of Plan B for Rx availability to one patient population and OTC availability to another, should be construed in light of section 353(b) as a whole. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989).

The text of section 353(b)(1) protects consumers from the dangers arising from OTC dispensing of drugs for which a physician's supervision is necessary for safe and effective use. This provision authorized FDA to restrict Plan B to Rx use by women age 17 and under.

The text of section 353(b)(3) addresses Congress's countervailing concern that consumer access to medications that are safe and effective for OTC use not be unduly impaired by a prescription requirement. It authorizes FDA, "by regulation," to determine as to a particular drug or a group of drugs that the requirements of section 353(b)(1) "are not necessary for the protection of the public health." 21 U.S.C. § 353(b)(3). FDA has promulgated the regulation contemplated by section 353(b)(3): 21 C.F.R. § 310.200(b) (2007). *See also* 21 C.F.R. § 330.10(a)(4)(vi) (2007). Section 353(b)(3), together with section 310.200(b), authorized FDA to permit Plan B to be dispensed OTC to women age 18 and older.

The express words of section 353(b)(3) are that FDA "may by regulation remove drugs subject to [21 U.S.C. § 355, *i.e.*, "new drugs"] from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health." In that statutory expression, the term "regulation" is singular, not plural; and the term "drugs" is plural, not singular. Thus, section 353(b)(3) unambiguously contemplates and authorizes removal by one regulation of multiple new drugs from the prescription requirement of section 353(b)(1). FDA has promulgated such a regulation, 21 C.F.R. § 310.200(b), which removes new drugs with certain characteristics from section 353(b)(1). Having once promulgated that

regulation, FDA thereafter need only decide by informal adjudication, case by case, whether this or that particular new drug satisfies the criteria stated in the regulation. Each set of conditions prescribed, recommended, or suggested in the labeling of an approved new drug constitutes a different new drug.[19] Therefore, section 353(b)(3) plainly and unambiguously authorizes FDA's interpretation of it here, which plaintiffs challenge.

That interpretation also serves the objectives manifest in the text of section 353. Section 353(b)(2), supplemented by section 353(b)(4), ensures that pharmacists receive from drug manufacturers adequate guidance regarding the lawful marketing and dispensing of drugs. *See* 21 U.S.C. § 353(b)(2), (4). Those provisions require that drugs be dispensed with an "Rx only" label if they are subject to a prescription limitation under section 353(b)(1).

This regulatory scheme, as interpreted and implemented by FDA, strikes the congressionally intended balance between ensuring that drugs for uses for which a prescription is needed are Rx only under section 353(b)(1), and that drugs for uses for which a prescription is not needed are available OTC under section 353(b)(3). Plaintiffs' proposed interpretation would upset this balance by denying FDA the authority and flexibility it needs (and that FDA's interpretation provides) to classify particular uses of drugs as Rx or OTC on a use-by-use basis

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[19] Under 21 C.F.R. § 310.3(h)(5) (2007), where a new drug is used by two different patient populations, the drug in each of those uses is a different "new drug." Any "new drug" needs approval by FDA. 21 U.S.C. § 355(a) (2000). (The term "new drug" is defined in 21 U.S.C. § 321(p).) The population for which a drug is recommended in its labeling is a "condition" within the scope of section 310.3(h)(5). Thus, where the labeling of a new drug provides for its use in two different patient populations, as to each such population the new drug is a different new drug. The reason why a manufacturer that has an approved NDA and seeks to expand the use of the approved new drug to an additional patient population (*e.g.*, a population with a less or more severe stage of the disease for which the new drug is already indicated or for a population with a different disease) must obtain FDA approval of an sNDA, *see* 21 C.F.R. § 314.70(b)(2)(v)(A), (C) (2007), is that such expansion creates a "new drug" that is different from the "new drug" previously approved. Thus, as a technical legal matter, a new drug with an FDA-approved NDA may constitute multiple different new drugs – one for each set of conditions prescribed, recommended, or suggested in its labeling.

as the circumstances of each drug separately warrant. Therefore, plaintiffs' theory of section 353(b) is contrary to the statutory text and the statutory objective of avoiding a prescription requirement where it is unnecessary for safe and effective use of a drug.

Indeed, plaintiffs' interpretation would lead to the absurd result of requiring FDA to regulate drugs as Rx-only for all uses by all patient populations even where the drugs are safe and effective for OTC use by certain patient populations. That interpretation fails because "interpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available." *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982); *FTC v. Ken Roberts Co.*, 276 F.3d 583, 590 (D.C. Cir. 2001).

2. Alternatively, Count II Fails Because FDA's Interpretation Is Reasonable and Entitled to Deference at *Chevron* Step Two.

FDA's statutory interpretation is entitled to deference under *Chevron* because it is reasonable. 467 U.S. at 844; *see also Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (granting FDA's interpretation of FDCA *Chevron* deference at step two). At a minimum, FDA's interpretation, like that of any agency interpreting its organic act, is entitled to respectful consideration under *Skidmore v. Swift & Co.*, 323 U.S. 134, 139-40 (1944).

a. FDA's August 24, 2006 Approval Letter Merits *Chevron* Deference.

