UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., 1601 N. Tucson Blvd., Suite 9, Tucson, AZ 85716,	)	
CONCERNED WOMEN FOR AMERICA, 1015 Fifteenth St. NW, Suite 1100, Washington, DC 20005,	)	
FAMILY RESEARCH COUNCIL, 801 G Street, NW Washington, DC 20001,	)	Civil Action No. 07:0668-RCL
and	)	
SAFE DRUGS FOR WOMEN, 1015 Fifteenth St. NW, Suite 1100, Washington, DC 20005,	)	
Plaintiffs,	)	
v.	)	
FOOD & DRUG ADMINISTRATION, 5600 Fishers Lane Rockville, MD 20857,	)	
ANDREW C. VON ESCHENBACH, COMMISSIONER OF FOOD & DRUGS, 5600 Fishers Lane Rockville, MD 20857, in his official and individual capacities,	)	
and	)	
UNITED STATES OF AMERICA,	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Association of American Physicians and Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), Family Research Council ("FRC"), and Safe Drugs for Women ("SDW") seek declaratory and injunctive relief based on the following allegations.

NATURE OF THE ACTION

1. Plaintiffs bring this action to enforce the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the Administrative Procedure Act ("APA"), and the Due Process Clause of the Fifth Amendment by vacating the approval by Defendants Food and Drug Administration ("FDA") and von Eschenbach of a supplemental new drug application for levonorgestrel tablets, 0.75 mg (hereinafter "Plan B"), as an over-the-counter ("OTC") drug for women 18 and older and a prescription ("Rx") drug for girls under 18.

2. As set forth more fully in Paragraph 110, Plaintiffs seek the following injunctive and declaratory relief:

(a) Vacate Defendants' approval of Plan B for OTC distribution;

(b) Declare that Defendants FDA and von Eschenbach lack authority to approve the same drug product for simultaneous OTC-Rx distribution;

(c) Declare that Defendants FDA and von Eschenbach lack authority to bifurcate a drug product's OTC versus Rx status based on the patient's age;

(d) Declare that Defendants FDA and von Eschenbach lack authority to create a hybrid "third class" of behind-the-counter drug beyond FFDCA's OTC and Rx classes;

(e) Declare that Defendants failed to conduct the required rulemakings necessary to authorize OTC distribution of Plan B; and

(f) Declare that Defendants FDA and von Eschenbach unlawfully approved Plan B for OTC distribution under improper pressure from Senators Clinton and Murray.

PARTIES

3. Plaintiff AAPS is a not-for-profit membership organization incorporated under the laws of Indiana and headquartered in Tucson, Arizona. AAPS' members include thousands

of physicians nationwide in all practices and specialties, but primarily in small and solo practices. AAPS was founded in 1943 to preserve the practice of private medicine, ethical medicine, and the patient-physician relationship. AAPS members include more than 100 obstetricians and gynecologists who practice medicine in states where only a physician lawfully may prescribe a prescription drug.

4. Plaintiff CWA is a nonprofit corporation formed under the laws of the District of Columbia and headquartered there. CWA represents a membership of 500,000 women in 50 states across the nation. CWA represents their interests before Congress and before federal, state, and international governmental bodies on issues of specific interest to women. CWA has been active in reproductive issues for over 25 years.

5. Plaintiff FRC is a nonprofit corporation formed under the laws of the District of Columbia and headquartered there. FRC is dedicated *inter alia* to valuing human life from conception until natural death and upholding the institution of the family, including parental oversight of children's health care. FRC has been active in reproductive issues for over 25 years.

6. Plaintiff SDW is a nonprofit corporation formed under the laws of the District of Columbia and headquartered there. SDW is dedicated *inter alia* to rational and safe health-care policies. Through its members and its members' members (collectively, "SDW Members"), SDW represents thousands of health-care professionals (including nurses, physicians, and pharmacists) and consumers nationwide. In particular, SDW Members include more than a thousand pharmacists and more than two thousand obstetricians and gynecologists in virtually every state, including more than 1,000 obstetricians and gynecologists who practice medicine in states where only a physician lawfully may prescribe a prescription drug.

7. Defendant FDA is an agency within the U.S. Department of Health and Human

Services ("HHS"), an executive department of the United States government. Defendant von Eschenbach is FDA's Commissioner. Defendant von Eschenbach is sued both in his official capacity and in his individual capacity under color of legal authority for actions unlawfully taken and not taken by him and by those under his control. Defendant von Eschenbach is not sued in his individual capacity for monetary or punitive damages. As FDA Commissioner, Defendant von Eschenbach has the ultimate responsibility for FDA's activities, including the complained-of actions here. Defendant United States of America is the federal sovereign.

JURISDICTION AND VENUE

8. This action arises out of Defendants' ongoing FFDCA, APA, and Due-Process violations and, therefore, raises federal questions over which this Court has jurisdiction pursuant to: 28 U.S.C. §§1331, 1361; the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended); D.C. Code §11-501; and this Court's equity jurisdiction.

9. Defendants' unlawful approval of the Supplemental New Drug Application ("SNDA") for Plan B's dual OTC-Rx distribution and their taking that action without convening the required rulemaking proceedings are final agency actions. First, Defendants' SNDA consummates the FFDCA decisionmaking process on the approvability of that SNDA and its compliance with all applicable legal requirements. Second, that approval establishes the obligations of pharmacists, alters the legal regime applicable to pharmacists, physicians, and their patients by allowing access to Plan B without prescription, and denies female patients their rights under the FFDCA. In particular, in those states where only physicians lawfully may prescribe prescription drugs, the OTC approval of Plan B authorizes pharmacists to distribute Plan B, which distribution would be unlawful in those states in the absence of Defendants' action approving Plan B for OTC distribution.

10. Pursuant to 28 U.S.C. §1391(e), venue is proper in the District of Columbia. Under 5 U.S.C. §703, venue is proper in any court of competent jurisdiction.

11. An actual and justiciable controversy exists between Plaintiffs and Defendants.

Ongoing Injuries to Plaintiffs

12. Plaintiffs AAPS, FRC, and CWA and SDW Members commented on the Defendants' Advance Notice of Proposed Rulemaking ("ANPRM") on the novel legal issues presented by Plan B's Rx-OTC switch, and Plaintiffs and their members wished to comment and would have commented in subsequent rulemaking proceedings, if Defendants had convened them. If the Court grants the relief requested in Paragraph 110, and Defendants initiate a rulemaking to effect an Rx-OTC switch for Plan B, Plaintiffs and their members would comment in that rulemaking proceeding. By taking the complained-of actions without the rulemaking proceedings required by the APA and FFDCA, Defendants denied Plaintiffs and their members' procedural rights conferred by Congress. In addition to that procedural injury, Plaintiffs and their members suffer concrete injuries to their interests. *See* Paragraphs 13 to 16; *see also* Exhibit 1 (incorporated herein by reference).

