IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, in her individual capacity, as Vice-Chair of the Women's Liberation Birth Control Project, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; ERIN T. MAHONEY, in her individual capacity, as Chair of the Women's Liberation Birth Control Project, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; CAROL GIARDINA, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; KELLY MANGAN, in her individual capacity, as President of the University of Florida Campus Chapter of the National Organization for Women, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; STEPHANIE SEGUIN, in her individual capacity, as Chair of the Florida National Organization for Women Young Feminist Task Force, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; LORI TINNEY, in her individual capacity, as President of the Gainesville Chapter of the National Organization for Women, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; JENNIFER BROWN, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; CANDACE CHURCHILL, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; and FRANCIE HUNT, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS, on its own behalf and on behalf of its members and women who need Emergency Contraception; and NATIONAL LATINA INSTITUTE FOR REPRODUCTIVE

CV-05-0366 (ERK/VVP)
CV-12-0763 (ERK/VVP)

HEALTH, on its own behalf and on behalf of women who need Emergency Contraception; ROBERT JAFFE; AURORA DEMARCO; ANGELICA JAFFE; CATHERINE LEDERER-PLASKETT; ALIZA LEDERER-PLASKETT; JONATHAN MARKS; GABRIELLE MARKS,

Plaintiffs,

v.

ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the Food and Drug Administration,

Defendant.

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FIFTH AMENDED COMPLAINT

Plaintiffs, by and through their undersigned attorneys, bring this complaint against the defendant, his agents and successors in office, and in support thereof aver the following:

1. This is a challenge under the Administrative Procedures Act (APA) and the United States Constitution to the denial by the Food and Drug Administration (FDA) of a Supplemental New Drug Application (SNDA) and a citizen petition ("citizen petition") seeking to switch the emergency contraception ("EC") drug Plan B from prescription-only availability to unrestricted over-the-counter status[1] ("OTC switch") and to the establishment by the FDA of an age-restricted, behind-the-pharmacy-counter, dual prescription/nonprescription regime for Plan B ("BTC regime"). Plaintiffs claim that the BTC regime and the denial of the OTC switch violate their rights and the rights of women who need Plan B to privacy and equal protection under the Fifth Amendment, and that the BTC regime and the denial of the OTC switch violate their rights

[1] Plaintiffs will use the term "unrestricted OTC status" to mean over-the-counter availability without a requirement that the drug be kept behind the pharmacist's counter, without a restriction on the types of venues where the product may be distributed, and without an age restriction. In other words, "unrestricted status" is used to mean the status of numerous other drugs and devices, such as aspirin, condoms, dextromethorphan, ibuprofen, acetaminophen, etc.

and the rights of women who need Plan B because it exceeds the statutory authority of the FDA and is arbitrary and capricious. Plaintiffs seek injunctive relief requiring the defendant to approve the OTC switch for women of all ages, or such other equitable relief as the Court may deem appropriate, and a declaratory judgment that the FDA's denial violates the APA and violates the constitutional rights of women who need Plan B.

I. Jurisdiction and Venue

2. This Court has jurisdiction under 28 U.S.C. § 1331 because this case arises under the Constitution and laws of the United States.

3. Venue is proper in this district under 28 U.S.C. § 1391(d) because one of the plaintiffs resides in this district and the defendant is an officer of the United States acting in his official capacity.

II. The Parties

A. Plaintiffs

4. Plaintiff Annie Tummino is a resident of Brooklyn, New York. She sues on her own behalf, in her individual capacity as Vice-Chair of the Women's Liberation Birth Control Project and as Coordinator of the Morning-After Pill Conspiracy ("MAP Conspiracy"), and on behalf of women who need Plan B.

5. Plaintiff Erin T. Mahoney is a resident of New York, New York. She sues on her own behalf, in her individual capacity as Chair of the Women's Liberation Birth Control Project and as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

6. Plaintiff Carol Giardina is a resident of New York, New York. She sues on her own behalf, in her individual capacity as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

7. Plaintiff Kelly Mangan is a resident of Gainesville, Florida. She sues on her own behalf, in her individual capacity as President of the University of Florida Campus Chapter of the National Organization for Women, as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

8. Plaintiff Stephanie Seguin is a resident of Gainesville, Florida. She sues on her own behalf, in her individual capacity as Chair of the Florida National Organization for Women Young Feminist Task Force and as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

9. Plaintiff Lori Tinney is a resident of Gainesville, Florida. She sues on her own behalf, in her individual capacity as President of the Gainesville Chapter of the National Organization for Women, Gainesville, FL and as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

10. Plaintiff Jennifer Brown is a resident of Gainesville, Florida. She sues on her own behalf, in her individual capacity as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

11. Plaintiff Candace Churchill is a resident of Gainesville, Florida. She sues on her own behalf, in her individual capacity as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

12. Plaintiff Francie Hunt is a resident of Nashville, Tennessee. She sues on her own behalf, in her individual capacity as Coordinator of the MAP Conspiracy, and on behalf of women who need Plan B.

13. The MAP Conspiracy is a coalition of feminist organizations leading the grassroots movement to make the Morning-After Pill an over-the-counter drug by raising public consciousness about the ways that women have to conspire to obtain it. Since February 2004, the MAP Conspiracy has organized speak-outs where women publicly testify from their own experience about their need for the Morning-After Pill and the obstacles they face obtaining it. Members of the MAP Conspiracy also testified at the December 2003 FDA public hearings on the Barr application for approval of over-the-counter status for Plan B.

14. Each of the individual plaintiffs listed in paragraphs 4-13 above has access to one or more doses of Plan B, and each of them intends, plans, and has pledged to provide Plan B to friends or other women of any age -- including women under the age of 18 and women over 18 who lack government issued identification or who lack timely access to a pharmacy or health clinic -- whom they learn need Plan B to prevent pregnancy. None of the individual plaintiffs listed in paragraphs 4-13 above is licensed or authorized by law in any state to prescribe or dispense drugs. Consequently, unless unrestricted OTC status for Plan B is implemented, each of the individual plaintiffs listed in paragraphs 4-13 above risks violating federal and state criminal statutes if she carries through on her plan to provide Plan B to women of all ages who need it to prevent pregnancy. *See*, *e.g.*, 21 U.S.C. §§ 353(b)(1), 333(a), 333(b) (2005); § 465.015, Fla. Stat. (2004).

15. Each of the individual plaintiffs listed in paragraphs 4-13 above objects to the requirement contained in the BTC regime that she must disclose her name, address and age to a

pharmacist and/or pharmacy employee in order to obtain Plan B. In addition, each individual plaintiff listed in paragraphs 4-13 above objects to the disclosure of information to third parties about her personal sexual activity that will occur because, in order to obtain Plan B without a prescription, she is required to present identification to a pharmacist or pharmacy employee.