The issues relating to Plan B arose in the context of a supplement to an NDA. Final FDA action on an NDA or supplement takes the form of a letter. *See* 21 C.F.R. §§ 314.105, 314.125 (2007). An approval letter is a form of license; a letter refusing approval is a denial of a license. In APA terms, each such letter is an "order" within the meaning of 5 U.S.C. § 551(6) (2000); and an administrative proceeding on an NDA or supplement is an informal "adjudication" within the meaning of 5 U.S.C. § 551(7). FDA approved the sNDA on August 24, 2006. FAC ¶ 76; Ex. 1.

Both the Supreme Court and the D.C. Circuit have granted *Chevron* deference to statutory interpretations embodied in agency documents indistinguishable from FDA's August 24, 2006 letter and related FDA memoranda. In *Barnhart v. Walton*, 535 U.S. 212 (2002), the Court held that there is no bar to granting deference to an agency interpretation that did not emerge from notice-and-comment rulemaking. *Id.* at 222. Instead, it held that "whether a court should give such deference depends in significant part upon the interpretive method used and the nature of the question at issue." *Id.* (*citing United States v. Mead Corp.*, 533 U.S. 218, 229-31 (2001)). The Court held that deference to the agency's interpretation was due because of "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." *Id.*

In *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004), the D.C. Circuit granted *Chevron* deference to an FDA letter because "[t]here is no denying the complexity of the statutory regime under which the FDA operates, the FDA's expertise or the careful craft of the scheme it devised to reconcile the various statutory provisions. Further, the FDA's decision made no great legal leap but relied in large part on its previous determination of the same or similar issues and on its own regulations." *Id.* at 1280.

Similar circumstances here require *Chevron* deference to FDA's interpretation of section 353(b), as reflected in 21 C.F.R. §§ 310.200(b) and 330.10(a)(4)(vi) and in its letter approving the Plan B sNDA. FDA's interpretation (i) involves the exercise of scientific and medical judgment regarding the safety and effectiveness of Plan B when dispensed OTC for use by women age 18 and older and when dispensed Rx for use by women age 17 and younger; (ii) is the product of a number of formal adjudications (the Plan B adjudication and the adjudications as

to other NDAs or sNDAs for simultaneous Rx and OTC distribution of a drug);[20] (iii) was developed in response to particular factual circumstances in the regulated industry, as to which FDA has expertise; (iv) was made by the Commissioner, the agency head, personally;[21] (v) addresses a question that has historically been of particular importance in the administration of the FDCA, *see* 70 Fed. Reg. 52,050; (vi) is in an area of the law in which the federal courts do not have extensive experience; and (vii) was made under the undeniably "complex" FDCA regulatory scheme.

Finally, there can be no denying the complexity and specialized nature of the question whether, and, if so, to what extent, to approve a proposed Rx-to-OTC switch. FDA's scientific and medical judgments bear on that determination. It is FDA's responsibility to ensure that its classification of a drug as Rx or OTC is neither over-regulatory (making drugs that in certain circumstances are safe and effective for OTC use available only by prescription), or under-regulatory (making fully available OTC drugs for which in certain circumstances a physician's supervision is needed for safe and effective use).

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[20] FDA has approved simultaneous Rx and OTC distribution of, *inter alia*, the following drugs: Meclizine (Rx for vertigo; OTC for nausea with motion sickness); Clotrimazol (Rx for candidiasis; OTC for athlete's foot, ring worm, jock itch); Loperamide (Rx for chronic diarrhea; OTC for acute diarrhea); nicotine products (Rx for administration through inhalers and nasal sprays; OTC in gums, lozenges and patches); ibuprofren (Rx at 400mg+ for arthritis; OTC at 400mg and below for aches and pains); and H2 blockers (Rx at 300mg+ for ulcers; OTC at 200mg for heartburn). *See* 70 Fed. Reg. 52,050 (Sept. 1, 2005).

[21] FDA Commissioner Von Eschenbach personally made the decision to approve Plan B for simultaneous OTC and Rx distribution to different patient populations. *See* FAC ¶ 76; Ex. 5. The decision was based, in part, on his acknowledgement of existing "well-established state and private-sector infrastructures to restrict certain products to consumers 18 and older." *Id.* at 1-2 (giving as examples tobacco, non-prescription nicotine replacement therapy products, and non-prescription cold and cough products).

b. FDA's Interpretation Is Consistent with the Statutory Scheme.

Plaintiffs allege that FDA lacks authority to permit distribution of the "same drug product, with the same labeling, for simultaneous distribution as both an OTC and an Rx product." FAC ¶ 102. FDA does have such authority.