13. Plaintiffs' members include women, girls, and parents of girls who reside in states where only physicians can prescribe an Rx drug and who will receive inadequate health care, drug-labeling information, and counseling related to Plan B and contraceptives as the direct result of Defendants' unlawful approval of Plan B for OTC distribution. Further, Plaintiffs' members include the physicians of such women and girls, who also reside and practice medicine in such states. In addition to the injuries alleged and incorporated in Paragraph 12, these physicians seek to protect the patient-physician relationship and the FFDCA-granted rights to adequate health care, drug-labeling information, and counseling on Rx drugs on behalf of their

patients. These physicians have close and confidential relationships with such patients. Moreover, because the patients lack a formal understanding of the risks posed by foregoing medical screening and by using Plan B without fully understanding the potential complications, these patients cannot and will not adequately assert their rights.

14. Plaintiff SDW's members include practicing pharmacists – licensed to practice in states where only physicians can prescribe an Rx drug – who face expanded legal liability from the removal of the otherwise-applicable protections afforded to pharmacists who dispense an Rx drug pursuant to a physician's prescription as the direct result of Defendants' unlawful approval of Plan B for OTC distribution.

15. Plaintiff SDW's members include practicing pharmacists – licensed to practice in states where only physicians can prescribe an Rx drug – who as the direct result of Defendants' unlawful approval of Plan B face added expense and administrative burdens in their practice of their profession via requirements not applicable to either OTC or Rx drugs.

16. Plaintiff SDW's members include practicing pharmacists – licensed to practice in states where only physicians can prescribe an Rx drug – who as the direct result of Defendants' unlawful approval of Plan B are subject to compelled speech to further a customer's use of Plan B in violation of these pharmacists' conscience-based objections to Plan B.

17. To the extent that they relate to third parties (as distinct from Plaintiffs and Plaintiffs' members), the allegations of injury (Paragraphs 12-16) are made on the basis of knowledge, information, and belief, formed after reasonable inquiry, which likely could be proved conclusively after a reasonable opportunity for discovery.

Sovereign Immunity

18. Defendant United States has waived its sovereign immunity for actions against

the United States, its instrumentalities, and officers for non-monetary injunctive and equitable relief and for the entry of judgments and decrees against the United States in such actions. Defendant United States has waived sovereign immunity for this action and for the relief sought in Paragraph 110.

19. With Defendant von Eschenbach named and served in his official and individual capacities, sovereign immunity does not shield Defendant von Eschenbach's *ultra vires* actions. Further, mandamus claims against a named federal officer do not require a waiver of sovereign immunity. This Court possesses equity jurisdiction over federal officers derived both from the Court's enabling legislation and from the historic equity jurisdiction of Maryland courts over Maryland officers, prior to Maryland's ceding the District of Columbia as a federal enclave.

20. As a matter of historical fact, at the time that the states ratified the U.S. Constitution, the equitable, judge-made doctrine that allows use of the sovereign's courts in the name of the sovereign to order the sovereign's officers to account for their conduct (*i.e.*, the rule of law) was as least as firmly established and as much a part of the legal system as the judge-made doctrine of federal sovereign immunity. *See, e.g.*, Louis L. Jaffee, *The Right to Judicial Review I*, 71 HARV. L. REV. 401, 433 (1958). No act of Congress limits this Court's equity jurisdiction for an action against Defendant von Eschenbach's *ultra vires* acts.

Irreparable Harm and Inadequacy of Alternate Remedies

21. This action is not barred by the APA's "adequate-remedy bar," 5 U.S.C. §704, or analogous equitable doctrines because neither FFDCA nor any other provision of law provides an alternate legal remedy for Plaintiffs' injuries. Neither the FFDCA nor the APA imposes any mandatory administrative remedy that Plaintiffs must exhaust prior to initiating this action.

22. Because this Court has jurisdiction as a threshold matter, the Declaratory

Judgment Act, 28 U.S.C. §§2201-2202, provides this Court the power to "declare the rights and other legal relations of any interested party…, whether or not further relief is or could be sought." 28 U.S.C. §2201; *accord* FED. R. CIV. P. 57 advisory committee note ("the fact that another remedy would be equally effective affords no ground for declining declaratory relief").

23. A plaintiff's irreparable injury and lack of an adequate legal remedy justify injunctive relief. In addition to the declaratory relief requested in Paragraph 110, Plaintiffs are entitled to injunctive relief because (a) imminent and ongoing exposure to inadequate health care, drug-labeling information, and counseling, unlawful competition, expanded legal liability, expense, and administrative burden, and compelled speech constitute irreparable injury; (b) as set forth in Paragraph 21, Plaintiffs lack any alternate legal remedy against Defendants' FFDCA, APA, and Due-Process violations.

STATUTORY BACKGROUND

Federal Food, Drug, and Cosmetics Act

24. Although FFDCA assigns the applicable duties to HHS and the HHS Secretary, *see* 21 U.S.C. §321(c)-(d), the HHS Secretary has delegated the pertinent authorities to the FDA and the FDA Commissioner.

25. FFDCA prohibits marketing and sale of a "new drug" unless it has been proven safe and effective through approval of a new drug application ("NDA") or supplemental new drug application ("SNDA"), requiring the applicant to submit an extensive battery of analytical tests, animal studies, and human clinical safety and efficacy trials. 21 U.S.C. §355(a)-(b).

26. FDA cannot lawfully approve an NDA or SNDA that fails even one of seven FFDCA-specified "grounds for denying approval." 21 U.S.C. §§355(c)(1), 355(d)(1)-(d)(7). If one or more of the seven grounds applies, FDA "shall issue an order refusing to approve the

application." 21 U.S.C. § 355(d).

27. In pertinent part, FDA must deny an NDA or SNDA if:

> (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section [505], do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof[;]
>
> (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions[;]
>
> ***
>
> (4) upon the basis of the information submitted to [FDA] as part of the application, or upon the basis of any other information before [FDA] with respect to such drug, [FDA] has insufficient information to determine whether such drug is safe for use under such conditions[;]
>
> *** [or]
>
> (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular[.]

21 U.S.C. § 355(d)(1), (2), (4), (7).

28. A drug's labeling is false or misleading *per se* if the drug is misbranded. A drug is misbranded, *inter alia,* if its labeling or advertising fails to reveal material facts made material by its labeling's affirmative statements with respect to consequences that may result from the use of the drug under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. A drug is misbranded if its labeling bears both the Rx-only and OTC legends. A drug is misbranded if the data supporting such SNDA or NDA did not include data required by the Pediatric Research Equity Act.