16. Plaintiff Association of Reproductive Health Professionals (ARHP) is a non-profit membership association composed of experts in reproductive health. These professionals include physicians, advanced practice clinicians (nurse practitioners, nurse midwives, physician assistants), researchers, educators, pharmacists, and other professionals in reproductive health, some of whom have authority to prescribe drugs and some of whom do not. ARHP and its members provide reproductive health services and education, conduct reproductive health research, and influence reproductive health policy. Specifically, ARHP works to improve the reproductive health of women by reducing the number of unintended pregnancies among women. ARHP, along with Princeton University's Office of Population Research (OPR), manages the *Emergency Contraception Hotline* (1-888-Not-2-Late) and *Website* (www.not-2-late.com), which aim to prevent unintended pregnancy by providing women of all ages and their partners information about, and rapid access to, emergency contraception. Both the *Hotline* and *Website* are highly utilized tools, currently receiving an average of 60,000 calls and 650,000 unique website visits per year. These calls and visits include calls and visits by women under the age of 18, women over 18 who lack government issued identification, and women who lack timely access to a pharmacy or health clinic. The *Hotline* is an automated, toll-free, 24-hour, confidential service available in both English and Spanish that gives callers general emergency contraception information and a list of the five emergency contraception providers nearest to them (including a list of pharmacists in states where pharmacists are permitted by state law to

dispense Plan B to those who require a prescription). It is available from any phone in the United States, Puerto Rico, U.S. Virgin Islands, British Columbia, and the Yukon Territory. The *Website*, available in English, French, Spanish, and Arabic, is the most comprehensive emergency contraception clearinghouse in the world available to anyone via the World Wide Web. It features frequently asked questions about emergency contraception, a publications bibliography, a Plan B materials database, and a searchable database of Plan B providers across the country, Puerto Rico, Guam, U.S. Virgin Islands, and British Columbia. The full directory of providers can be searched by city, state, area code, and zip code. The NOT-2-LATE database also lists pharmacists in Alaska, California, Washington State, New Mexico, and British Columbia. ARHP and OPR work closely with local pharmaceutical associations to sign up pharmacists who dispense Plan B behind the counter. Vermont has recently become the ninth state—joining Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Washington—to allow direct dispensation of Plan B by pharmacists. FDA admitted on June 9, 2006 that it had denied ARHP's petition to the FDA to switch Plan B to OTC status for women of all ages. The BTC regime and the denial of unrestricted OTC status interfere with ARHP's ability to educate health care providers and the public about emergency contraception, interfere with ARHP's efforts to reduce the number of unintended pregnancies and its efforts to use the *Emergency Contraception Hotline* and *Website* to achieve that goal, and interfere with its members' ability to accomplish the goal of improving the reproductive health of women. ARHP sues on its own behalf, on behalf of its members who lack prescribing authority and their patients and clients who seek Plan B who are under 18, are over 18 and lack government issued identification, lack timely access to a pharmacy or health clinic, or are over 18 and object to

showing identification in order to obtain Plan B, and on behalf of the women who utilize the Hotline and Website to obtain access to Plan B.

17. Plaintiff National Latina Institute for Reproductive Health (NLIRH) is a non-profit organization formed under section 501(c)(3) of the Internal Revenue Code. NLIRH conducts a Plan B education and outreach project which seeks to educate providers of Plan B and potential users of Plan B about what Plan B is, how to use it, and how to obtain it and, for providers, how to incorporate it into their practice. NLIRH has conducted such an education and outreach project in the Bronx, and plans additional such projects at several locations in Brooklyn and the Bronx through June of 2005. NLIRH's Plan B education outreach projects are impeded by the age-restricted behind-the-counter dual prescription/nonprescription status for Plan B. If Plan B is switched to OTC for women of all ages, NLIRH will be able to improve access to Plan B by enhancing its Plan B educational programs for both the health care providers and the public participants involved in those projects. NLIRH sues on its own behalf and on behalf of the women participants in its Plan B projects who are of childbearing age, including women who are under 18, are over 18 and lack government issued identification, lack timely access to a pharmacy or health clinic, or are over 18 and object to showing identification in order to obtain Plan B.

18. Plaintiff Robert Jaffe is a resident of Brooklyn, New York and is the father of a 13-year-old daughter, Angelica Jaffe. He sues on behalf of himself and his daughter because he wants his daughter to be able to obtain Plan B without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

19. Plaintiff Aurora DeMarco is a resident of Brooklyn, New York and is the mother of a 13-year-old daughter, Angelica Jaffe. She sues on behalf of herself and her daughter because she

wants her daughter to be able to obtain Plan B without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

20. Plaintiff Angelica Jaffe is a resident of Brooklyn, New York and is a 13-year-old young woman. She sues on her own behalf because she wants to be able to obtain Plan B without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

21. Plaintiff Catherine Lederer-Plaskett is a resident of Hartsdale, New York and is the mother of a 16-year-old daughter, Aliza Lederer-Plaskett. She sues on behalf of herself and her daughter because she wants her daughter to be able to obtain Plan B without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

22. Plaintiff Aliza Lederer-Plaskett is a resident of Hartsdale, New York and is a 16-year-old young woman. She sues on her own behalf because she wants to be able to obtain Plan B without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

23. Plaintiff Jonathan Marks is a resident of Brooklyn, New York and is the father of a 13-year-old daughter, Gabrielle Marks. He sues on behalf of himself and his daughter because he wants his daughter to be able to obtain Plan B without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

24. Plaintiff Gabrielle Marks is a resident of Brooklyn, New York and is a 13-year-old young woman. She sues on her own behalf because she wants to be able to obtain Plan B

without a prescription and without any restriction on its point of sale so as to maximize the likelihood that she will avoid unwanted pregnancy.

25. Each woman who is (1) under 18 years of age and needs Plan B; (2) over 18 but lacks adequate proof of age to obtain Plan B without a prescription; (3) over 18 but lacks timely access to a pharmacy or health clinic so as to maximize the effectiveness of Plan B; or (4) must present identification including proof of age to a pharmacist or health clinic and thereby disclose at least her name and possibly her address to third-parties to obtain Plan B, is irreparably injured as a direct result of the FDA's age-restricted behind-the-counter dual prescription/nonprescription regime for Plan B. Each of the Plaintiffs listed in paragraphs 4-13, 16, and 17 above wants to and intends to try to make Plan B available to women in each of these categories, and asserts third-party standing to assert their interests.

26. Each of the plaintiffs is aggrieved on a continuing and ongoing basis by the FDA's rejection of the OTC switch of Plan B for women of all ages.

27. Each of the plaintiffs is injured on a continuing and ongoing basis by the FDA's rejection of the OTC switch for women of all ages, and the FDA's rejection is the cause of that injury.

28. The relief sought in this complaint will redress the injury suffered by each of the plaintiffs that is caused by the FDA's rejection of unrestricted OTC status for Plan B.

B. Defendant

29. Andrew C. von Eschenbach is the acting commissioner of the FDA. Von Eschenbach is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. He is also responsible for advancing the public

health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. He is sued in his official capacity.

III. Statutory and Regulatory Background

30. Under FDA regulations, "[a]ny drug limited to prescription use . . . shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.200(b) (2005); *see also* 21 U.S.C. § 353(b)(3) (2005) ("The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.").

31. The FDA views OTC status as the "default" status for drugs. *See* http://www.fda.gov/cder/Offices/OTC/FDA-CHPA%20seminar%20Oct%202/tsld013.htm (attached as Exhibit U).

32. An approved drug is suitable for OTC use when: (1) the drug is safe for self-medication, 21 C.F.R. § 310.200(b); 21 C.F.R. § 330.10(a)(4)(i); (2) the drug is effective when self-administered, 21 C.F.R. § 310.200(b); 21 C.F.R. § 330.10(a)(4)(ii); (3) the condition to be treated is self-diagnosable; and (4) the drug's labeling is tailored to self-administration, 21 C.F.R. § 310.200(b); 21 C.F.R. § 330.10(a)(4)(v).

33. The FDA has developed its own internal criteria for assessing OTC switch applications, known as the "Peck criteria" after former CDER Director Carl Peck. These criteria

are: 1.) Does the product have an acceptable margin of safety based on prior prescription marketing experience; 2.) Does the product have low misuse and abuse potential; 3.) Can the condition be adequately self-recognized and successfully self-treated with minimal health care provider intervention; 4.) Do the benefits from the switch to non-prescription status clearly outweigh the risks; and 5.) Is the self-treatment product safe and effective during consumer use. Plan B meets each of these criteria.

34. By statute, the manufacturer of a prescription drug may file a supplemental new drug application with the FDA seeking to switch the drug to OTC status. 21 U.S.C. § 355(b). Such an application must be acted upon by the FDA within 180 days of its filing. 21 U.S.C. § 355(c).