Although Plan B, when dispensed OTC, bears adequate directions for OTC use by women age 18 and older, who, in accordance with the approved labeling, may buy it OTC, it does not (in legal contemplation) bear adequate directions for OTC use by women age 17 and younger, who, in accordance with the approved labeling, may buy it only with a prescription.[22] Therefore, when dispensed to a woman under age 18, Plan B must comply, and does comply, with all the conditions, set forth in 21 C.F.R. § 201.100 (2007), for exemption from the requirement of adequate directions for use by the Rx population, 21 U.S.C. § 352(f)(1) (2000 & Supp. IV 2006).

Apart from allegations relating to FDCA § 353(b)(4), discussed in the next paragraph, the FAC does not allege that there is any obstacle to simultaneous compliance by Plan B with all the FDCA's labeling requirements for OTC drugs and all its labeling requirements for Rx drugs. Indeed, because, as determined by FDA, the product information, including all directions for use, is exactly the same for the Rx and the OTC users of Plan B, the presence of the OTC information and directions on the packages dispensed to Rx users enhances their safe and effective use of the product. The FAC does not allege that either the patient population of women age 17 and younger or the patient population of women age 18 and older is in any way adversely affected by

[22] The legal theory justifying prescription status as to those patients is that adequate directions for use by them, without a physician's supervision, cannot be written. *See* 21 U.S.C. § 353(b)(1)(A) (requiring Rx status for any drug that "is not safe for use except under the supervision of a practitioner licensed by law to administer such drug"). Necessarily, in the case of a drug that is within the scope of section 353(b)(1)(A), directions for use without medical supervision cannot substitute for medical supervision. Therefore, such directions cannot be adequate for safe use.

the presence on or in the Plan B package of any information placed there in order to comply with a regulatory requirement for the protection of the other population. Nor does the FAC allege that Plan B fails to comply with any labeling requirement applicable to it when dispensed OTC or applicable to it when dispensed Rx.[23]

FDCA § 353(b)(4) provides:

> (A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".
>
> (B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

21 U.S.C. § 353(b)(4) (2000). Whether a drug product is subject to section 353(b)(4)(A) or to section 353(b)(4)(B) depends solely on whether it "is subject to paragraph (1)" of section 353(b). Under the FDA Decision, Plan B remains an Rx product for women age 17 and younger. Therefore, at all times, it remains "[a] drug that is subject to paragraph (1)" of section 353(b). Even units of Plan B dispensed OTC for women age 18 and older are subject to a prescription restriction under section 353(b)(1) against their being dispensed OTC for women age 17 and younger. Consequently, Plan B, whether dispensed Rx or OTC, is subject to section 353(b)(4)(A), and not to section 353(b)(4)(B), which applies only to drug products that are not subject to any prescription requirement under section 353(b)(1). Accordingly, units of Plan B dispensed OTC are subject to section 353(b)(4)(A), not to section 353(b)(4)(B).

Plan B complies with section 353(b)(4)(A) by bearing on its label the legend: "Rx only

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[23] The FDCA, in 21 U.S.C. § 353(b)(2), exempts an Rx drug from many of the requirements of 21 U.S.C. § 352, if its label contains (i) the name and address of the dispenser; (ii) the serial number and date of the prescription or its filing; (iii) the name of the prescriber; (iv) if stated in the prescription, the name of the patient; and (v) the directions for use and cautionary statements, if any, contained in such prescription. The information required by section 353(b)(2) appears on an Rx label the pharmacist attaches to the package when dispensing the product pursuant to a prescription.

for women age 17 and younger." Ex. 2. Section 353(b)(4)(A) requires that "the symbol 'Rx only'" appear on Plan B's label. The symbol "Rx only" appears on that label as part of the statement "Rx only for women age 17 and younger." *Id.* (emphasis added).

Nothing in section 353(b)(4)(A) precludes the appearance of the symbol on a label as part of a truthful and non-misleading statement of the prescription limitation applicable to the labeled drug under its approved NDA (including all approved sNDAs). Indeed, the expression "at a minimum" in section 353(b)(4)(A) expressly contemplates that the words "Rx only" may appear with other words on the label. Thus, Plan B's Rx legend complies literally with the text of section 353(b)(4)(A). It also fully serves the objective of section 353(b)(4): to make clear to pharmacists and the public when a drug product is to be dispensed OTC or only by prescription.

c. FDA's Interpretation Is Consistent with Congressional Intent.

Plaintiffs allege that, in enacting the Durham-Humphrey Amendments, Pub. L. No. 82-215, 65 Stat. 648 (1951), which added section 353(b) to the FDCA, "Congress expressly deemed the presence or absence of the Rx legend as mutually exclusive for Rx and OTC products, respectively." FAC ¶ 50. As shown at pages 23-31, *supra*, however, neither the statutory text nor the plainly evident statutory purposes require such mutual exclusivity (which, indeed, would be contrary to the statutory purposes). Nor does the statute's legislative history require it.

