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

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ANNIE TUMMINO, *et al*.,

Plaintiffs,

CV-05-0366 (ERK/VVP)

v.

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

Defendant.

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs respectfully submit this memorandum of law in support of their motion for summary judgment.[1] Plaintiffs seek a judgment commanding the Defendant (hereinafter "the FDA") to switch the emergency contraceptive drug Plan B to unrestricted over-the-counter status. Following years of resistance to removing Plan B from the category of drugs available only with prescription, and over the nearly universal opposition of the agency's professional staff, the FDA has recently established a regime for marketing of Plan B that is unwarranted and unprecedented in the agency's history. Under the new regime, for the first time, a drug for which no prescription is required is available only at pharmacies and health clinics. Moreover, only

[1] In this Memorandum, documents supplied by the Government pre-stamped as "Tummino PAGE," are so cited and collected as Exhibit A. The Report of the Government Accountability Office on the FDA's May 2004 rejection of OTC status for Plan B is Exhibit B. Declarations submitted in support of Plaintiffs' Motion for Summary Judgment are Exhibits C-1 through C-6. Cited excerpts of deposition transcripts are contained in Exhibit D. Exhibit E contains other cited documents. Exhibit F, to be filed under seal, contains cited documents and deposition excerpts protected under a stipulation of the parties regarding confidential commercial information.

women (and men, for whom Plan B has no approved use) who are willing to present government-issued identification proving that they are at least 18 years of age will be able to obtain Plan B from pharmacies without a prescription. Other women, including all women under 18 and women who either do not have government-issued proof of age or are unwilling to display it to pharmacy staff, must have a prescription in order to obtain Plan B. (We refer to this regime below, which requires Plan B to be kept behind the pharmacy counter, as "the BTC regime.")

The FDA's continuing invidious treatment of Plan B is not only arbitrary and capricious within the meaning of the Administrative Procedure Act ("APA") but also violates the constitutional rights to privacy and equal protection of the law of women seeking Plan B as a means of preventing pregnancy. In addition, the BTC regime exceeds the FDA's statutory mandate by impermissibly controlling the point of sale of a non-prescription drug and because it is based on factors Congress did not intend the agency to consider in determining the prescription status of drugs. Furthermore, Plaintiffs' entitlement to summary judgment on each of these claims is either conclusively demonstrated or considerably strengthened by the FDA's bad faith and improper actions throughout its consideration of Plan B's prescription status, as well as the Government's bad faith actions in the course of this litigation. For the reasons set forth below, the Court should grant Plaintiffs' motion for summary judgment.

HISTORY OF THE PROCEEDINGS

The Government has consistently resisted all efforts to allow judicial scrutiny of the FDA's handling of the Plan B switch application. Plaintiffs filed this action on January 21, 2005, the date on which the FDA missed its statutory deadline for formal action on the then-pending application of Barr Laboratories (hereinafter "Barr" or "the sponsor" or "the

manufacturer") to switch Plan B to non-prescription status for women age 16 and over.[2] At the time, the FDA had also failed for four years to act on a Citizen Petition filed by one of the Plaintiffs, which similarly sought a switch of all emergency contraception from prescription to OTC status for all women. The Plaintiffs – individual activists who have transferred doses of Plan B to women at protest events and non-profit organizations whose missions and work include making Plan B accessible to women by educational outreach and information[3] – sought essentially the same relief they seek now: an injunction commanding the FDA to make Plan B available as an OTC drug without age or other restrictions, i.e., in the same manner in which FDA has made available numerous drugs with greater toxicity and more severe side effects than Plan B.

The Government initially responded to the complaint on April 18, 2005, with a motion to dismiss. After Plaintiffs served their response, the Government withdrew its motion and instead sought a stay of proceedings. In its application for a stay, the Government represented to this Court that there existed a plan that the FDA would take action on Barr's application before September 1, 2005, which the Commissioner had announced on July 13, 2005, to the United States Senate, and that action would, in the Government's words, "supplement and potentially supersede the provisional determination embodied in the May 2004 letter." (Def.'s July 25, 2005 Letter at 2.) Based on that representation, the Court granted the stay.