Durham-Humphrey Amendments

29. Prior to the enactment of the Durham-Humphrey Amendments in 1951, FFDCA

addressed the distinction between Rx and OTC drugs by regulation. Congress enacted the Durham-Humphrey Amendments as a "remedial" measure "in the sense that they are intended to protect the public." S. REP. 946, 82nd Cong., 1st Sess., at 3 (Oct. 12, 1951). Congress intended the Durham-Humphrey Amendments both "to protect the public from abuses in the sale of potent prescription drugs" and "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs safe for use without the supervision of a physician." S. REP. 946, at 1; *accord* H.R. REP. 700, 82nd Cong., 1st Sess., at 2 (Jul. 16, 1951).

30. Under the Durham-Humphrey Amendments, as amended, FFDCA's Rx-drug requirements apply (a) to so-called "dangerous drugs," and (b) to new drugs limited by an approved NDA to use under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. §353(b)(1)(A)-(B). The Durham-Humphrey Amendments defined the former category to apply when a drug "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. §353(b)(1)(A).

31. As used in the Durham-Humphrey Amendments, a drug's safety for use without medical supervision means safe in the "ordinary meaning." S. REP. 946, at 4. The definition of "safe" includes "other potentialities for harmful effect… and the collateral measures that may be necessary in order to use the drug safely," and the definition "clearly shows that toxicity is only one factor to be considered by the courts in determining whether a particular drug is safe for use without medical supervision." *Id.* Congress intended "this broad language… to comprehend all drugs that in fact should be administered under medical supervision in order to [e]nsure their safe use," S. REP. 946, at 9, and to include "drugs that are too dangerous, *or otherwise*

unsuitable, to be used by a layman without medical diagnosis *or supervision.*" H.R. REP. 700, at 7 (emphasis added). In reviewing NDAs and SNDAs under those criteria, FDA not only can, but also must and routinely does consider the potential for misuse as part of the drug's safety.

32. Due to the Durham-Humphrey Amendments' OTC-Rx distinction, FDA's labeling requirements for OTC and Rx differ significantly, beyond the mere absence or presence of the "Rx Only" legend. *Compare* 21 C.F.R. pt. 201, subpt. C (OTC labeling) *with id.* subpt. B (Rx labeling). The detail required for Rx labeling's medical audience (*e.g.*, 21 C.F.R. §201.57), is inconsistent with the brevity and clarity required for an OTC Drug Facts Panel's lay audience (21 C.F.R. §201.66).

33. When enacting the statutory OTC-Rx dichotomy in the Durham-Humphrey Amendment, Congress expressly deemed the presence or absence of the Rx legend as mutually exclusive for Rx and OTC products, respectively. The Senate Report expressed this intent:

> Paragraph (4) of the new subsection requires that, in addition to the labeling requirements of prescription drugs specified in paragraph (2) of the subsection, the interstate label on such drugs must bear the statement "Caution: Federal law prohibits dispensing without prescription." On the other hand, *over-the-counter drugs are forbidden to bear a label containing this caution statement.*

S. REP. 946, at 10 (emphasis added). When amending §503(b)(4) in 1997 to replace the Durham-Humphrey Amendment's Rx legend (*i.e.*, "Caution: Federal law prohibits dispensing without prescription") with the current Rx legend (*i.e.*, "Rx only"), Congress did not provide any evidence that it relaxed the Durham-Humphrey Amendment's mutual exclusivity of OTC and Rx labeling.

34. For new drugs limited by an approved NDA to use under professional supervision, the Durham-Humphrey Amendments allow FDA to exempt such drugs from the Rx requirements by regulation "when such requirements are not necessary for the protection of the

public health." 21 U.S.C. §353(b)(3); H.R. REP. 700, at 16.

35. As FDA now interprets it, an FDA regulation, 21 C.F.R. §310.200(b), purports to allow an Rx-to-OTC switch for a new drug, based on FDA's finding that the drug meets the Durham-Humphrey Amendments' statutory standard for dangerous drugs and that the drug is safe and effective for use in self-medication as directed in proposed labeling. An alternate FDA regulation, 21 C.F.R. §330.13, related to Rx-to-OTC switches based on OTC monograph proceedings. FDA did not conduct an OTC monograph proceeding for Plan B.

36. Prior to its approval of Plan B for dual OTC-Rx distribution, FDA had interpreted the statutory and regulatory OTC-Rx distinctions to allow marketing of the same active ingredient in different drug products in the Rx and OTC markets based on a "meaningful difference" between the two drug products. Prior to its approval of Plan B for dual OTC-Rx distribution, FDA interpreted this meaningful-difference standard to include five parameters (namely, the product's active ingredient, indication, strength, route of administration, and dosage form), across which FDA determined whether a meaningful difference existed. Prior to its approval of Plan B for dual OTC-Rx distribution, FDA has never approved the same drug and drug labeling for simultaneous Rx and OTC distribution.

Pediatric Research Equity Act

37. The Pediatric Research Equity Act ("PREA") requires NDAs and SNDAs filed after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to include an assessment and relevant data for each relevant pediatric age group to enable FDA (a) to assess the drug's safety and efficacy for the claimed indications in all relevant pediatric subpopulations, and (b) to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. 21

U.S.C. §355c(a)(2)(A)(i)-(ii). Of these two PREA criteria, the first criterion is limited to claimed indications, and the second criterion is not limited to claimed indications. *Id.* A drug's status as OTC versus Rx constitutes an "indication" under FFDCA and PREA.

38. Congress patterned the Pediatric Research Equity Act on FDA's prior Pediatrics Rule, 63 Fed. Reg. 66,632 (Dec. 2, 1998). In promulgating its final rule, FDA accepted comments that opposed the rigid age ranges of the proposed rule and adopted a flexible approach that considers stages of development. 63 Fed. Reg. at 66,650-51. In addition to considering pediatric populations aged up to 21 years old in its rulemaking, 63 Fed. Reg. at 66,651, the Pediatrics Rule expressly covered adolescents as well as neonates, infants, and children. 63 Fed. Reg. at 66,668 (former 21 C.F.R. §201.23(a)). Like FDA's rule, the Pediatric Research Equity Act does not specify or define rigid age ranges for covered pediatric subpopulations.

Administrative Procedure Act

39. The APA requires executive agencies to conduct notice-and-comment rulemaking when promulgating or amending certain rules. 5 U.S.C. §553(b)-(c). Although an initial interpretation of a regulatory or statutory provision often is exempt from the notice-and-comment requirements, 5 U.S.C. §553(b)(A), the APA nonetheless requires agencies to undergo notice-and-comment rulemaking when *amending* an interpretation.