The Senate Report on the Amendments stated their intent "to deal more directly and realistically with the labeling and dispensing of drugs . . ." S. Rep. No. 82-946, at 1-2. The Amendments had two objectives: "(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." *Id.* The House Report is in accord: it uses the same language to describe the amendments' "two broad objectives." Ex. 7 (H.R. Rep. No. 82-700, at 2-3 (1951)).

As to the first objective, prior to the Amendments the initial responsibility was on a manufacturer to decide whether its drug was unsuitable for self-medication and therefore must be labeled with a cautionary legend that a prescription was required for dispensing. *See* H.R. Rep. No. 82-700, at 3-5. To no great surprise, manufacturers did not discharge that responsibility consistently; and the result was "great confusion in the use of the prescription legend." *Id.* at 5. If FDA disagreed with a manufacturer's determination, it would bring an enforcement action to require the appropriate label to be placed on the product. *Id.* at 4-5.

Under that system, "the retail druggist [was] often unable to know, until the question [wa]s settled by litigation, whether a particular drug can be sold on prescription only." *Id.* at 4. Moreover, the practical effect was that "[m]any products of identical composition, placed on the market by different manufacturers . . . would bear the prescription legend while another of the same composition would provide direction for use [OTC legend]." *Id.* at 5. In some instances, the "druggist would not even know . . . the class in which the manufacturer intended to place such drugs." *Id.* The Amendments solved this problem by requiring FDA involvement *ex ante*, as opposed to *ex post*, in the Rx-or-OTC determination.

FDA's interpretation, permitting certain drugs to be marketed simultaneously Rx for one population and OTC for a different population, is entirely consistent with this goal of the Amendments. Pursuant to FDA's approval, Plan B's labeling includes a legend that unambiguously informs pharmacists (and others) as to its classification for purposes of dispensing: "Rx only for age 17 and younger." Plaintiffs have not made a single factual allegation that this labeling has caused confusion among pharmacists.

As to the second objective, Congress sought to alleviate the real public-health concern that drugs that were safe and effective for OTC use were being dispensed only by prescription, thereby placing undue burdens on pharmacists and restricting the public's ready access to such

drugs. Section 353(b)(3), permitting the agency to remove drugs from the prescription requirement, was a "relaxation . . . necessary to permit the sale without prescription of drugs . . . when that safeguard is unnecessary." *Id.* at 16. *See also* 70 Fed. Reg. at 52,051.

FDA's interpretation achieves this second objective. By contrast, achievement of that objective would be prevented if FDA were prohibited from using its regulatory authority and expertise to make necessary distinctions between uses of a drug that are appropriate for OTC access and uses that are appropriate only with a prescription. *See supra*, pp. 23-26.

Plaintiffs rest their construction of the statute on one line from the Senate Report – not found in the statute – which states that, under the labeling requirements of section 353(b)(4), "over-the-counter drugs are forbidden to bear a label containing this caution statement ['Caution: Federal law prohibits dispensing without prescription']." S. Rep. 82-946 at 10. Contrary to plaintiffs' allegations, that statement does not prohibit a drug from containing a label that states: "Rx only for age 17 and younger."

The statement on which plaintiffs rely refers to drugs that are appropriate for OTC dispensing for all populations and uses. "[O]ver-the-counter drugs" are drugs that are not subject to any prescription limitation at all. The statement plaintiffs rely on has no bearing on what is permissible for a drug that FDA determines should have Rx and OTC distribution for use by different patient populations, and therefore should be subject to a prescription limitation. As explained at page 34, *infra*, Plan B is not an "over-the-counter" drug: at all times, as to all units, and even when dispensed OTC, it is subject to a prescription limitation.

Moreover, the statement plainly was intended to address a situation in which the appearance of the caution statement on a drug label would be false: *i.e.*, an OTC drug bearing a statement that it may be dispensed only Rx. Here, plainly, the appearance of the Rx legend on Plan B's label is not false. Indeed, Plan B's label stating when a prescription is required (and, by

necessary implication, when OTC dispensing is permitted) is true, and well serves the congressional objectives of providing certainty to pharmacists, making drugs available OTC where that is appropriate, and restricting drugs to prescription use where that is appropriate.

B. Count IV Fails To State a Claim Because Plaintiffs Have Not Alleged that FDA Has Mandated that Plan B Be Treated as a Third Class of Drug.

Plaintiffs allege that FDA lacks authority to create a "third class" of drug, which they define as "a class of drugs that require pharmacists to supplement the labeling or that certain subpopulations might misuse with direct access." FAC ¶ 115. They allege that such a class of drugs creates "anti-competitive and anti-consumer effects on the distribution of nonprescription drugs." *Id.* ¶ 116. This count fails for the reasons asserted with respect to Count II at pages 22-34, *supra*, and for the following additional reasons.