35. In addition, FDA regulations explicitly authorize the use of a citizen's petition to seek a switch from prescription to OTC status: "A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by . . . any interested person . . . fil[ing] a petition . . . pursuant to Part 10 of this chapter . . . ." 21 C.F.R. § 310.200(b). Once a citizen's petition has been filed, the FDA is required by its regulations to either approve the petition, deny the petition, or "[p]rovide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information." 21 C.F.R. § 10.30(e)(2).

36. During the process of considering an application for an OTC switch, the FDA typically receives the advice of the FDA's OTC advisory committee meeting together with the FDA's advisory committee that has specific expertise in the product under consideration. In the case of Plan B, the latter committee is the Advisory Committee for Reproductive Health Drugs. These advisory committees are authorized by, *inter alia*, 21 U.S.C. § 355(n) (2005).

37. The FDA lacks the statutory authority to restrict the types of businesses that can sell OTC drugs.

38. Dispensing a prescription drug other than by prescription is an act of "misbranding" under federal law. 21 U.S.C. § 353(b)(1). Introducing a misbranded drug into interstate commerce is a "prohibited act," 21 U.S.C. § 331(a), punishable by not more than one year imprisonment or a fine of up to $1000 or both. 21 U.S.C. § 333(a)(1).

IV. Factual Allegations

A. Making Plan B Available OTC to Women of All Ages Would Improve the Public Health and Enable Women to Reduce their Risk of Unplanned Pregnancies.

39. Unintended pregnancy is a significant public health problem in the United States. The United States has one of the highest rates of unintended pregnancy compared to other developed countries. The rate of teen pregnancy in the United States is also one of the highest among developed countries. Wider access to Plan B will reduce unintended pregnancies, including among teenagers.

40. The risks of pregnancy and childbirth, including maternal death, can be serious and far exceed the risks associated with Plan B.

41. Plan B is a drug used only by women, and every woman of childbearing age is a potential user of Plan B.

42. Plan B (Levonorgestrel) is an emergency contraceptive drug in tablet form that can be used to prevent pregnancy following an act of intercourse in which no contraceptive was used or the contraceptive method used failed.

43. When taken within 72 hours of unprotected intercourse, Plan B reduces the risk of pregnancy by approximately 89 percent after a single act of unprotected sex. As the interval

between intercourse and the start of treatment increases, Plan B's effectiveness declines, and the risk of pregnancy increases. Plan B does not interfere with an established pregnancy.

44. Switching Plan B to OTC status for women of all ages will promote public health because Plan B is only effective for a short time after unprotected sex, and it works most effectively if used within twenty-four hours of unprotected sex. Because contacting a physician and obtaining and filling a prescription hinder women from obtaining Plan B in a timely fashion, making Plan B available OTC will allow more women to use the treatment, and enable more women to prevent unwanted pregnancies, to the benefit of public health.

45. Limiting Plan B to prescription use is not necessary for the protection of public health.

46. Plan B is safe for self-medication because it is not toxic to the woman (or to the embryo or fetus if a pregnancy had been previously established in the woman).

47. Plan B has a low risk of abuse or overdose, and if overdose occurs is unlikely to lead to serious consequences.

48. Plan B's side effects are well-known and minor.

49. Plan B is effective when self-administered. Its administration is simple and relies only on assessments as to time elapsed since sexual intercourse that can be independently made by the woman, and any interaction between Plan B and other drugs would be nonfatal and unlikely to seriously affect Plan B's efficacy.

50. The condition Plan B treats — contraceptive failure or failure to use contraception during intercourse — is one that is readily diagnosable by a woman.

51. Plan B has no contraindications that would pose a danger to the patient.

52. The existing patient labeling for Plan B is tailored to self-administration in that it is simple, clear, comprehensive and easy to follow.

53. The American Medical Association and the American College of Obstetricians and Gynecologists both support switching Plan B to OTC status for women of all ages. *See* Dec. 5, 2000 Statement of American Medical Association; February 14, 2001 Statement of the American College of Obstetricians & Gynecologists. In addition, the American Academy of Pediatrics supports switching Plan B to OTC status for women of all ages. (Attached hereto as Exhibit T).

B. Public Health Organizations Filed Two Citizen Petitions with the FDA Seeking to Increase Access to Emergency Contraception.

54. On November 23, 1994, the Center for Reproductive Law and Policy (now the Center for Reproductive Rights) submitted a Citizen Petition (Docket No. 94P-0427) on behalf of the American Women's Health Association, the American Public Health Association, and Planned Parenthood of New York City, asking the FDA to require two drug manufacturers to amend the labeling and package inserts of certain of their oral contraceptive products to include information regarding the use of these products as emergency contraception. On May 22, 1995, the FDA issued an "interim response" indicating that the request was "still under consideration" and that the agency required more time to "thoroughly evaluate[] the issues raised" in the petition and to finalize its decision. (Letter of Janet Woodcock, M.D., Director, CDER, dated May 22, 1995 (attached hereto as Exhibit A).)

55. On May 9, 1996, the FDA issued a letter denying the 1994 Citizen Petition because "[a]lthough FDA agrees in principle that it has discretion to require that certain conditions of use be included in a product's labeling . . . we decline to exercise our discretion to require the relabeling of these products in the manner you suggest." (Letter of Janet Woodcock, M.D., Director, CDER, dated May 9, 1996 (attached hereto as Exhibit B).) However, the agency

determined "that it would be appropriate to discuss the issue of the safety and effectiveness of oral contraceptives for postcoital emergency use with the Reproductive Health Drugs Advisory Committee at its June 28, 1996 meeting. [The Center for Reproductive Law and Policy] will be invited to present [its] views at that meeting." *See id.*

56. On February 24, 1997, the Center for Reproductive Law and Policy received notice from FDA Deputy Commissioner Mary K. Pendergast that "today the Food and Drug Administration placed on public display a Federal Register notice concluding that certain combined oral contraceptives . . . are safe and effective for use as postcoital emergency contraception. The notice requests submission of new drug applications for this use . . . ." (Letter of Mary K. Pendergast, Deputy Commissioner, Senior Advisor to the Commissioner, FDA, dated February 24, 1997 (attached hereto as Exhibit C); *see also* Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception (Docket No. 96N-0492) (attached hereto as Exhibit D).)

57. FDA Federal Register Notice stated that "[t]his notice is intended to encourage manufacturers to make this additional contraceptive option available." Ex. D at 1. The agency agreed with the unanimous conclusion of the Advisory Committee, which met on June 28, 1996 to consider this issue, that several regimens of oral contraception were safe and effective for postcoital emergency contraception. *Id.* at 3. The agency concluded that "[b]ecause of the publicly available safety and effectiveness data documenting the drugs' use, the safety and effectiveness requirements of § 314.50 may be met by citing the published literature listed in the references in section III. of this document." *Id.* at 8.

58. In 1999, the FDA approved Plan B as a prescription drug. Since that date, Plan B has been prescribed many thousands of times.

59. On February 14, 2001, a group of citizen organizations, including Plaintiff ARHP, filed a petition ("the Citizen Petition") with FDA asking the agency to switch Plan B (and another drug, Preven, that has since been removed from the market for reasons unrelated to safety and effectiveness) to OTC status for women of all ages.

60. The FDA's consideration of the Citizen Petition was inextricably intertwined with its consideration of the application by the manufacturer of Plan B to switch Plan B to OTC status, described below.

61. On June 9, 2006, the FDA issued a letter directly prompted by this lawsuit in which it acknowledges that it has denied the Citizen Petition. (*See* Exhibit V.)