FACTUAL BACKGROUND

40. Plan B's active ingredient (levonorgestrel) is a synthetic progestogen hormone. As used in Plan B, levonorgestrel is a non-food article intended to affect the function of female humans' bodies. Levonorgestrel is a "drug" within the meaning of 21 U.S.C. §321(g)(1).

41. Levonorgestrel was not subject to the Food and Drugs Act of June 30, 1906, on or before June 25, 1938. Experts qualified by scientific training and experience to evaluate the

safety and effectiveness of drugs do not generally recognize levonorgestrel as safe and effective for use under the conditions prescribed, recommended, or suggested by Plan B's labeling. Levonorgestrel has not been used to a material extent or for a material time under conditions prescribed, recommended, or suggested by Plan B's labeling. FDA approved the initial NDA for Plan B on July 28, 1999, and an SNDA for Plan B on August 26, 2006. In light of the foregoing, levonorgestrel is a "new drug" within the meaning of 21 U.S.C. §321(p).

FDA's Division of Reproductive and Urologic Drug Products

42. As outlined in Paragraphs 43-47, the methodologies used and the workproduct prepared by the staff at Defendant FDA's Reproductive Health Division diverge from accepted scientific and regulatory methods.

43. In testing the safety of drugs related to reproductive health, Defendants consider safety data on only healthy women, without considering other populations (*e.g.*, overweight women, smokers, adolescents) and without applying safety factors for intra-species variability. Failure to consider these other populations can have serious – even deadly – results for members of the excluded populations. *See, e.g.*, Michael Mason, *The Consumer: Pressing to Look Closer at Blood Clots and the Pill*, N.Y. TIMES, at F5 (Feb. 13, 2007).

44. For contraceptives and abortifacients, Defendants determine relative safety by comparing the new drug or treatment with the risks of pregnancy (which include the safety risks associated with not only abortifacients and abortions, but also the safety risks of childbirth) instead of comparing the new drug or treatment with the risks of comparable pharmaceutical and surgical treatments for terminating a pregnancy.

45. In addressing the safety of drugs like Plan B, the Defendants considered only acute data (*e.g.*, adverse reactions over five days to a week), without assessing chronic impacts,

and considered only single dosages (*i.e.*, two .75 mg tablets or 1.5 mg), without considering the impact of multiple doses per month or successive months of repeat use. Typically, where the safety data for a drug covers only limited dosages to determine the drug's health effects, the labeling must provide warnings that limit use accordingly (*e.g.*, "Do Not Use More than Once per Month" or "Not Safe for Use More than Once a Month").

46. In a *Federal Register* notice dated February 25, 1997, one of Defendant von Eschenbach's predecessors and Defendant FDA issued a blanket determination of safety and efficacy for combined oral contraceptives taken up to 72 hours after unprotected intercourse and containing a total of up to 0.12 mg. ethinyl estradiol and 0.60 mg. levonorgestrel. 62 Fed. Reg. 8610, 8611 (1997). These blanket determinations are unprecedented and unsupported in FDA practice. Because Plan B involves 0.75 mg levonorgestrel, the blanket determinations do not apply directly to Plan B. Further, the data cited in the *Federal Register* notice do not establish the safety or efficacy of Plan B under the standards identified in this Complaint for Declaratory and Injunctive Relief.

47. Defendants have relied on historically controlled trials, rather than actively or randomly controlled trials, to establish the safety of hormonal contraceptives. FDA's review of contraceptives does not present the "special circumstances" that could justify FDA's use of historically controlled trials. In deviating from the "gold standard" of actively or randomly controlled trials, Defendants have failed to correct their departures with additional safety factors.

Approval of Plan B

48. On January 29, 1999, Women's Capital Corp. ("WCC") submitted the original NDA for prescription Plan B. Just six months later, on July 28, 1999, FDA approved Plan B as a "new drug" for Rx distribution.

49. In approving Plan B for Rx distribution in 1999, FDA granted a temporally limited waiver of the then-applicable pediatric data requirements: "we are waiving the pediatric study requirement for this application *at this time.*" Letter from Lisa D. Rarick, M.D., Center for Drug Evaluation and Research, to Sharon Camp, Ph.D., Women's Capital Corp., at 2 (Jul. 28, 1999) (emphasis added). By its express terms and as intended by FDA, the 1999 waiver did not apply prospectively to future SNDAs for Plan B.

50. In an SNDA dated April 16, 2003, WCC sought an Rx-to-OTC switch for Plan B for consumers of all ages. On or about February 26, 2004, Barr Pharmaceuticals, Inc., acquired WCC by stock purchase and merged WCC into Barr's subsidiary, Duramed Research, Inc. From the date of the merger, Barr Pharmaceuticals, Inc. and Duramed Research, Inc. (collectively, hereinafter "Barr") have worked jointly on seeking OTC approval of Plan B.

51. By correspondence dated May 6, 2004, Dr. Steven Galson – then the Acting Director of the Center for Drug Evaluation and Research ("CDER") – issued a "not approvable" letter in response to the Plan B SNDA, citing Barr's failure to demonstrate that adolescents under 16 could use Plan B without professional supervision by a practitioner licensed to administer the drug. In addition to Barr's FFDCA-granted right to request a hearing to challenge FDA's not-approvable finding, Dr. Galson described two additional options: (a) provide the data to demonstrate safety for the targeted adolescents, or (b) seek OTC status only for women and girls 16 and over. Under the second option (which Barr had suggested), Dr. Galson advised Barr that it bore the burden of demonstrating the lawful implementation of a dual Rx-OTC distribution, which FDA would need to find consistent with its statutory authority under FFDCA.

52. On July 21, 2004, Barr filed an amended SNDA to retain Rx status for girls under 16 and to confine the OTC switch to those 16 and over (*i.e.*, Barr declined to fill the age-related

gap in the safety data for Plan B). By letter dated August 26, 2005, the FDA Commissioner (who then possessed the authority to make the approvable versus non-approvable decision) advised Barr that CDER found the scientific data sufficient to support safe use only for women and girls aged 17 and older. The FDA Commissioner also advised Barr that FDA was unable to reach an approvability decision because of "three difficult and novel issues" presented by Barr's age-bifurcated, dual Rx-OTC proposal: (a) whether FDA should initiate a rulemaking to codify its interpretation of when FFDCA permits simultaneous marketing, (b) whether FDA could enforce an age-related limitation for Rx vs. OTC sales, and (c) whether the FFDCA authorizes sale of the same drug in the same packaging to both the Rx and OTC markets.