Plaintiffs do not, and cannot plausibly, allege that FDA regulates Plan B as a third class of drugs. Every unit of Plan B is subject to a prescription limitation: that it not be sold to a consumer age 17 or under without a prescription. Of course, therefore, like packages of all other drugs subject to a prescription limitation, packages of Plan B must be kept behind a pharmacy counter, and cannot be sold by, *e.g.*, a grocery store. This treatment of Plan B as a drug subject to a prescription limitation – dispensing only by physicians and pharmacists in neighborhood pharmacies, clinics, hospitals, and other medical facilities; storage behind the counter rather than on open shelves accessible to consumers – follows necessarily from Plan B's availability as a drug subject to a prescription limitation. Similarly, the age restriction applicable to OTC dispensing of Plan B also follows from the definition of the Rx population in terms of age. As Commissioner Von Eschenbach noted, identical age restrictions already apply to other drugs dispensed OTC. *See* note 15, *supra*. Plaintiffs do not allege any other way in which Plan B constitutes a "third class of drugs" uniquely different from existing Rx and OTC drugs.

Plaintiffs do not allege any harm to distribution. They do not allege any facts amounting to an anticompetitive effect (*e.g.*, facts constituting an anticompetitive reduction of supply or increase in price). Moreover, plaintiffs fail to allege that they or their members have been harmed by any anticompetitive effect.[24] They do not allege that they are or represent market participants (*e.g.*, owners of gas stations or convenience stores) that complain that they are not able to sell Plan B because its sale is restricted to pharmacies and other medical facilities. They do not allege that they are or represent purchasers of Plan B who, somehow, have suffered from some anticompetitive effect. Indeed, the remedy plaintiffs seek – elimination of any OTC availability of Plan B – would not change the number of outlets that sell Plan B, and so would not change whatever competitive effects Plan B currently has. For these reasons, in addition to those at pages 4-19, *supra*, plaintiffs lack standing to proceed with this Count (and they would lack it even if, contrary to pages 4-19, *supra*, they had alleged harm sufficient to confer standing for the other Counts in the FAC).

Finally, although plaintiffs allege in conclusory terms that FDA exceeded its authority, they do not allege any facts showing that FDA compelled Duramed to do anything beyond treating Plan B as a drug subject to a prescription limitation and an age restriction. Even if, somehow, FDA exceeded its authority in imposing some burden on Duramed, because plaintiffs have not alleged how any burden imposed on Duramed injures them or their members, plaintiffs lack standing to complain of any such burden.

C. Count V Fails To State a Claim Because the APA Does Not Require Notice-and-Comment Rulemaking in the Circumstances Here.

"FDA has interpreted . . . [section 353](b)(1) of the act to allow marketing of the same

[24] Indeed, plaintiffs complain of increased competition between physicians and pharmacists. FAC ¶ 20. Plaintiffs' mutually inconsistent allegations with respect to competition are mirrored by plaintiffs' claims to represent physicians, pharmacists, and consumers, *see* FAC ¶¶ 3-6, whose interests with respect to competition in the sale of drugs are mutually conflicting.

active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner." 70 Fed. Reg. at 52,051. Plan B is the first instance of FDA approval of the "marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation" with no physical difference between the product dispensed Rx and the product dispensed OTC. *Id.* FDA's approval of Plan B does not, however, involve any new general legal interpretation as to which rulemaking is required by law.

Count V complains, nevertheless, that FDA did not conduct a rulemaking to add a "patient-based 'age' parameter" to its "meaningful difference" test. FAC ¶ 121. Count V fails. No rulemaking was legally required or factually warranted in the circumstances here. The "meaningful difference" standard (which is discussed in FAC ¶ 53) does not appear in any FDA regulation. The approval Duramed sought from FDA was specific to NDA 21-045, Supplement 011 as amended, and did not raise any issue of broad applicability.

FDA's approval of the partial switch of Plan B from Rx to OTC dispensing and its approval of the labeling of Plan B involved interpretations of the FDCA and application of FDA policy. It did not involve any new interpretation of any substantive rule embodied in a regulation, and was not a departure from any previous FDA policy that was authoritatively adopted, communicated to the public through adjudications amounting to an administrative common law, and relied on by regulated parties. Therefore, here, FDA's approval was not subject to the requirement of notice and comment under the APA, 5 U.S.C. § 553 (2000).

1. FDA Has Broad Discretion To Proceed by Adjudication Without Notice-and-Comment Rulemaking.

The Supreme Court has made clear that federal agencies have broad discretion to resolve interpretive and policy issues in adjudications without rulemaking. *SEC v. Chenery Corp.* ("*Chenery II*"), 332 U.S. 194 (1947), involved an SEC adjudication that raised interpretive and

policy issues. The Commission had to decide whether to approve an amendment to a reorganization plan. The Court rejected the argument that the Commission was required to use notice-and-comment rulemaking, rather than adjudication, to decide the issues presented.

The Court first made clear that, in adjudicating a matter before it, an agency must apply its interpretation of the statute to the facts found, even if that interpretation has not previously been subjected to notice and comment. *See Chenery II*, 332 U.S. at 201.