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[2] The Government has previously argued that the statutory deadline contained in 21 U.S.C. § 355(c) is not binding, rather than mandatory, because subsequent Congressional action renders the deadline merely "aspirational." Def.'s Mot. for J. on the Pleadings at 33. A recent decision from the United States District Court for the District of Columbia rejects exactly this argument, holding instead that the statutory deadline is mandatory. *Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d 29 (D.D.C. 2006).

[3] Plaintiffs now also include three young women under 18 and their parents, all of whom are directly injured by the FDA's BTC regime.

In fact, the only "action" the FDA took before September 1, 2005, was not action on the application at all. Rather than issuing a decision, the FDA initiated a process to determine whether a rulemaking process should begin. (Tummino 1922-23; Jenkins Dep. 290:14-291:9, June 21, 2006). It invited public comment on whether the agency should engage in proposed rulemaking that would determine whether the agency has the legal authority to mandate split marketing not only of Plan B, but of any drug requiring FDA approval, and if so whether it would be efficacious to do so.

Following the FDA's non-action, the Court lifted the stay and ordered production of the administrative record over the Government's vehement objections. (*See* Aug. 2, 2004 Korman Order at 1.) In response to the Court's order, the Government produced voluminous materials which it denominated the administrative record. In the so-called administrative record, the Government included numerous documents disclosing the FDA's deliberative process regarding Plan B. Indeed, the Government stated that it had "made the decision not to raise the deliberative process privilege with regard to documents in the administrative record to which that privilege may apply." (Nov. 8, 2005 Hr'g Tr. 15.) The Government erroneously represented that the record contained all of the information relevant to the FDA's deliberations. In fact, for example, numerous substantive e-mail deliberations have been withheld to this date on deliberative process grounds. (*See, e.g.*, Privilege Log submitted by the FDA on March 29, 2007 (Doc. 233 Attachment 2).)

The Government then filed a motion for judgment on the pleadings, principally raising procedural objections to the Court's review of the agency's actions. This Court denied the motion on December 22, 2005, and at the same time authorized Plaintiffs to undertake limited

discovery beyond the administrative record as determined in the first instance by the Magistrate Judge assigned to the case.

Plaintiffs accordingly sought to depose certain FDA current and former employees whom the administrative record disclosed had played a role in the agency's consideration of Plan B. The Government resisted all of these efforts, essentially re-arguing to the Magistrate Judge the same contentions it had urged upon this Court in its rejected motion to dismiss. The Magistrate Judge similarly rejected the Government's effort to block all discovery, finding that discovery was authorized both because Plaintiffs had alleged an unreasonable delay claim and because Plaintiffs had made a strong preliminary showing of bad faith and improper agency action. *See Tummino v. von Eschenbach*, 427 F. Supp. 2d 212, 231-32 (E.D.N.Y. 2006). The Government did not appeal that ruling to the Court, and it remains law of the case. Although the Magistrate issued the discovery ruling on February 24, 2006, including in it authorization for depositions of specific witnesses, the Government did not make a single witness available for deposition until April 26, 2006, and it was not until December 11, 2006, that Plaintiffs were able to complete a total of eleven depositions.

Faced with the prospect of judicial review of its non-action on the Citizen Petition, on June 9, 2006, some five years after action on it was due, and 17 months after this action was commenced, and after Plaintiffs had amended their complaint to allege an unreasonable delay claim, the FDA admitted that it had denied the Citizen Petition. (Ltr. from Randall W. Lutter, formally denying the Citizen Petition, dated June 9, 2006 (hereinafter "Cit. Pet. Denial Ltr."), attached to Def.'s Ltr. to Chief Judge Korman, dated June 28, 2006 (Doc. 160-2).) Although it had never issued any public statement, the FDA averred that Plaintiffs should have recognized in May of 2004 that the Citizen Petition was denied when the FDA issued a non-approvable letter