62. In that letter, the FDA alleges: "Soon after [the] petition was filed, [FDA] made a preliminary determination that your petition and its supporting information did not provide sufficient data to satisfy the statutory requirements to approve an OTC switch for emergency contraceptives, as documented in memoranda dated February 28, 2001 and April 12, 2001." (*See* Exhibit V at 1.) However, this determination was not communicated to the petitioners until June 9, 2006. Rather, the FDA gave a tentative response to the Citizen Petition on September 6, 2001, stating the FDA "has not yet resolved the issues raised in your Citizen Petition because it raises significant issues requiring extensive review and analysis by Agency officials."

C. Barr Laboratories Filed a Supplemental New Drug Application Seeking OTC Status for Plan B, Which Was Not Approved by the FDA Contrary to the Overwhelming Consensus of the Review Staff and Advisory Committee in Support of Approving the Application.

63. On April 16, 2003, Women's Capital Corporation, the former owner of Plan B, filed a supplemental new drug application (SNDA) asking the agency to approve Plan B for OTC sale. Plan B was subsequently sold to Barr Laboratories, which maintained the SNDA. The SNDA

contains no scientific data whatsoever on the safety or effectiveness of Plan B for any medically approved use for men.

64. On April 21, 2003, FDA Commissioner McClellan held a teleconference with Jay Lefkowitz, Deputy Assistant to the President for Domestic Policy at the White House, regarding WCC's submissions to the FDA on Plan B. Commissioner McClellan continued to have periodic discussions with White House staff regarding the Plan B SNDA.

65. Prior to the submission of the manufacturer's OTC switch application, but after the FDA became aware of the manufacturer's intent to file such an application, three new members were appointed to the Advisory Committee for Reproductive Health Drugs at the insistence of the FDA Commissioner's Office and despite strongly voiced concerns from FDA's career scientists about their qualifications. In addition, despite the usual practice by which members of the advisory committees are proposed by career scientists with relevant expertise, these three members were proposed by political appointees. Each of the three voted contrary to the majority vote of the Committee on one or more votes taken regarding Plan B.

66. On December 16, 2003, FDA's Non-prescription Drugs Advisory Committee and Advisory Committee for Reproductive Health Drugs held a joint session to discuss possible OTC status for Plan B.

67. The advisory committees, comprised of 28 members, voted as follows:

> (1) Does the Actual Use Study (AUS) demonstrate that consumers used [Plan B] as recommended in the proposed labeling?
>
> Yes – 27 No – 1
>
> (2) Are the AUS data generalizable to the overall population of potential non-Rx users of Plan B?
>
> Yes – 27 No – 1

(3) Based on the AUS and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraception for the regular use of other methods of contraception?

Yes – 0 No – 28

(4) Do the data demonstrate that Plan B is safe for use in the non-prescription setting?

Yes – 28 No – 0

68. According to the Manual of Policies and Procedures (MAPP) of the FDA's Center for Drug Evaluation and Research (CDER), the authority to approve a product for initial OTC marketing and for initial Rx-to-OTC switch for the first in a class of products is delegated to the office director level. MaPP 6020.5 at 13 (MaPP 6020.5 is attached hereto as Exhibit S). The authority to not approve an OTC switch for a drug is the responsibility of the "Specific Subject Matter Review Division" that approved it as a prescription drug. MaPP 6020.5 at 15. The FDA violated these policies in its actions regarding the Plan B SNDA and the Citizen Petition.

69. The composition of the Joint Advisory Committee was likewise determined in a manner that departed from the normal process because nominations to the Committee were made by FDA political appointees rather than FDA career scientists.

70. During late December of 2003 or early January of 2004, Drs. Janet Woodcock (Director of CDER and acting Deputy Commissioner of the FDA) and Steven Galson (acting Director of CDER) informed Drs. John Jenkins and Sandra Kweder (Director and Deputy Director of CDER's Office of New Drugs) that Commissioner McClellan had made a determination that the Plan B SNDA would not be approved. This decision also constructively denied the Citizen Petition.

71. The FDA decided by January 2004 at the latest to require an age restriction in any possible nonprescription approval for Plan B.

72. The determination by the Commissioner described in ¶ 70 that the Plan B SNDA would not be approved was made by the Commissioner (1) without attending the Joint Advisory Committee meeting; (2) before scientific reviews of the Plan B SNDA were completed by the FDA's scientific review staff; and (3) without any direct discussions with the FDA's scientific review staff conducting the review of the Plan B SNDA.

73. On January 15, 2004, Dr. Galson informed FDA scientists conducting the agency's review of the Plan B SNDA that the Commissioner's position was that the application could not be approved. At this same meeting Dr. Galson conveyed that one option that might lead to approval was an age restriction on Plan B that would keep it as a prescription drug for women under 18, even though he only invoked alleged deficiencies in data for women under 16. This option was proposed before scientific reviews of data submitted with the Plan B SNDA were complete.

74. On or about January 16, 2004, Dr. Woodcock informed the Director of the Office of Drug Evaluation III that the non-approval action directed by Commissioner McClellan was the only course of action that would appease the Presidential administration's constituents and that might lead eventually to approval.

75. On February 19, 2004 Dr. Janet Woodcock stated at a meeting that both she and the Commissioner were concerned about the possibility of OTC Plan B acquiring 'urban legend' status and leading to extreme promiscuous behaviors, such as the development of sex based cults centered around the use of Plan B. At that meeting, Dr. Galson indicated that he shared Dr. Woodcock's concerns.

76. All but one scientific staff member below the Center Director level within CDER who reviewed the OTC switch application expressed the view based on scientific and medical

data that the OTC switch should be approved for women of all ages. The one staff member who disagreed believed the application was "approvable."

77. By memorandum dated April 22, 2004 and signed electronically on April 28, 2004, Dr. John Jenkins wrote a memorandum summarizing his "review, conclusions, and recommendations regarding" the OTC switch for Plan B (attached hereto as Ex. E) ("the Jenkins memorandum"). This memorandum states: "[The FDA] has not heretofore distinguished the safety and efficacy of Plan B and other forms of hormonal contraception among different ages of women of childbearing potential and I am not aware of any compelling scientific reason for such a distinction in this case." (Ex. E at 30898.) After a review of the record evidence supporting OTC use by women of all ages, the Jenkins memorandum accordingly concludes "that the available data clearly support a conclusion that Plan B meets the statutory and regulatory requirements for availability without a prescription for all age groups. Such a conclusion is consistent with how the Agency has made determinations for other OTC products, including other forms of contraception available without a prescription." (*Id.* at 30899.)

78. The Jenkins memorandum further states that "[o]ther senior officials within the Agency, including the former Commissioner (Dr. McClellan) and the Acting Center Director (Dr. Galson), have expressed concerns about the potential for unsafe, ineffective, or inappropriate use of Plan B by adolescents if it were to be made available without a prescription. These concerns appear to have been based primarily on the limited number of adolescent women included in the sponsor's label comprehension and actual use studies." (*Id.* at 30897.)

79. Though Jenkins said that he "[is] sensitive to and respect[s] the concerns that some may have regarding non-prescription access to Plan B by adolescents," (*Id.* at 30898), he stated that "[p]roducts that are indicated for uses related to sexual activity in adolescents raise concerns

for some people that go beyond a finding based on clinical trial data that the product is safe and effective for its intended use in adolescents. These concerns derive from individual views and attitudes about the morality of adolescent sexual behavior and also overlap with concerns about the role for parents and health care professionals in decisions about contraceptive use in adolescents." (*Id*. at 30898-99.) He concluded: "While OTC access to Plan B for adolescents may be controversial from a societal perspective, I cannot think of any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling." (*Id*. at 30899.)

80. On May 6, 2004, CDER Acting Director Steven Galson issued a "non-approvable" letter (attached hereto as Ex. F) ("the Galson letter") to Barr rejecting the OTC switch for Plan B. That action also constructively denied the Citizen Petition.

81. The Galson letter asserts that Barr's SNDA could not be approved because Barr had "not provided adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug." (Ex. F at 10796.) This assertion is not supported by the agency record.