The Court then described the discretion agencies have to proceed either by adjudication or by notice and comment. "Not every principle essential to the effective administration of a statute can or should be cast immediately into the mold of a general rule." *Id.* at 202. "Some principles must await their own development, while others must be adjusted to meet particular, unforeseeable situations. In performing its important functions in these respects, therefore, an administrative agency must be equipped to act either by general rule or by individual order." *Id.* "[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency." *Id.* at 203.

That rationale applies here. Adoption of an age restriction as the dividing line between OTC and Rx availability was a reasonable and appropriate means to resolve the concerns raised in the letter from Steven Galson, M.D., M.P.H. (May 6, 2004), denying approval of NDA 21-045/S-011. FAC ¶ 69. Yet, FDA has little prior experience with such use of an age restriction or its reflection in labeling. Therefore, it is reasonable for the agency to proceed case by case to accumulate experience before embodying a particular approach in a rule of general applicability.

In fact, FDA did provide ample opportunities for public comment. It invited "interested persons" to submit "data, information or views" to the public meeting of advisory committees at which the Plan B sNDA was considered. *See* http://www.fda.gov/oc/advisory/accalendar/cder12541d121603.html. It also published the ANPRM, 70 Fed. Reg. 52,050, and received

approximately 47,000 comments, FAC ¶¶ 71-72. Three of the four plaintiffs here commented. FAC ¶ 27. Plaintiffs cannot plausibly claim they were denied an opportunity to be heard as to the proposed Rx-to-OTC switch of Plan B.[25]

2. The sNDA Approval Involved Interpretation of Section 353(b), Not Interpretation of a Substantive Rule.

The legal issues relating to the FDA Decision and the means to comply with section 353(b)(4) all involve an interpretation of section 353(b), and do not involve any exercise of delegated law-making authority. Therefore, under the APA, the legal interpretations FDA relied on to approve the partial switch and the means of compliance with section 353(b)(4) have the status of interpretive rules or, possibly, statements of policy, both of which are exempted by 5 U.S.C. § 553(b)(A) from section 553's requirement of notice-and-comment rulemaking .

The APA categories relevant here are: general statement of policy, interpretive rule, and substantive (or legislative) rule. In *Syncor International Corp. v. Shalala*, 127 F.3d 90 (D.C. Cir. 1997), the D.C. Circuit distinguished among them.

A policy statement "does not seek to impose or elaborate or interpret a legal norm. It merely represents an agency position with respect to how it will treat – typically enforce – the governing legal norm." *Syncor*, 127 F.3d at 94. A policy statement is not binding. *Id.*[26]

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[25] Plaintiffs claim a due process violation on the ground that they would have provided comments in a notice-and-comment procedure. FAC ¶ 27. Of course, plaintiffs do not have a due process right to provide comments in a rulemaking procedure that the agency is not required to undertake and did not undertake.

Plaintiffs' due process claim also fails for the straightforward reason that plaintiffs were required to, but did not, file a Citizen's Petition with FDA to obtain the relief they now seek from this Court. *See* pp. 19-21, *supra*.

[26] *See, e.g., Burroughs Wellcome Co. v. Schweiker*, 649 F.2d 221 (4th Cir. 1981) (FDA's paper NDA policy); *Pacific Gas & Elec. Co. v. Federal Power Commission*, 506 F.2d 33, 37-39 (D.C. Cir. 1974); *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 173 (D.D.C. 2000) (FDA issuance is a policy statement because it "merely creates a presumption and does not ultimately bind the agency's discretion.").

Here, to the extent the FDA Decision involved the application of section 353(b) to a set of facts that, thus far, is unique, FDA was entitled to treat any elaboration of policy it applied in resolving the matter as non-binding (*i.e.*, as not thereafter limiting its discretion under the FDCA), and as establishing, at most, a presumption as to how the agency will resolve proposals for partial switches by exercising its discretion in the future. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979); *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 173.

In contrast to a policy statement, a rule (whether interpretive or substantive) binds the agency to a particular legal position until the agency changes it. *Syncor*, 127 F.3d at 94.

An interpretive rule "reflects an agency's construction of a statute that has been entrusted to the agency to administer. The legal norm is one that Congress has devised; the agency does not purport to modify that norm, in other words, to engage in law-making." *Id*. The interpretive rule "simply states what the administrative agency thinks the statute means, and only reminds affected parties of existing duties." *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc) (internal quotation omitted). The statutory construction is interpretive (rather than substantive or legislative), even though courts defer to it under *Chevron*. The agency is not asserting authority to make positive law on its own. "Instead, it is construing the product of congressional lawmaking . . . ." *Syncor*, 127 F.3d at 94. "A rule that clarifies a statutory term is the classic example of an interpretative rule." *National Family Planning & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227, 236 (D.C. Cir. 1992); *American Postal Workers Union v. United States Postal Serv.*, 707 F.2d 548 (D.C. Cir. 1983) (change in method by which agency calculated benefits was interpretative rule, though it affected pay of over 11,000 workers); *American Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1111-12 (D.C. Cir. 1993) ("Where a statute or legislative rule has created a legal basis for enforcement, an agency can simply let its interpretation evolve ad hoc in the process of enforcement . . . .").