in response to Barr's application. (Cit. Pet. Denial Ltr. at 7 n.9.) At a July 26, 2006, status conference, this Court characterized the FDA's letter announcing its denial of the Citizen Petition as "reek[ing] of bad faith." (*See* July 26, 2006 Hr'g Tr. 9.) At that same conference, the Court suggested to the Government that there was no reason that the FDA could not approve Plan B as a non-prescription drug for women 17 and older. The Government vigorously rejected that possibility, contending that an age-restricted non-prescription regime could not be implemented by the FDA without "well established . . . statutory and regulatory authority to undertake such a split marketing approach." (*See* July 26, 2006 Hr'g Tr. 21.) Despite the Government's protestations, within one month the FDA implemented an age-restricted non-prescription regime similar to that which the Court had suggested, albeit with a higher age cutoff than had ever previously been contemplated and with an unprecedented restriction on businesses which could sell Plan B as a non-prescription drug.

Since the FDA's implementation of the BTC regime, the Government has continued to resist outstanding discovery. Notwithstanding its waiver of the deliberative process privilege when it disclosed documents that depicted its version of the decision-making process, the Government has repeatedly relied on that privilege to block access to numerous documents which, on inspection, the Magistrate Judge found to contain evidence of the FDA's bad faith. The Government also has resisted all efforts by Plaintiffs to obtain evidence from the White House regarding its involvement in the Plan B process. The Court has held resolution of these outstanding discovery matters in abeyance pending submission of the parties' cross-motions for summary judgment, while recognizing that it may be necessary to revisit the issue if the Court determines that the discovery will be needed to decide the dispositive motions.

STATUTORY AND REGULATORY SCHEME

By statute, the FDA is authorized to limit a drug to prescription status only when "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer [it]." 21 U.S.C. § 353(b)(1)(A). As a result of this statutory provision ("the Durham-Humphrey Amendment"), enacted in 1951, 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. A drug which has initially been assigned prescription status "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.").

Under the FDA's regulations, 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). 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. (Tummino 10137-38; Jenkins Dep. 192:9-193:17, Aug. 14, 2006.)

In addition, FDA regulations explicitly authorize the use of a citizen 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). Within 180 days after a citizen 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).

STATEMENT OF FACTS

I. Scientific Information About Plan B.

Plan B is a progestin-only contraceptive that can be used to reduce the risk of pregnancy after unprotected intercourse. (Jordan Decl. ¶ 3.) It acts to prevent fertilization and/or implantation and does not interfere with an established pregnancy. It is the only emergency contraceptive product that is on the market in the United States. Plan B has no known serious side effects or serious long term health effects. Instead, it has mild and short-term side effects such as nausea. When used as directed, Plan B can reduce the risk of unintended pregnancy by

up to 89%. The effectiveness of Plan B is greater the sooner after unprotected intercourse it is used, and may be higher if taken within the first 24 hours. (Jordan Decl. ¶ 4).

The approved regimen for Plan B is two doses of levonorgestrel taken twelve hours apart. (Tummino 11030.) Recent studies show that Plan B is equally effective if the two doses are taken closer together than 12 hours apart or at the same time. (Jordan Decl. ¶ 3; Houn Dep. 122:11-123:2, July 20, 2006; Tummino 11031.) The approved instructions for using Plan B can be comprehended adequately by all women of child-bearing age without the assistance of a physician or other learned intermediary. (Tummino 31085.) Indeed, the instructions for its use are far simpler than the instructions for the proper use of numerous other OTC drugs. (Tummino 31097; Jenkins Dep. 101:1-18.) The FDA's Division of Pediatric Drug Development recognized that the age breakdown in the studies submitted by Barr reflected the age breakdown of Plan B consumers:

> The relative distribution of adolescent data reflects the use of Plan B and EC in adolescents, as well as the relative proportions of adolescents requesting Plan B. According to Advance PCS (prescription use data found in Appendix C), the youngest adolescents (8-14 years) accounted for <0.5% of total claims for either Plan B or Preven during 2002-2004. Teenagers, age 15-17 years, represented 5% of total claims. Use in children under age 12 was minimal, accounting for no more than 8-12 of the over 10,000 prescriptions per year.