53. In conjunction with the correspondence dated August 26, 2005, FDA released an advance notice of proposed rulemaking ("ANPRM"), which sought public comment on the issues raised by the FDA Commissioner's letter. *See* 70 Fed. Reg. 52,050 (2005). In its ANPRM, FDA set forth its consistent policy on the "meaningful difference" necessary to distribute the same active ingredient as both OTC and Rx. From the time Congress enacted the Durham-Humphrey Amendments through the date of the ANPRM, FDA had adopted only that one, consistent policy on that "meaningful difference" test.

54. FDA received approximately 47,000 comments on its ANPRM, including comments from Plaintiffs AAPS, CWA, and FRC that indicated that FDA must conduct a rulemaking before approving Plan B's dual Rx-OTC distribution.

55. On or about March 15, 2006, U.S. Senators Hillary Clinton of New York and Patty Murray of Washington – both members of the Senate's Committee on Health, Education, Labor and Pensions ("HELP") – placed holds on that Committee's consideration of Defendant von Eschenbach (then FDA's Acting Commissioner) for confirmation as FDA Commissioner.

Senators Clinton and Murray conveyed their holds to Defendants publicly and privately.

56. On the eve of his confirmation hearing before the Senate HELP Committee, by letter dated July 31, 2006, Defendant von Eschenbach advised Barr that FDA would approve OTC distribution for women aged 18 and older and that no rulemaking was necessary to resolve the novel issues raised by Barr's SNDA for Plan B. Defendants timed the release of the letter to coincide with Defendant von Eschenbach's hearing. On July 31, 2006, Senator Clinton issued a press release to indicate that "[she and Senator Murray] will maintain our hold on Dr. von Eschenbach's nomination until a decision is made."

57. At his confirmation hearing before the Senate HELP Committee, Defendant von Eschenbach offered testimony that "[i]n the 11 months since President Bush appointed me as Acting Commissioner, I have become acutely aware of the Agency's need for strong and permanent leadership with a Commissioner that is not only the choice of the President but also confirmed by the United States Senate." He also indicated that the timing of his letter dated July 31, 2006 (*i.e.,* the day before his hearing), resulted from the timing of the legal process unfolding within FDA (*e.g.,* Defendants' deciding that the information submitted in response to the ANPRM indicated no need for a rulemaking and deciding that Barr's risk management plan would ensure that the girls for whom Defendants found Plan B unsafe would receive the necessary medical supervision). Assuming *arguendo* that the timing of Defendant von Eschenbach's letter was unrelated to the timing of his hearing the next day, the nexus between the two events has the appearance that the two events were related in their timing, with the letter calculated to secure a release of the Senators' holds.

58. By memorandum dated August 23, 2006, Defendant von Eschenbach concluded that (while Plan B was not safe or efficacious for OTC distribution to girls aged 16 and under)

enforcement issues and Barr's voluntary "CARE" program to limit distribution warranted FDA's limiting OTC approval to women aged 18 and older to protect the public health by minimizing the likelihood of younger girls' having access to Plan B without professional supervision. By memorandum dated August 24, 2006, Dr. Galson concurred with Dr. von Eschenbach. Dr. Galson's memorandum expands FDA's meaningful-difference policy to include a sixth factor (namely, the age of the drug's consumer).

59. By press release dated August 24, 2006, Senators Clinton and Murray released their holds on the Senate HELP Committee's consideration of Defendant von Eschenbach's confirmation as FDA Commissioner.

60. By letter dated August 26, 2006, Dr. Galson made an approvable finding for Plan B for OTC distribution to women aged 18 and older, while retaining Rx distribution for girls under 18. In the approvable letter, FDA conditioned its approval on Barr's Convenient Access Responsible Education ("CARE") program and dual Rx-OTC labeling to require keeping Plan B "behind the counter" and distributed only by pharmacies. Because Dr. Galson viewed the approval to change the prior NDA only for women aged 18 and older, the approval letter indicates that PREA does not apply.

61. As approved for Plan B's dual OTC-Rx distribution, the Plan B labeling contains the legend "Rx only for age 17 and younger" and directions for use that purport to comply with both FDA's OTC-labeling and Rx-labeling requirements.

62. On September 27, 2006, the Senate HELP Committee approved Defendant von Eschenbach's nomination as FDA Commissioner and reported it to the full Senate. On December 7, 2006, the full Senate confirmed Defendant von Eschenbach as FDA Commissioner. Consistent with information that they received publicly and privately from Senators Clinton and Murray,

Defendants believed that without their actions on Plan B, the Senate HELP Committee would not have voted Defendant von Eschenbach's confirmation out of Committee to the full Senate.

63. On October 2, 2006, in a meeting with Plaintiffs CWA and FRC to seek support for his confirmation by the full Senate, Defendant von Eschenbach and FDA staff confirmed that Dr. Galson's memorandum dated August 24, 2006, added age as a new criterion to FDA's meaningful-difference test. At that meeting, FDA's General Counsel, Sheldon Bradshaw, argued for the FDA attendees that – because the prior criteria were not created by statute or notice-and-comment rulemaking – FDA could add age as a new criterion without notice-and-comment rulemaking.

Plan B's Safety and Efficacy for Adults

64. As explained in Paragraph 31, the FFDCA and the Durham-Humphrey Amendments require consideration of more than mere toxicity in the assessment of a drug's "safety" for OTC distribution. In states where only a physician may issue a prescription for an Rx drug, Plan B's OTC availability will cause women to obtain non-prescription Plan B without the doctor visit previously required. These women and girls therefore will forego (a) direct medical advise about drug interactions, including those drugs indicated on Plan B's labeling, (b) medical screening for medical contraindications for the known and expected risks of oral contraceptives, (c) physician counseling about the various health risks associated with sexual activity, and (d) medical screening (*e.g.*, pap smear; breast-cancer screening; mammograms for women over 40; sexually transmitted diseases; cervical cancer; human papilloma virus prevention; cholesterol, blood pressure, and other cardiovascular screening).

65. OTC availability of Plan B causes an increase in the incidence of sexually transmitted diseases. In response to Defendants' ANPRM, Plaintiffs submitted comments to

FDA that provided Defendants notice that OTC availability of Plan B will cause an increase in the incidence of sexually transmitted diseases. Defendants' approval of Plan B did not consider these impacts.

66. OTC availability of Plan B causes a decrease in the medical visits, counseling, and screening of women. In response to Defendants' ANPRM, Plaintiffs submitted comments to FDA that provided Defendants notice that OTC availability of Plan B will cause a decrease in the medical visits, counseling, and screening of women. Plaintiffs' comments cited peer-reviewed literature for the proposition that emergency-contraceptive users are significantly less likely than controls never to have had a pelvic examination (26% vs. 6%, P<0.002) or a pap smear (24% vs. 6%, P<0.002). Defendants' approval of Plan B did not consider these impacts.