Here, the FDA Decision, including FDA's approval of Plan B's labeling can properly be viewed as reflecting the evolution of the agency's interpretation of section 353(b) in the course of reviewing NDAs and sNDAs ("other applications" of the statute, in the words of *American Mining Congress*, 995 F.2d at 1112). The evolution remains interpretive, not substantive; and it will continue on a case-by-case basis in the future. This characterization of FDA's rationale for approving the partial switch and the means of complying with the labeling requirements of section 353(b)(4) is faithful to the facts and circumstances, places the rationale in the most appropriate legal category, and fully preserves the agency's discretion and flexibility to adapt its statutory interpretation to whatever circumstances may be presented in the future.

A substantive rule is an exercise of policy (and therein is similar to a policy statement), and is a rule (and therein differs from a policy statement). A substantive rule differs from a policy statement and from an interpretive rule because it modifies or adds to a legal norm through action based on the agency's own delegated authority to make law. Because the agency is engaged in law-making, the APA requires notice and comment for promulgation of a substantive rule. *Syncor*, 127 F.3d at 95.

The D.C. Circuit has articulated four questions useful in determining whether a rule is interpretive or substantive:

> (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, [the pronouncement is] a legislative, not an interpretive rule.

Am. Mining Cong., 995 F.2d at 1112.

The legal interpretations underlying the FDA Decision, including FDA's approval of Plan B's labeling, are permissible under section 353(b), and constitute an interpretive rule or policy

statement, not a substantive rule. These interpretations warrant a negative answer to each of the four questions in *American Mining Congress*. First, an adequate legislative basis for an enforcement action is provided by 21 U.S.C. §§ 353(b)(1), (4), 331(a), 332-34. Second, the legal interpretations FDA developed in connection with its review of the sNDA for Plan B have not been published in the C.F.R. Third, in approving the sNDA, FDA has not explicitly invoked its general legislative authority. Fourth, FDA has not effectively amended any prior legislative rule.

FDA's legal position is interpretive because it elaborates or interprets the legal norms set forth in section 353(b) in general, and explains how Duramed may comply with the requirements of section 353(b)(4). Arguably, it would be a policy statement analogous to that in *Hudson v. FAA*, 192 F.3d 1031, 1036 (D.C. Cir. 1999): *i.e.*, a statement as to how the agency will regard a means of compliance with the statute. Such a position certainly would not be substantive because the legal norms at issue are solely those created by Congress in section 353(b), not ones created by FDA. FDA applied to a factual situation the established legal norms and policies governing Rx and OTC dispensing and the communication to pharmacists and others of clear guidance as to how a drug is to be dispensed.

3. An Agency May Change an Interpretation of a Statute, an Interpretive Rule, or a Policy Statement Without Notice and Comment.

Paralyzed Veterans of America, Inc. v. D.C. Arena L.P., 117 F.3d 579 (D.C. Cir. 1997), expressly rejected the argument that "an agency has the same latitude to modify its interpretation of a regulation as it does its interpretation of a statute under *Chevron*." *Id.* at 586 (emphases added). The court's statement that "there is no barrier to an agency altering its initial interpretation to adopt another reasonable interpretation – even one that represents a new policy response," *id.*, plainly means that notice-and-comment rulemaking is not required for a change in an agency's interpretation of a statute.

If the change is made by an interpretive rule (*i.e.*, an interpretation of a legal norm

created by Congress, as distinguished from an interpretation of a legal norm created by the agency), then notice-and-comment rulemaking is not required, even if the new interpretation differs from a prior interpretation. In *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074 (D.C. Cir. 1987), for example, the court held that it was proper for FERC, in an adjudication, (i) to adopt a statutory interpretation directly contrary to FERC's prior interpretation of the same statute, (ii) to do so without notice and comment, and (iii) to apply the new interpretation in that very adjudication.

The situation is otherwise, however, with respect to a change in an agency's interpretation of a substantive rule embodied in a regulation. *Paralyzed Veterans*, 117 F.3d at 586. As to a substantive regulation, an agency may change its interpretation only by notice and comment where the change would constitute an amendment of the regulation.

Even as to substantive regulations, however, not every change in interpretation constitutes an amendment. "A rule does not, in this inquiry, become an amendment merely because it supplies crisper and more detailed lines than the authority being interpreted." *Am. Mining Cong.*, 995 F.2d at 1112. "Agencies need not provide notice and comment for every meaningful policy decision. Interpretations of ambiguous or unclear regulations by agencies may be exempt from the APA's notice and comment requirements." *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 n.6 (5th Cir. 2001). In *Orengo Caraballo v. Reich*, 11 F.3d 186, 195 (D.C. Cir. 1993), the court made clear that the APA category of interpretive rules includes interpretations of regulations as well as interpretations of statutes. *Id.* at 195-96.