(Tummino 10941.) This usage profile is similar to the age breakdown in Barr's Label Comprehension and Actual Use studies, particularly for the younger age groups. In addition, the age breakdown is similar to that in the other studies of Plan B reviewed by the FDA.

Although the FDA does not require the submission of Label Comprehension or Actual Use studies in support of over-the-counter (OTC) switch applications (*see* Center for Drug Evaluation and Research, Manual of Policies and Procedures 6532.1, Review Management, Over-the-Counter (OTC) Labeling and Use Studies, *available at*

http://www.fda.gov/cder/mapp/6532.1.pdf), Barr submitted both types of studies. In addition to Barr's studies, the FDA's professional staff reviewed dozens of other published and unpublished studies that examined the safety and effectiveness of Plan B and which also examined whether use of Plan B caused changes in participants' sexual or contraceptive behavior. (Tummino 30745-83; 30784-828; 31095-99.) The professional staff also reviewed several studies which examined whether women of child-bearing ages could use Plan B effectively without the guidance of a learned intermediary. None of these studies revealed the existence of any significant difference between women under 17 and those 17 and over (nor between women under and over 18) in their changes in contraceptive behavior, sexual behavior, or ability to use Plan B effectively.

The equivalent of Plan B is available as an OTC drug without age restriction in India, the Netherlands, Norway, and Sweden. (Jordan Decl. ¶ 9.) No adverse health or behavioral effects are known to have arisen in these countries as a result of OTC availability of the drug. (*Id.*) Plan B is available without a physician's prescription or age restriction in Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington. (Jordan Decl. ¶ 8.) There are no known adverse health or behavioral effects in these states from this wider availability of the OTC drug. (*Id.*) Plan B is also available without a physician's prescription in 38 countries. (Jordan Decl. ¶ 11.) The United States is the only country on Earth that imposes a different regime for the availability of Plan B for women under 18. (Jordan Decl. ¶ 11.)

Numerous medical and public health organizations, recognizing the importance of wide and easy access to Plan B as a means to reduce the number of unintended pregnancies and subsequent abortions, have supported unrestricted OTC access for Plan B. Each of the following has endorsed OTC status for Plan B without age restriction: the American College of

Obstetricians and Gynecologists, a leading organization of medical specialists in the United States in Obstetrics and Gynecology; the American Academy of Pediatrics, a leading organization of medical specialists in the United States in Pediatrics; the American Public Health Association, a leading organization of public health specialists in the United States; and the American Medical Association (AMA), a leading organization of physicians in the United States. (Grimes Decl. ¶ 9.)

The FDA's own internal processes confirm that Plan B is safe for use as an OTC product without age or point-of-sale restrictions. A Joint Advisory Committee composed of experts in reproductive medicine and science and experts in OTC drugs that the FDA convened to consider the OTC switch of Plan B overwhelmingly recommended approval of the switch without age restriction. (Tummino 10792.) Both Office Directors who are assigned by FDA policies the responsibility to approve or disapprove OTC switch applications recommended approval of the Plan B OTC switch without age restriction. Numerous FDA Medical officers recommended approval for the Plan B OTC switch without age restriction: John Jenkins (Dir. Offc. of New Drugs), Sandra Kweder (Deputy Dir. Offc. of New Drugs), Jonca Bull (Dir. Offc. of Drug Evaluation V), Florence Houn (Dir. Offc. of Drug Evaluation III), Julie Beitz (Deputy Dir. Offc. of Drug Evaluation III), Charles Ganley (Dir. of Div. of OTC Drug Products), Donna Griebel (Deputy Dir. Div. of Reproductive and Urologic Drug Products), Curtis Rosebraugh (Deputy Dir. Div. of OTC Drugs), Daniel Davis (Medical Officer of Div. of Reproductive and Urologic Drug Products), and Andrea Leonard-Segal (Medical Team Leader of Div. of OTC Drugs). In contrast, no FDA employee has offered a coherent, much less legally relevant, scientific explanation for the imposition of any age restriction or point-of-sale restriction on Plan B.

Rather, only vague and non-scientific explanations have been offered by FDA officials who opposed unrestricted OTC status.