67. The Plan B labeling falsely and misleadingly claims that Plan B "reduces the risk of pregnancy by at least 75%" for "[t]reatment initiated within 72 hours of unprotected intercourse." More credible and more recent data put the efficacy above 23% (at a 95% level of confidence) but suggest that the "the published efficacy figures calculated from currently available data on this regimen—on average, approximately 80%—may overstate actual efficacy, possibly quite substantially." Elizabeth G. Raymond, M.D., M.P.H., James Trussell, Ph.D., & Chelsea B. Polis, *Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review*, 109 OBSTETRICS & GYNECOLOGY 181, 187 (American College of Obstetricians and Gynecologists 2007). Although the 2007 article by Dr. Raymond *et al.* was not before Defendants when they acted to approve Plan B in 2006, the data that the article cites were available, and would be before the agency in any remand or reconsideration of the Plan B approval ordered by this Court or initiated by Defendants if this Court vacates the 2006 approval.

68. The Plan B labeling misleadingly compares an efficacy rate of 75% (*i.e.*, a failure

rate of 25%) for perfect use, *in a single instance*, versus the failure rates of traditional contraceptives for both typical and perfect use, *over an entire year*. To avoid misleading the OTC public, Plan B's labeling should compare the same statistic for each method (*e.g.*, single-instance perfect use versus single-instance perfect use).

69. Plan B's label warnings include "not *effective* in terminating an existing pregnancy" (emphasis added) to convey its lack of efficacy to terminate an implanted fetus, but use the lesser warnings "not *recommended* for routine use as a contraceptive" and "Not *Intended* To Replace Regular Birth Control" (emphasis added) to describe its efficacy as a replacement for traditional contraceptives. Given Plan B's low efficacy versus traditional contraceptives, that labeling is inadequate to alert consumers of Plan B's lack of effectiveness. In order to provide the appropriate warning to consumers, Plan B's labeling must explicitly and prominently warn consumers that Plan B is "not effective for routine use" or words to that effect.

70. The label comprehension test submitted to support Plan B demonstrates that only 75% of respondents understood Plan B's label to caution against taking Plan B in the presence of unexplained vaginal bleeding, and only 67% understood its statement that Plan B is not a replacement for regular methods of contraception. As an empirical matter, Plan B's label comprehension test establishes that significant groups do not understand the labeling to limit Plan B's usage as a replacement for traditional contraceptives.

71. Separate and apart from the label's facial failure to convey the limitations on Plan B's safety and efficacy as an alternative to traditional contraceptives and from the label comprehension test's confirmation that failure for a substantial percentage of women, Defendants should have considered the effect of Plan B's proponents on misleading substantial numbers of women. By letter dated November 19, 2002 (MACMIS ID #11214), FDA's Division

of Drug Marketing, Advertising, and Communications issued a warning letter asking Plan B's sponsor to cease disseminating false and misleading advertising that overstated Plan B's efficacy. The mindset that created the false and misleading advertising continues to exist among Plan B proponents and directly and indirectly continues to mislead a substantial numbers of women to view Plan B as a panacea.

72. Given Plan B's poor efficacy vis-à-vis traditional contraceptives, the use of Plan B as a replacement for traditional contraceptives by a nontrivial segment of contraceptive users would create more unintended pregnancies than the number of unintended pregnancies that Plan B would prevent through its intended (but improperly communicated) use.

PREA and Plan B's Safety and Efficacy for Adolescents

73. Defendants premised their authority to approve OTC status only for women 18 and over, without requiring PREA data, on the SNDA's changing the Plan B labeling only for non-PREA subpopulations (*i.e.*, "adults" aged 18 and older). Contrary to Defendants' premise, PREA does not include such rigid age ranges, and puberty extends beyond the eighteenth birthday for a significant pediatric subpopulation of young women. *See, e.g.*, Leon Speroff & Mark A. Fritz, *Clinical Gynecologic Endocrinology and Infertility*, at 370 (Lippincott Williams & Wilkins 7th ed. 2005); FDA, "International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population," 65 Fed. Reg. 19,777, 19,780 (2000); FDA, "International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population; Availability," 65 Fed. Reg. 78,493 (2000); FDA, "Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population," at 9 (Dec. 2000).

74. The data supporting Plan B fail to establish the safety of Plan B's high doses of a

systemically absorbed hormone in females (of whatever age) undergoing puberty's time-sensitive and cellular-level changes. The label's inadequacy exacerbates the lack of data supporting safety during puberty because the label does not adequately warn against use of Plan B as an alternative to traditional ("Plan A") contraceptives. The failure of the labeling exposes women and girls to multiple uses per month and regular (*i.e.*, month to month) use, neither of which dosages were addressed by Plan B's safety data in either pubescent females or mature females.

75. Under the heading "Pediatric Use," Plan B's labeling includes the following:

> Safety and efficacy of progestin-only pills have been established in women of reproductive age for long-term contraception. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of Plan B® emergency contraception before menarche is not indicated.

The foregoing labeling statement (a) expressly implies that Plan B is safe and efficacious for adolescents over the age of puberty; (b) by negative implication, implicitly authorizes use of Plan B after menarche; and (c) inaccurately implies that Plan B has been found safe for pubertal adolescents aged 16 and over. Because Plaintiffs' review of Plan B labeling on Defendants' website and in the medical literature did not establish whether the foregoing Pediatric Use language appeared in Plan B's labeling as originally approved in 1999, Plaintiffs allege in the alternative that FDA approved the foregoing Pediatric Use language as part of the original NDA and that FDA approved the foregoing Pediatric Use language in a subsequent SNDA.

76. FFDCA does not prohibit someone 18 or older from purchasing Plan B and giving it to someone younger than 18. Notwithstanding the Rx-only labeling for girls under 18, that population certainly will have widespread FFDCA-noncompliant access to Plan B, without prescription, through older friends and siblings and others. Similarly aged children readily obtain

access to alcohol and tobacco products, notwithstanding government and merchant efforts to restrict or even criminalize distribution of such products to minors. *See, e.g.,* D.F. Preusser & A.F. Williams, *Sales of Alcohol to Underage Purchasers in Three New York Counties and Washington D.C.,* J. OF PUB. HEALTH POLICY 13(3):306-317 (1992) (underage alcohol purchasers in Washington succeeded in 97% of purchase attempts); A.C. Wagenaar & M. Wolfson, *Enforcement of the Legal Minimum Drinking Age in the United States,* J. OF PUB. HEALTH POLICY 15(1):37-58 (1994) (for every 100,000 occasions of underage drinking, only 5 alcohol outlets incur actions by a state alcohol beverage control agency).