82. In November of 2004, FDA's Office of Counter-Terrorism and Pediatric Drug Development concluded that the data submitted by the manufacturer reflected the age distribution, including among younger adolescents, of actual prescription users of the product.

83. In about January 2005, Steven Galson was prepared to approve Plan B for OTC status for women ages 17 and over, but his authority to do so was removed by the Commissioner of the FDA. Indeed, Dr. Galson had asked the Director of the Office of New Drugs to draft approval letters for him.

84. At least one of the FDA scientists who supported OTC status for Plan B fears retaliation from the Agency for her truthful testimony in this lawsuit.

85. Dr. Galson was concerned that if he did not implement or disagreed with the decision of the Office of the Commissioner to reject unrestricted OTC status for Plan B, his career at the FDA would be jeopardized.

D. Barr Laboratories Filed an Amended Supplemental New Drug Application Seeking Age-Restricted OTC Status for Plan B, Which Also Was Not Approved, Contrary to the Overwhelming Consensus among Agency Reviewers in Favor of Approving the Application.

86. On July 22, 2004, Barr filed an amended SNDA seeking the OTC switch only for women aged 16 and higher. By statute, the defendant was required to act on Barr's amended SNDA within 180 days after it was filed. *See* 21 U.S.C. § 355(c)(1). On January 21, 2005, the FDA announced a delay of its decision on Barr's application beyond this statutory time limit.

87. The reviewing divisions and offices of FDA reviewed Barr's amended application and examined the concerns raised by senior officials to support their decision to issue a non-approvable letter for OTC use of Plan B, but found that scientific evidence did not support these concerns. (Excerpts from Mem. of Donna J. Griebel, M.D., dated January 12, 2005 (attached hereto as Exhibit G) at 31033.)

88. In its review of Barr's amended SNDA, the FDA review staff unanimously agreed that despite Barr's application for limited OTC status for Plan B for women 16 and older, that the drug was suitable for -- and thus should be approved for -- full OTC access for women of all ages. (Review of Complete Response by Daniel Davis, M.D., dated January 12, 2005 (attached hereto as Exhibit H) at 1; Mem. Add. of Curtis J. Rosebraugh, M.D., dated January 12, 2005 (attached hereto as Exhibit I) at 2; Ex. G at 31031-33; Mem. of John Jenkins, M.D., dated

January 14, 2005 (attached hereto as Exhibit J) at 31096-98; *see also* Mem. of Steven Galson, M.D., dated August 26, 2005 (attached hereto as Exhibit K) at 1.)

89. The Director and Deputy Director of the Division of OTC Drug Products and the Director of the Office of Drug Evaluation V stated that Plan B meets the criteria for unrestricted OTC access, that data to the contrary was lacking, and that because of the strength of the data before the agency, it is "unclear what additional data could be provided on adolescent use that would be sufficient to lift the age restriction in the future." (Ex. I at 205.) Under the FDA's own policies, these FDA employees would ordinarily have made the final decision to approve the OTC switch.

90. FDA documents indicate that prior to January 21, 2005, the review staff at FDA were actively reviewing Barr's application for split-label access to Plan B. FDA has disclosed approximately sixteen documents that were placed in the Plan B docket during the month of January 2005. After January 21, 2005 and prior to August 2005, only two additional documents were submitted.

91. On July 13, 2005, the Secretary of Health and Human Services Michael O. Leavitt assured United States Senator Michael Enzi that "the FDA will act on this application [regarding OTC status for Plan B] by September 1, 2005." (*See* Letter of M. O. Leavitt, dated July 13, 2005 (attached hereto as Exhibit L).) Counsel for the Government submitted the Leavitt letter to the Court and requested that the Court delay the judicial proceedings: "[g]iven the agency's commitment to take action on the pending Plan B application within the next 45 days, we respectfully submit that the most appropriate course of action would be to suspend the current briefing schedule and stay this case until the FDA takes the anticipated action. . . ." (Def.'s Letter to the Court, dated July 25, 2005 (attached hereto as Exhibit M), at 2.)

92. Instead of the promised action, on August 26, 2005, FDA Commissioner Lester Crawford issued a letter to Joseph A. Carrado, stating that "the Agency is unable at this time to reach a decision on the approvability of the application because of unresolved issues that relate to your NDA . . . ." (*See* Letter of Lester Crawford, M.D., dated August 26, 2005 (attached hereto as Exhibit N) at 5.) The letter indicated that "[t]he Center for Drug Evaluation and Research (CDER) has completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an OTC product, but only for women who are 17 years of age and older." (*Id.*) In this letter, FDA further stated that age-restricted OTC access would not be available for Plan B before the agency reaches a decision on "unresolved issues" regarding the feasibility of approving split-label access. (*Id.*)

93. At or around the time of the August 26, 2005, Crawford decision, Deputy Commissioner Woodcock expressed her concern that the agency's handling of Plan B had the potential to damage her professional credibility.

94. United States Senator Enzi wrote to Commissioner Crawford after Crawford's August 26, 2005, letter, stating that he was "deeply disappointed that your announcement did not comport with the agreed-upon deadline for a decision."

95. FDA sought public comment on "whether we should initiate a rulemaking to codify our interpretation of section 503(b) regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product." (Ex. N at 2.)

96. The FDA made the unusual decision to outsource to a private contractor the task of collecting and reviewing comments submitted to the FDA regarding Plan B.

97. On August 31, 2005, Dr. Susan F. Wood, assistant FDA commissioner for women's health and director of the Office of Women's Health announced that she was resigning from her post in reaction to the agency's decision to continue to limit access to Plan B, stating: "I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled." *See* Marc Kaufman, *FDA Official Quits Over Delay on Plan B*, WASH. POST., Sept. 1, 2005, at A08 (attached hereto as Exhibit O) at 1 (quoting Susan F. Wood).

98. On September 27, Dr. Wood appeared on the ABC television news program *Nightline* to discuss the failure of the agency to act in accordance with the scientific consensus in favor of approving Plan B for OTC use. *See* ABC News transcript, dated September 27, 2005 (attached hereto as Exhibit P) at 4-6 (citing "consensus . . . amongst the scientists and health professionals there that it should be approved," and the fact that "all of the scientific and professional staff who normally are the part of the decision-making at the agency . . . were cut out of the decision.").

99. Dr. Wood also stated that she was concerned about the lengthy delay that she anticipated as a result of the upcoming rule-making:

> Dr. Wood: . . . But I would argue that the decision to delay approval of this product over-the-counter is, in fact, a denial. And this is, again, in part why I resigned. Because by couching it as a delay and a non-decision, in fact denied women of all ages, not just teens but women of all ages access to timely use of this product.
>
> Ted Koppel: (Off Camera) If you had thought that it was a brief delay, in other words, if you thought it was only going to be a delay of a couple of months, you wouldn't have resigned.
>
> Dr. Wood: Probably not.
>
> Ted Koppel: (Off Camera) So, you obviously think that what we're talking about here is not really a delay but a way of shelving it and not dealing with the issue.

> Dr. Wood: Right. The mechanism is a rather bureaucratic one to potentially open it up to rulemaking. Which, to make a long story short, means opening up to a process that usually takes many months to years, if in fact that's the way they go.

(*See* Ex. P at 6-7.)

100. Dr. Frank Davidoff, a member of the Advisory Committee for Reproductive Health Drugs, which considered the OTC switch application for Plan B, resigned from the advisory committee due to the FDA's lack of "rational science-based decision-making." He is the only person ever to resign from an FDA advisory committee in protest of an agency action.

E. The Government Accountability Office Investigated FDA's May 2004 Decision Not to Approve Plan B for Full OTC Status and Found that the FDA's Review Process Regarding Plan B Was "Unusual."