Thus, an agency may adopt or change an interpretation of a statute or a regulation (where the adopted or changed interpretation does not amount to an amendment of the regulation) by means of an interpretive rule, which, under 5 U.S.C. § 553(b), need not be promulgated through notice-and-comment rulemaking. Notice-and-comment is not required even if the agency views

the new interpretation as binding, *i.e.*, as an interpretive rule. All rules, as such, bind the agency that adopts them until it changes them, *Syncor*, 127 F.3d at 94; but, under section 553(b), an interpretive rule may be changed without notice and comment.

Association of American Railroads v. Department of Transp., 198 F.3d 944, 947 (D.C. Cir. 1999), interpreted *Alaska Professional Hunters Ass'n v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999), as holding that notice-and-comment rulemaking is required for a change in agency interpretation where (i) there has been a prior, different interpretation that was "express, direct, and uniform"; (ii) that interpretation has been publicly "reflected in official agency adjudications," amounting to "administrative common law"; and (iii) there has been substantial reliance on that interpretation by regulated parties. *Association Am. R.R.*, at 949-50 (quotations omitted); *see also Air Transp. Ass'n of Am., Inc. v. FAA*, 291 F.3d 49, 58 (D.C. Cir. 2002).

Here, no prior, different administrative interpretation of section 353(b) would preclude the FDA Decision, including approval of Plan B's labeling, and would satisfy any of the three triggering conditions relied on in *Association of American Railroads*. The FAC does not allege any facts that would constitute a basis for applying *Alaska Professional Hunters Ass'n* here.

4. Approval of the Plan B sNDA Did Not Involve Departure from Any Established FDA Interpretation of a Regulation.

Approval of the Plan B sNDA and associated labeling did not involve FDA committing itself to a new interpretation of any substantive (or interpretive) regulation. There is no FDA regulation that, as previously interpreted, stood as an obstacle to approval of the Plan B sNDA, including the labeling of Plan B, and therefore had to be reinterpreted if FDA were to approve the sNDA. The "meaningful difference" policy is merely a policy, as recognized in FAC ¶ 71. Under the APA, an agency may change a policy without notice-and-comment rulemaking. Therefore, cases requiring notice and comment to amend a substantive regulation do not apply here. Indeed, as just noted, of the three elements necessary to the analysis in *Association of*

American Railroads, none is alleged in the FAC to be present here.

Any new interpretation that would have been needed would have been of section 353(b) of the FDCA. FDA's approval did not supplement the statute, but merely interpreted it. It did not involve the exercise of any law-making authority under 21 U.S.C. § 371(a) (authorizing FDA to issue regulations), but was merely a direct interpretation of section 353(b), one FDA could make even if section 371(a) did not exist.

In its articulation of rationales for the approval of the Plan B sNDA, FDA was elaborating the concepts and provisions in section 353(b). It explained how those provisions were satisfied and how their purposes were served in the context of Plan B. *See* Ex. 8 (Memorandum from Steven Galson, M.D., Director, CDER, Subject: Plan B, at 2-3 (Aug. 24, 2006)). No new legal norms or purposes were created.

In sum, even if the FDA Decision were viewed as committing FDA to a new interpretation of section 353(b), FDA could, under APA § 553(b)(A), commit itself to that new interpretation and approve the sNDA without notice and comment.

D. Count VI Fails To State a Claim Because It Is Based on an Incorrect Statutory Interpretation.

FDA "may by regulation remove drugs subject to [21 U.S.C. § 355] from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health." 21 U.S.C. § 353(b)(3). An FDA regulation, 21 C.F.R. § 310.200(b), implements this statutory authorization. This text is analyzed at page 24, *supra*.

Count VI of the Complaint misconstrues the statutory expression "may by regulation." Plaintiffs' position is that the statute requires FDA to engage in a separate rulemaking each and every time it removes a drug from section 353(b)(1), *i.e.*, from prescription-only status. Nothing in the text of section 353, section 310.200(b), the APA, general principles of administrative law, or sound public policy warrants burdening FDA and those affected by Rx-

to-OTC switch decisions with such a cumbersome and inefficient procedure.

FDA has stated that, from 1976 to 1996 alone, it approved over 600 Rx-to-OTC switches. *See* Tamar Nordenberg, *Now Available Without A Prescription*, FDA Consumer Magazine (Nov. 1996), *available at* http://www.fda.gov/fdac/features/996_otc.html. Under plaintiffs' interpretation of section 353(b)(3), to approve those switches FDA would have had to conduct more than 600 separate and useless notice-and-comment rulemakings. A statute should not be read to lead to such an absurd result. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. at 575; *FTC v. Ken Roberts Co.*, 276 F.3d at 590.

FDA's interpretation of section 353(b)(3) is reasonable, and is entitled to *Chevron* deference. *See* pages 26-34, *supra*.

CONCLUSION

For the foregoing reasons, the Court should dismiss the FAC with prejudice.

Respectfully submitted,

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