COUNT I
UNSAFE FOR OTC DISTRIBUTION

77. Plaintiff incorporates Paragraphs 1-76 and 82-109 as if fully set forth herein.

78. To qualify for OTC distribution, the manufacturer must establish the drug's safety and effectiveness for use by consumers without the professional supervision of a practitioner licensed by law to administer drugs. The SNDA data submitted to support Plan B's Rx-to-OTC switch do not establish either Plan B's safety or its effectiveness.

79. As confirmed by its label comprehension test results (Paragraph 70), Plan B's labeling does not adequately warn consumers of Plan B's ineffectiveness for routine contraception. For the reasons set forth in Paragraphs 64-72 and 73-76, Plan B is neither safe nor efficacious for OTC use.

80. For the foregoing reasons, the data submitted to support the SNDA for Plan B did not include adequate tests by methods reasonably available to show that Plan B is safe and effective for use under the conditions prescribed and suggested by Plan B's labeling, the results of the label comprehension test and safety testing do not show that Plan B is safe and effective

for use under such conditions, and FDA had inadequate data to determine that Plan B is safe and effective under such conditions.

81. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires,* and without observance of procedure required by law.

COUNT II
UNLAWFUL DUAL OTC/RX APPROVAL

82. Plaintiff incorporates Paragraphs 1-81 and 85-109 as if fully set forth herein.

83. FFDCA authorizes approval of a drug product for only one of two mutually exclusive modes of distribution and labeling: OTC or Rx. FFDCA does not authorize approval of the same drug product, with the same labeling, for simultaneous distribution as both an OTC and an Rx product. To the contrary, FFDCA prohibits the simultaneous distribution of the same drug product as both an Rx and OTC drug.

84. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires,* and without observance of procedure required by law.

COUNT III
UNLAWFUL BIFURCATION BY AGE

85. Plaintiff incorporates Paragraphs 1-84 and 93-109 as if fully set forth herein.

86. Assuming *arguendo* that FFDCA authorizes dual OTC-Rx distribution of the same drug product with the same labeling (or alternatively that FFDCA authorizes dual OTC-Rx distribution of the same drug product with *different* labeling), the FFDCA does not authorize the Defendants' approval of Plan B for simultaneous OTC distribution for women 18 and over and Rx distribution to girls under 18. Specifically, FDA lacks the authority to enforce Plan B's age

limitations.

87. Assuming *arguendo* that FFDCA authorizes approval of a drug product for simultaneous OTC distribution to adults 18 and over and Rx distribution to girls under 18, Defendants' approval of Plan B for OTC distribution to women 18 and over nonetheless would violate the FFDCA and APA because Plan B's free availability OTC guarantees that – as with widespread underage access to alcohol and tobacco products – underage girls will obtain unsupervised access to Plan B, which FDA has found unsafe for such girls.

88. Defendants made four distinct legal errors in determining that PREA does not apply to Plan B's SNDA because the label changes concerned only non-PREA subpopulations (*i.e.,* adults 18 and over). First, and most obviously, the SNDA includes changed label indications for *all* women past their eighteenth birthday, which includes significant numbers of females still within puberty and adolescence (*i.e.,* FDA incorrectly reasoned that the eighteenth birthday truncates all relevant pediatric subpopulations). Second, by its terms, the temporal "at this time" limitation of the 1999 NDA's waiver of pediatric data (Paragraph 73) did not prospectively waive PREA for all future SNDAs for Plan B. Third, the label's claimed indication of safety and efficacy for "postpubertal adolescents under the age of 16 and for users 16 years and older" (Paragraph 75) requires PREA data. Fourth, even if Defendants' "adults-only" OTC approval did not change the indications for PREA subpopulations, the provisions of 21 U.S.C. §355c(a)(2)(A)(ii) are not limited to "claimed indications," which renders Defendants' rationale inapposite: the 2006 SNDA requires data to support dosing and administration under §355c(a)(2)(A)(ii) for all pediatric subpopulations, even if it does not require data to support the safety or effectiveness under §355c(a)(2)(A)(i) for any of those subpopulations.

89. Because PREA applies past the eighteenth birthday for systemically absorbed

hormonal drugs like Plan B, the Plan B SNDA required not only dosage and administration data to support all indications for all pediatric subpopulations (*i.e.*, regardless of Rx versus OTC distribution), but also safety and efficacy data to support the OTC indication for pediatric subpopulations past their eighteenth birthday but still within puberty and/or adolescence. For the foregoing reasons, the data submitted to support Plan B's age-bifurcated Rx-to-OTC switch did not satisfy PREA's (and thus FFDCA's) requirements.

90. Even under Defendants' view of PREA, the Plan B SNDA required data on relevant PREA subpopulations (namely, girls from menarche up to their eighteenth birthday), based on foreseeable misuse by those subpopulations.

91. For the foregoing reasons, the data submitted to support the SNDA for Plan B did not include adequate tests by methods reasonably available to show that Plan B is safe for use under the conditions prescribed and suggested by Plan B's labeling, the results of the label comprehension test and safety testing do not show that Plan B is safe for use under such conditions, and FDA had inadequate data to determine that Plan B is safe under such conditions.

92. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires*, and without observance of procedure required by law.

COUNT IV
UNLAWFUL "THIRD CLASS" OF DRUG

93. Plaintiff incorporates Paragraphs 1-92 and 99-109 as if fully set forth herein.

94. FDA lacks the authority to go beyond FFDCA's OTC-Rx dichotomy to create a "third class" of drugs (*i.e.*, a class of drugs that require pharmacists to supplement the labeling or that certain subpopulations might misuse with direct access).

95. Such a third class of drugs creates anti-competitive and anti-consumer effects on the distribution of nonprescription drugs. The U.S. Justice Department and the National Association of Attorneys General oppose creating such a third class of drugs.

96. FDA lacks the authority to impose, or to authorize the imposition of, the anti-competitive and anti-consumer impacts created by a third class of drugs generally or by Plan B's CARE program specifically.

97. FDA lacks authority to impose, or to authorize the imposition of, controls such as the CARE program's prohibiting or restricting shipment of FDA-approved drugs to duly licensed pharmacies.

98. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires*, and without observance of procedure required by law.

COUNT V
FAILURE TO CONVENE APA RULEMAKING

99. Plaintiff incorporates Paragraphs 1-98 and 102-109 as if fully set forth herein.

100. By failing to convene a rulemaking to add its new, patient-based "age" parameter to the its prior, drug-based, five-parameter interpretation of the meaningful-difference test, FDA amended a rule without the required notice-and-comment rulemaking. 5 U.S.C. §553(b)-(c).

101. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires*, and without observance of procedure required by law.

COUNT VI
FAILURE TO CONVENE FFDCA RULEMAKING

102. Plaintiff incorporates Paragraphs 1-101 and 105-109 as if fully set forth herein.

103. By purporting to remove a new drug (Plan B) from FFDCA's Rx requirements in an approved NDA without the required rulemaking, FDA violated the Durham-Humphrey Amendments, which require FDA to remove drugs *by regulation.* 21 U.S.C. §353(b)(3). To the extent that FDA's general removal regulation, 21 C.F.R. §310.200(b), purports to replace the statutorily required "regulation" with a "finding" in an FDA order, 21 C.F.R. §310.200(b) exceeds FDA's authority under the FFDCA and APA. Agencies lack authority to exempt themselves, by rule, from otherwise-applicable statutory rulemaking requirements.

104. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires*, and without observance of procedure required by law.

COUNT VII
UNLAWFUL POLITICAL PRESSURE

105. Plaintiff incorporates Paragraphs 1 through 104 as if fully set forth herein.

106. The "holds" that Senators Clinton and Murray placed on the Senate HELP Committee's consideration of the nomination of then-Acting Commissioner von Eschenbach as FDA Commissioner improperly influenced consideration of the Plan B SNDA and the accompanying Rx-to-OTC switch by Defendants United States and FDA institutionally, Defendant von Eschenbach in his official capacity as Acting FDA Commissioner, and Defendant von Eschenbach personally.

107. In the alternative, the foregoing Senate holds create the improper appearance of improper influence over Defendants United States and FDA institutionally and Defendant von Eschenbach, both in his official capacity as Acting FDA Commissioner and personally.

108. By linking Defendant von Eschenbach's confirmation (which all Defendants

desired) with approval of the Plan B SNDA (which all Defendants had to decide), the "holds" by Senators Clinton and Murray had an immediate and direct nexus with the approval of Plan B.

109. For the foregoing reasons, Defendants' approval of Plan B for OTC distribution and their decisions to forego notice-and-comment rulemaking are arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires,* and without observance of procedure required by law.

PRAYER FOR RELIEF

110. WHEREFORE, Plaintiffs respectfully asks this Court to grant the following relief:

A. Pursuant to 5 U.S.C. §706, 28 U.S.C. §§1331, 1361, 1651(a), 2201-2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C. Code §11-501, Fed. R. Civ. Proc. 57, and this Court's equitable powers, a Declaratory Judgment that:

(i) When the safety studies submitted to support an OTC drug rely on lower than expected dosages, FDA and its Commissioner cannot approve the drug for OTC distribution unless the labeling reflects the low dosages in language designed to alert the consumer that the drug is unsafe or not approved for use above that dosage;

(ii) When considering the safety of an Rx drug for OTC distribution, FDA and its Commissioner must assess (and where relevant require data on) the "safety" of that switch under all potentialities for harmful effect, collateral measures needed to use the drug safely, and the suitability of the drug for use without medical supervision, which for contraceptives or abortifacients includes anticipated misuse of the drug, any increase or decrease in risky or unsafe sexual activity, any

increase or decrease in the rates of unintended pregnancies and abortions, and the health effects of foregoing medical counseling and screening;

(iii) When comparing the safety of a drug intended as a contraceptive or abortifacient, FDA and its Commissioner must test the drug's safety against alternate pharmaceutical or surgical treatments, not against pregnancy;

(iv) FDA and its Commissioner lack the authority to approve the same drug product for simultaneous OTC-Rx distribution under the same labeling;

(v) Any drug product labeled for simultaneous OTC-Rx distribution is misbranded;

(vi) FDA and its Commissioner lack the authority to approve the same drug product for simultaneous OTC-Rx distribution under different labeling;

(vii) In approving an NDA or SNDA, FDA and its Commissioner must consider likely misuse in making the safety determination under 21 U.S.C. §353(b)(1);

(viii) For SNDAs filed after April 1, 1999, FDA must require applicants to submit data pursuant to the Pediatric Research Equity Act of 2003 ("PREA") to support any misuse likely to affect relevant PREA subpopulations, even if the SNDA's changes in claimed indications (or other changes) do not concern such subpopulations;

(ix) FDA and its Commissioner lack the authority to create or to approve the creation of a "third class" of pharmacist-dispensed drugs;

(x) FDA must conduct notice-and-comment rulemaking before it can consider a patient's age or other subpopulation criteria in determining whether to approve an NDA or SNDA that results in an Rx-to-OTC switch for a drug product based on labeling that restricts use by age or by such other subpopulation criteria;

(xi) Defendants violated the APA's and FFDCA's rulemaking requirements by purporting to add an age parameter to the meaningful-difference test for Rx-to-OTC switches and by purporting to remove Plan B from Rx status by order, without promulgating a regulation;

(xii) Notwithstanding 21 C.F.R. §310.200(b), FDA must conduct a rulemaking to exempt a new drug from Rx requirements in an approved NDA when acting pursuant to the authority conferred by 21 U.S.C. §353(b)(3);

(xiii) FDA and Commissioner von Eschenbach approved the OTC switch for Plan B and decided to forego notice-and-comment rulemaking under actual and improper congressional pressure; and

(xiv) In the alternative, FDA and Commissioner von Eschenbach approved the OTC switch for Plan B and decided to forego notice-and-comment rulemaking under the improper appearance of improper congressional pressure.

B. Pursuant to 5 U.S.C. §706, 28 U.S.C. §§1331, 1361, 1651(a), 2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C. Code §11-501, and this Court's equitable powers, an Order providing that

(i) Defendants' approval of Plan B for OTC distribution is vacated; and

(ii) Defendants are enjoined from approving Plan B for OTC distribution via SNDA or NDA unless such approval is fully consistent with the declaratory relief in Paragraph 110(A).

C. Pursuant to 28 U.S.C. §2412 and any other applicable provisions of law or equity, award Plaintiffs' costs and reasonable attorneys fees.

D. Such other relief as may be just and proper.

Dated: April 12, 2007

Respectfully submitted,

/s/ Lawrence J. Joseph

Lawrence J. Joseph, D.C. Bar No. 464777

2121 K Street, NW, Suite 800
Washington, DC 20037
Telephone: (202) 669-5135
Telecopier: (202) 318-2254

Counsel for Plaintiffs Association of American Physicians and Surgeons, Inc., Concerned Women for America, Family Research Council, and Safe Drugs for Women