101. The Government Accountability Office commenced an investigation for the United States Congress into why the FDA rejected the OTC switch on May 6, 2004.

102. On November 14, 2005, the Government Accountability Office issued a report to members of Congress examining the FDA's May 6, 2004 issuance of a "non-approvable" letter with regard to Barr Laboratory's SNDA request that Plan B be made available over-the-counter. (attached hereto as Exhibit Q, also available at http://www.gao.gov/new.items/d06109.pdf).

103. The report, titled "Food and Drug Administration Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual," found that FDA's review process was "unusual" in four aspects:

> ***First***, the Directors of the Offices of Drug Evaluation III and V, who would normally have been responsible for signing the Plan B action letter, disagreed with the decision and did not sign the not-approvable letter for Plan B. The Director of the Office of New Drugs also disagreed and did not sign the letter. ***Second***, FDA's high-level management was more involved in the review of Plan B than in those of other OTC switch applications. … ***Third***, … there are conflicting accounts of whether the decision to not approve the application was made before the reviews were completed. ***Fourth***, the rationale for the Acting Director of CDER's decision was novel and did not follow FDA's traditional

> practices. Specifically, the Acting Director was concerned about the potential impact that the OTC marketing of Plan B would have on the propensity for younger adolescents to engage in unsafe sexual behaviors because of their lack of cognitive maturity compared to older adolescents. He also stated that it was invalid to extrapolate data from older to younger adolescents in this case. FDA review officials noted that the agency has not considered behavioral implications due to differences in cognitive development in prior OTC switch decisions and that the agency has considered it scientifically appropriate to extrapolate data from older to younger adolescents. [Emphasis added]

(Ex. Q at 5.)

104. In summary, the GAO found that the decision-making process was "not typical," was unlike all of the 67 other OTC switch applications filed between 1994 and 2004, and that the Plan B OTC switch application was the only one during that 10 year time period that "was not approved after the joint committee voted to recommend approval of the application." *Id.* The GAO Report concludes that the FDA's decision-making process was unusual and that high-level officials were reported to be involved in the decision-making process.

105. Former FDA Commissioner Mark McClellan provided only an evasive and non-responsive written statement to detailed written questions submitted by the GAO regarding the decision to issue a non-approvable letter to Barr in May 2004 (questions and non-response attached as Exhibit W).

106. Former FDA Commissioner Mark McClellan improperly deleted electronic correspondence related to the OTC application for Plan B. *See* Letter of United States Congressman Henry Waxman, dated November 15, 2005 (attached hereto as Exhibit R).

107. Former FDA Commissioner Lester Crawford also declined to be interviewed by the GAO in conjunction with their report.

F. Government Documents Confirm the Findings of the GAO Report that Upper Level Management Were Unusually Active in the Decision-Making Process Regarding the OTC Switch Application for Plan B, and that Upper Level Management Overrode the Recommendations of the Review Staff.

108. The administrative record compiled by the agency confirms that as early as January 15, 2004, upper level management at FDA had decided that the OTC switch for Plan B would not be approved, and that this decision was made before the scientific review of the OTC switch application was complete.

109. The administrative record compiled by the agency confirms that the Office of the Commissioner was involved in the agency's review of the OTC switch application for Plan B since at least December 10, 2003, and that the concerns about adolescent use of Plan B expressed by Dr. Galson in his May 2004 non-approvable letter, as well as the concerns about adolescent use of Plan B expressed by Dr. Galson in his August 26, 2005 memorandum, echo and reflect the concerns of the Office of the Commissioner expressed in January of 2004.

110. Documents show that both the Commissioner of the FDA and the Deputy Commissioner of Operations played an unusually active role in the decision to issue a non-approvable letter, as well as in subsequent agency action on Plan B. The Directors of the Offices of Drug Evaluation III and V told GAO investigators that they were asked by high level management to draft and sign a non-approvable letter for Plan B, but that they declined to do so because they did not agree with that action. The Director of the Office of New Drugs was then asked to review the Plan B application. Involving the Director of the Office of New Drugs in issuing such a letter is very rare and, according to FDA policy and procedure manuals, is limited to situations where there is disagreement between the two reviewing offices. (Ex. Q at 20). The Director of the Office of New Drugs also declined to sign a non-approvable letter based on his disagreement with the decision. *Id.*

111. The FDA's Deputy Director of the Office of Drug Evaluation V stated in a memorandum that the issues raised by FDA political appointees concerning adolescents' access to Plan B "spuriously raise the review standard for approval of this product and indeed any contraceptive product," and are not supported by the data nor the medical literature.

112. In the past ten years, except in the case of Plan B and certain nicotine-related drugs, the FDA has never requested additional data regarding adolescents to be submitted by manufacturers seeking OTC switches.

113. The non-approvable letter in May 2004 and the August 26, 2005 decision to further withhold approval of Plan B for OTC use were opposed by the scientific review staff that would normally be responsible for making decisions approving drugs for OTC use. CDER reviewers in the Divisions of Reproductive and Urologic Drug Products and the Division of Over-the-Counter Drug Products, the Deputy Directors of the Offices of Drug Evaluation III and V, and the Director of the Office of New drugs all recommended that Plan B should be switched OTC for women of all ages.

G. Barr Laboratories Was Asked to File Another Amended Supplemental New Drug Application Seeking Further Arbitrary Age-Restricted OTC Status for Plan B, which Resulted in Plan B Remaining Behind-the-Counter and Available Without a Prescription Only For Some Persons 18 and Older.

114. On July 31, 2006, the day before Dr. Andrew von Eschenbach's Senate confirmation hearing, the FDA announced that it would work with Barr Pharmaceuticals to allow for OTC sales to persons 18 and older, hoping to "wrap[] up the process in a matter of weeks." (FDA Statement, dated July 31, 2006, http://www.fda.gov/bbs/topics/NEWS/2006/NEW01421.html).

115. Also on July 31, 2006, von Eschenbach wrote to Barr Pharmaceuticals and stated that while he would not approve Barr's request for OTC sales for those 16 and over, he would

reconsider allowing nonprescription sale of Plan B to persons 18 and older if the company met certain restrictions. This letter offered no explanation for the scientific or policy reasoning to support the line being drawn at the age of 18. (Letter from Andrew von Eschenbach M.D. to Joseph A. Carrado, dated July 31, 2006, http://www.fda.gov/oc/planb/duramed073106.html).

116. On August 8, 2006, personnel from the Center for Drug Evaluation and Research met with Barr to discuss the restrictions outlined in von Eschenbach's July 31 letter, specifically with regard to nonprescription packaging for purchasers 18 and over.

117. On August, 17, 18 and 23, 2006, Barr amended its application to reflect changes in compliance with von Eschenbach's proposed restrictions, specifically with regard to labeling and the Convenient Access Responsible Education (CARE) Program.

118. In light of Barr's revised SNDA, the FDA again reviewed Plan B and again its medical reviewers confirmed that an age restriction for Plan B as an OTC drug is medically and scientifically unsupported.

119. On August 22, 2006, Julie Beitz, M.D., Acting Director of the Center for Drug Evaluation and Research, stated: "This memo documents my view that there are sufficient data on the safety and effectiveness of Plan B to approve its use in the OTC setting without age-restriction. In the absence of new data to support an age-restriction, my conclusions as stated in my previous memos, dated April 2, 2004, and January 12, 2005, remain unchanged."

120. On August 22, 2006, Charles J. Ganley, M.D., Director of the Office of Nonprescription Products (ONP), stated: "Previous reviews from the Division of Over-the-Counter Drug Products (DOTCDP) and Office of Drug Evaluation V (ODE V), signed by Dr. Rosebraugh and Dr. Bull, recommended the sale of Plan B over-the-counter without restrictions. DOTCDP and ODEV have evolved into the ONP. No new data was provided to suggest the

restriction based on age is necessary. Based on the previous findings . . . ONP continues to believe that restriction on access is not necessary."