II. Plaintiffs and Their Injury.

Plaintiffs comprise individual activists who seek unrestricted OTC status for Plan B in part because they want to be able to transfer Plan B to women of any age without fear of criminal prosecution, and in part because their own constitutional rights are violated by the BTC regime; individuals under the age of 18 and their parents, each of whom wants unrestricted OTC access to Plan B; and two organizations whose mission of enhancing awareness about and access to Plan B is thwarted by the BTC regime.

Plaintiffs Annie Tummino, Erin T. Mahoney, Carol Giardina, Kelly Mangan, Stephanie Seguin, Lori Tinney, Jennifer Brown, Candace Churchill, and Francie Hunt are Coordinators of the Morning After Pill Conspiracy. One or more of them has access to one or more doses of Plan B, and each 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 these plaintiffs 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 them 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). Each of them also 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 objects to the disclosure of information to third parties about her personal sexual activity that may occur because, in order to obtain Plan B without a prescription, she is required to present identification to a pharmacist or pharmacy employee.

Some of the Plaintiffs have recently attempted to obtain Plan B under the BTC regime, and their experiences confirm that the BTC regime imposes barriers to women's access. For example, Plaintiff Mahoney was not permitted to purchase more than one package of Plan B from a pharmacy in New York. (Mahoney Decl. ¶ 7.) Plaintiff Brown was told by a pharmacist in Gainesville, Florida, that she should not purchase multiple packages of Plan B for possible transfer to friends because doing so would deprive pharmacists of the opportunity to discuss these friends' birth control practices with them; and the pharmacist inquired in front of other customers about Brown's own methods of contraception. (Brown Decl. ¶¶ 6-9.) In addition, because she tried to purchase Plan B after 9 p.m., she had to visit two stores before she found a third with a pharmacy that was open. (Brown Decl. ¶¶ 4-5.) When Plaintiff deMarco tried to purchase Plan B and stated that she wanted it for her 13-year-old daughter's possible future use, she was told by the pharmacist she visited that she could not do so. (deMarco Decl. ¶ 12.) And Plaintiff ARHP has received numerous reports of difficulties women have faced in trying to obtain prescriptions for Plan B and in filling those prescriptions. (Jordan Decl. ¶ 19.) Obviously, unrestricted over-the-counter status for Plan B would not subject consumers to any of these intrusive inquiries or limitations. Plaintiffs' experiences confirm that the BTC regime imposes barriers and, because of its oddity among regimes with which pharmacists are familiar, actually encourages pharmacist refusal to sell Plan B. Of course, even without the encouragement of the BTC regime, some pharmacists already refuse to sell Plan B, even as a prescription drug. *See,*

e.g., Morr-Fitz, Inc. v. Blagojevich, No. 4-05-1050, 2007 WL 900463 (Ill. App. Ct. Mar. 19 2007; *see also* Tummino 31032.)

Plaintiffs Robert Jaffe and Aurora deMarco are the parents of a 13-year-old daughter, Plaintiff Angelica Jaffe. Robert and Aurora want their daughter to be able to obtain Plan B without a prescription and without any restriction on its point-of-sale in order to maximize the likelihood that she will avoid unwanted pregnancy. (DeMarco Decl. ¶¶ 3-4.) Angelica herself 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. In addition, Aurora believes that the BTC regime perpetuates outmoded and demeaning stereotypes of women that undermine her efforts to teach her daughter Angelica that women are not inferior to men. (DeMarco Decl. ¶¶ 8-10.) Plaintiff Catherine Lederer-Plaskett is the mother of a 16-year-old daughter, Plaintiff Aliza Lederer-Plaskett.[4] Both want Aliza 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. Plaintiff Jonathan Marks is the father of a 13-year-old daughter, Plaintiff Gabrielle Marks. They both want Gabrielle 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.

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,

[4] Aliza will turn 17 before this motion is fully briefed, and thus falls into the category of women (who all scientists at FDA agreed could safely and appropriately use Plan B as an OTC drug, but are barred from doing so by the BTC regime), which imposes an age cut-off of 18. *See infra* at 38.

some of whom have authority to prescribe drugs and some of whom do not. (Jordan Decl. ¶ 13.) 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. (Jordan Decl. ¶ 14.) 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 66,600 calls and 1,180,000 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. (Cit. Pet. Denial Ltr.) 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. (Jordan Decl. ¶¶ 17-19.) 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.