121. On August 22, 2006, John K. Jenkins, M.D., Director of the Office of New Drugs, stated: "As documented in my reviews dated April 28, 2004, and January 18, 2005, I believe the available data are adequate to support a conclusion that Plan B can be safely and effectively marketed as a nonprescription product for all women of child-bearing potential . . . I am not aware of any new data that supports an age restriction for OTC marketing of Plan B . . . I continue to recommend that Plan B be approved for OTC marketing without an age restriction."

122. On August 23, 2006, von Eschenbach issued a memorandum that outlined his conclusions regarding the appropriateness of 18 as a cut-off age for OTC usage of Plan B.

123. The August 23, 2006 von Eschenbach memorandum begins by stating that Barr Pharmaceuticals amended its SNDA to make the OTC switch applicable only to those 18 and older.

124. The August 23, 2006 von Eschenbach memorandum states that in response to "the difficulty of enforcing an age-based restriction . . . I have concluded that 18 (rather than 17) is the more appropriate cutoff point . . ."

125. There are no scientific or health related reasons for choosing 18 as a cutoff age. The only asserted basis for choosing 18 is because dispensers of Plan B " . . . (as well as society as a whole) are more familiar with 18 as a cutoff age."

126. The August 23, 2006 memorandum purports to justify the 18 year old age cutoff by analogy to tobacco products. Tobacco products have proven and severe harmful health effects, including hundreds of thousands of deaths annually, on persons of all ages. There is no

scientific evidence that Plan B has any serious side effects whatsoever, nor is any such evidence cited in this or any other FDA memorandum.

127. The August 23, 2006 memorandum also purports to justify the 18 year old age cutoff by analogy to products containing pseudoephedrine. Such products have a demonstrated record of abuse, specifically as a compound used by illegal drug traffickers to manufacture methamphetamines, which are controlled substances. There is no evidence or even plausible scientific basis to believe that Plan B can be or is used to manufacture controlled substances, or that Plan B is abused in any way by any women, nor is any such evidence cited in this or any other FDA memorandum.

128. On August 24, 2006, Steven Galson issued an approval letter to Barr, granting limited approval for nonprescription sales of Plan B to those who could provide government issued proof that they are 18 years of age or older, and adopting von Eschenbach's stated rationale for the age 18 cutoff.

129. The FDA has therefore at long last admitted that it has rejected OTC status for Plan B.

130. In March 1991, the FDA stated: "Some health professional organizations have petitioned FDA to establish a third class of drugs that would be available without prescription, but only through a pharmacist. Pharmacists would advise consumers about proper use of the drug and serve to identify problems that might arise. In 1974, in connection with an FDA monograph on OTC antacids, some pharmacy organizations commented that such a third class of drugs should be created. Others, including the Department of Justice, objected to a third class of drugs, stating that it would restrain competition, inconvenience the consumer, depart from U.S. economic policy, and cause price increases for the consumer with no attending benefit. FDA

concluded that 'no controlled studies or other adequate research data have been supplied to support the position that any class of OTC drugs must be dispensed only by pharmacists in order to ensure their safe use. . . . There is at this time no public health concern that would justify the creation of a third class of drugs to be dispensed only by a pharmacist or in a pharmacy." *See* "Rx to OTC: The Switch Is On," http://www.fda.gov/bbs/topics/CONSUMER/CN00012c.html.

131. In its review of Barr's amended SNDA for limited OTC status for Plan B for women 16 and older, the FDA review staff, in addition to finding that the scientific data supported full OTC access for women of all ages, expressed strong concern over the regulatory precedent that approval of a dual prescription/nonprescription regime for Plan B would set and the possible unintended consequences of such a regime. (Ex. I at 31026-27; Ex. G at 31031-32; Mem. of Julie Beitz, M.D., dated January 12, 2005 (attached hereto as Exhibit X) at 31085-31087; Ex. J at 31096-98).

132. Plan B is the only nonprescription drug required by the FDA to be kept behind the pharmacy counter. Prior to August 24, 2006, "behind-the-counter" status was not mandated by the FDA for any drug. Thus, Plan B is the first nonprescription drug the FDA has ever mandated to be kept behind the counter.

133. In Canada, where levonorgestrel is available behind-the-counter from pharmacists, some pharmacists exploited the behind-the-counter status of the drug to ask women invasive questions about their sexual activity before providing the drug.

134. Numerous over-the-counter drugs available off the shelf in gas stations, convenience stores, drug stores, supermarkets and other points of sale have established records of misuse, abuse (including use as a means of committing suicide by overdose), and serious side effects. In no case does the FDA mandate age-restricted sales or proof of age.

135. Nicotine-replacement products are restricted as nonprescription products to persons over the age of 18, yet even these products, with proven harmful effects and serious side effects for certain high-risk populations, are not kept behind the pharmacy counter.

136. Contrary to the stated policy concerns regarding enforceability of an age cutoff, the requisite labeling included in a package of Plan B, which states the actual scientific findings of the FDA, makes clear that there is no data evidencing a danger of overdosage or drug dependence with regard to Plan B. (FDA Labeling, dated August 24, 2006, http://www.fda.gov/cder/foi/label/2006/021045s011lbl.pdf).

137. The labeling for Plan B states: "Pediatric Use: 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." (FDA Labeling, dated August 24, 2006, http://www.fda.gov/cder/foi/label/2006/021045s011lbl.pdf).

H. FDA's Failure to Approve Plan B for Full OTC Use Constitutes Bad Faith and Improper Agency Action, and Treats Plan B Differently than Other Drugs Without Any Medical or Scientific Basis for that Differential Treatment.

138. The FDA applied a different and higher standard to Plan B's OTC switch than it has applied to OTC switches of other drugs.

139. In the past ten years, Plan B is the only drug as to which the FDA has rejected advisory committee recommendations in favor of approving a drug for OTC status.

140. In the past ten years, Plan B is the only drug as to which the FDA has requested additional data regarding adolescents.

141. In the past five years, the FDA has approved several OTC switch applications without any label comprehension studies or actual use studies that included adolescents.

142. There is no medical or scientific basis for the FDA's application of a different and higher standard to Plan B's OTC switch for women of all ages.

143. The FDA's failure to approve Plan B for OTC use by women of all ages is based in part on outmoded stereotypes of women and girls.

144. For example, the FDA routinely extrapolates from data from one age group to draw conclusions about another age group. Indeed, prior to the manufacturer's 2003 submission of its OTC switch application, FDA informed the manufacturer that it would not obtain an extension of its patent for Plan B by conducting extra pediatric studies, for such studies were rendered unnecessary because information about adolescents could be extrapolated from data for adults. But Galson and his supervisors refused to implement this routine method as to Plan B.

145. In addition, the FDA rejected the manufacturer's pediatric exclusivity for Plan B, specifically informing the manufacturer in April of 2002 that it could conduct its "proposed trials [of Plan B] in the adult population and the results extrapolated to the postmenarcheal pediatric population." The FDA's subsequent rejection of extrapolation from studies in adult populations constitutes improper and bad faith agency action.

146. The FDA's application of a different and higher standard to Plan B's OTC switch was the result of factors that fall outside the FDA's statutory mandate, including impermissible ideological factors, such as appeasement of the President's constituents.

147. The FDA's rejection of the OTC switch for women of all ages is not supported by medical or scientific evidence and not supported by the agency record.

148. The fact that upper-level management at FDA removed the decision of whether to approve Plan B's OTC application from the hands of the professional review staff, that upper-level management dictated the outcome of the review process, and that upper-level management

deviated from the standard practices and policies set forth in their own manuals and handbooks, suggests that the FDA impermissibly held the Plan B OTC switch application to a higher standard than other drugs, and that doing so constitutes bad faith and improper agency action.

149. Where upper level agency management made decisions regarding the status of the Plan B application before the scientific review process has been completed, such premature decision-making constitutes bad faith and improper action by an agency dedicated to promoting and protecting public health.

150. The former FDA Commissioner Mark McClellan's destruction of email correspondence and refusal to cooperate with the GAO's investigation constitute bad faith and improper agency action.

151. The record indicates that Barr's application was not actively reviewed after January of 2005, causing the seven month delay between the conclusion of the scientific review and any further agency action. This was unreasonable and constituted bad faith and improper agency action.

152. The fact that the Secretary of Health and Human Services (HHS) submitted a letter to the Senate assuring Senators that FDA would act on the OTC application for Plan B by September 1, 2005, but that the only action subsequently taken by the agency was to invite public comment on a proposed rulemaking proceeding, constitutes bad faith and improper agency action.

153. The FDA's June 9, 2006 letter denying the Citizen Petition is evidence of bad faith and improper agency behavior. First, it asserts that the FDA made a determination in 2001 that the Citizen Petition could not be approved, but this determination was never communicated to the petitioners. Second, it asserts that the Citizen Petition filers cannot use evidence submitted

by Barr to support their Petition, but then relies on the Barr submissions extensively. Third, the letter contradicts statements made to the Court in December of 2005 by counsel for the Defendant to the effect that the Citizen Petition was still under active consideration by the FDA. Fourth, the letter is on its face a litigation document issued in direct response to this lawsuit rather than agency action taken in the ordinary course of agency business. For these and other reasons, the June 9, 2006, letter admitting denial of the Citizen Petition is evidence of improper and bad faith agency action.

154. The FDA's decision imposing "behind-the-counter" status for Plan B and controlling the point of sale of Plan B is unprecedented and discriminates against Plan B because it is a contraceptive drug and because it is used only by women without serving any compelling, significant, or even legitimate governmental interest. Indeed, by comparison to numerous OTC drugs available off the shelf and without any point-of-sale restriction, the FDA's restrictions on Plan B are invidious and contrary to public health. The selective imposition of a behind-the-counter regime for Plan B demonstrates improper agency action and bad faith.

155. The assertion by the Defendant that the FDA was adopting the "infrastructure" used by states to regulate tobacco products and applying it to Plan B demonstrates improper agency action and bad faith both because this adoption lacks any scientific or medical basis, and because the FDA's restrictions on Plan B have nothing other than the age of 18 in common with the infrastructure of state regulation of tobacco products.

156. The FDA's requirement of a prescription for Plan B for women aged 17 demonstrates improper agency action and bad faith because it lacks any scientific or medical basis and contradicts prior public statements by the FDA acknowledging the safety of Plan B as an OTC drug for women 17 and over.

157. The FDA's August 24, 2006, action rejecting OTC status for Plan B and instead imposing the BTC regime for Plan B specifically permits men 18 and over to buy Plan B without a prescription even though there is no FDA-approved use of Plan B for men, and no scientific data whatsoever about actual use or label comprehension by men is contained in the agency record. Permitting men 18 and over to buy Plan B without a prescription, even though there is no medical evidence supporting any use by men of Plan B, while denying nonprescription status for women under 18 despite extensive supporting scientific data, demonstrates that the FDA's August 24, 2006 decision is based on stereotypes of young women and is utterly irrational. It also demonstrates that the FDA's recent action establishing an age-restricted behind-the-counter dual prescription/nonprescription regime for Plan B is improper and was done in bad faith.

158. The behind-the-counter regime is demeaning to and discriminates invidiously against women of all ages because it poses unique barriers to access for a very safe drug that can be used safely and effectively without a prescription by all women of childbearing age while numerous other over-the-counter drugs are not subject to any such barriers, including many for which use without a prescription is discouraged for persons below a certain age because safe over-the-counter use by such younger age groups has never been established.

159. No drug used only by men and no drug used by both sexes is subject to the same behind-the-counter regime as Plan B.

160. The timing of the FDA's August 24, 2006 age-restricted behind-the-counter dual prescription/nonprescription regime for Plan B to coincide with the Senate confirmation hearing of the acting commissioner of the FDA evinces improper and bad faith agency action.

161. At his Senate confirmation hearing on August 1, 2006, the Defendant demonstrated improper agency behavior and bad faith by misleading the Senate Committee on

Health, Education, Labor and Pensions in testifying that the age 18 cutoff he was requiring for Plan B was based on inadequate data about OTC use of Plan B for 17-year-olds and based on public comments submitted in response to the advanced notice of proposed rulemaking. His August 23, 2006 memorandum and a review of the comments submitted contradict these bases for the age 18 cutoff.

V. Causes of Action

FIRST CAUSE OF ACTION: ARBITRARY AND CAPRICIOUS

162. Plaintiffs hereby incorporate by reference ¶¶ 1-161 above.

163. FDA's denial of the OTC switch for women of all ages and imposition of the BTC regime are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(a) (2005) in that the FDA required evidence of safety and efficacy beyond that required for approval of any other drugs and was improperly motivated by factors other than medicine and science, and because the evidence of safety and efficacy before the FDA demonstrates that it should be made available without prescription without any further restriction.

SECOND CAUSE OF ACTION: EXCEEDS STATUTORY AUTHORITY

164. Plaintiffs hereby incorporate by reference ¶¶ 1-163 above.

165. FDA's denial of the OTC switch for women of all ages and its imposition of the BTC regime exceed its statutory authority in violation of 5 U.S.C. § 706(2)(c) in that they were improperly motivated by factors other than medicine and science and in that the FDA lacks authority to control the point of sale of nonprescription drug products.

THIRD CAUSE OF ACTION: RIGHT TO PRIVACY

166. Plaintiffs hereby incorporate by reference ¶¶ 1-165 above.

167. FDA's denial of the OTC switch for women of all ages and its imposition of the BTC regime violate the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that it infringes the right to privacy of women who need Plan B without serving or being tailored to serve any compelling, significant, or legitimate governmental interest.

FOURTH CAUSE OF ACTION: EQUAL PROTECTION

168. Plaintiffs hereby incorporate by reference ¶¶ 1-167 above.

169. FDA's denial of the OTC switch for women of all ages and its imposition of the BTC regime violate the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that it discriminates on the basis of sex without serving or being tailored to serve any compelling, significant, or legitimate governmental interest.

170. FDA's denial of the OTC switch for women of all ages and its imposition of the BTC regime violate the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that it discriminates on the basis of the exercise of the fundamental right to privacy to obtain contraception and to keep certain personal information private without serving or being tailored to serve any compelling, significant, or legitimate governmental interest.

FIFTH CAUSE OF ACTION: INFORMATIONAL PRIVACY

171. Plaintiffs hereby incorporate by reference ¶¶ 1-170 above.

172. FDA's denial of the OTC switch for women of all ages and its imposition of the BTC regime violate the right to informational privacy for women who are required by the government to disclose their name, age, and address to private parties in order to obtain Plan B. This requirement does not serve and is not tailored to serve any compelling, significant, or legitimate governmental interest.

VI. Prayer for Relief

WHEREFORE, Plaintiffs ask this Court:

A. To issue an injunction ordering Defendant to approve Plan B as an over-the-counter drug without age or point of sale restriction for women of all ages;

B. To enter judgment declaring the denial of OTC status of Plan B to women of all ages in violation of the United States Constitution and 5 U.S.C. § 706; and

C. To grant such other and further relief as this Court should find just and proper, including attorneys' fees and costs.

Dated: October 10, 2006.

Respectfully submitted,

/s Simon Heller_____
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CERTIFICATE OF SERVICE

I, Simon Heller, hereby certify that on October 10, 2006, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification via electronic mail to F. Franklin Amanat.

Dated: October 10, 2006.

Respectfully submitted,

/s Simon Heller

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