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'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 status 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.

Some or all of the Plaintiffs assert the constitutional interests of all women to make Plan B as widely and easily accessible as possible. 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 BTC. All or some of the Plaintiffs above want to and intend to try to make Plan B available to women in each of these categories, and assert third-party standing to assert these women's interests.

III. The History of the FDA's Proceedings Regarding Plan B.

A. The Filing of the Citizen Petition and OTC Switch Application

On February 25, 1997, the FDA announced that certain combined oral contraceptives are safe and effective for emergency contraception, and requested the submission of NDAs for that use. (Tummino 30167.) That announcement led two manufacturers to obtain approval for emergency contraceptive pills, Plan B (on July 28, 1999) and Preven. Preven has since been withdrawn from the market. (GAO Rep. at 42.)

Recognizing that timely and wide access to emergency contraception pills would be improved by eliminating the requirement of a prescription, on February 14, 2001, plaintiff Association of Reproductive Health Professionals, together with the American Public Health Association, the American Medical Women's Association, the National Asian Women's Health Organization, the National Black Women's Health Project, the National Family Planning and Reproductive Health Association, and 60 other medical, public health, and other organizations filed a Citizen Petition asking the FDA to grant OTC status to Plan B, Preven, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to Preven or Plan B. The Citizen Petition asserted that emergency contraception is suitable for OTC status because it: 1.) is safe for self medication; 2.) has a low risk of abuse or overdose and has no contraindications that would pose a danger to the patient; 3.) can easily be self-administered; and 4.) would make emergency contraception more accessible to women because it would allow them to obtain it in a timely fashion, thereby allowing women to prevent unwanted pregnancies and promoting public health. (01P-0075 CP1.)

The Citizen Petition contained statements of support for OTC emergency contraception from some of the organizations that submitted it, and was accompanied by a supporting declaration of Drs. David Grimes and Elizabeth Raymond. Dr. Raymond conducted the Label-Comprehension and Actual Use studies submitted by the manufacturer in support of the Plan B switch application. Dr. Grimes chaired the World Health Organization's Task Force on Postovulatory Fertility Regulation, which conducted the largest and most definitive clinical trials of Plan B to date. (Grimes Decl. ¶ 2.) Supplements to the Citizen Petition were filed on August 7, 2001 and February 13, 2002. The FDA did not announce that it had denied the Citizen Petition until June 9, 2006.

Parallel to the Citizen Petition, Women's Capital Corporation (WCC), then the manufacturer of Plan B, began to consult with the FDA about submitting an OTC switch application and what the FDA would expect such an application to contain. On April 18, 2002, Dr. Daniel Shames, then-Acting Director of the Division of Reproductive and Urologic Drugs, issued a letter to WCC stating that the FDA declined to issue a Written Request for a proposed pediatric study (which, if WCC or Barr had conducted the requested pediatric study, would have triggered an additional six months of exclusive marketing, and thus additional revenue from Plan B for the manufacturer (*see* 21 U.S.C. § 355a(b)(2005)), on the grounds that the results of the proposed adult population trials *could be extrapolated to the postmenarchal pediatric population*, and that the current labeling regarding use of Plan B in the pediatric population was adequate. (Tummino 30100.)

The Office of the Commissioner of the FDA injected itself into discussions about the Plan B OTC switch application even before WCC filed the application. On June 5, 2002, in anticipation that WCC would be submitting an application to make Plan B available OTC, a briefing was held for the Office of the Commissioner. Among the discussion topics were the "political sensitivity" of the application and the question of whether the NDA would be assigned priority review status or standard review status upon submission. (Tummino 30167.) On July 10, 2002, Dr. Janet Woodcock, then Director of CDER, provided Dr. Crawford, then-Deputy Commissioner, and Daniel Troy, FDA's Chief Counsel, with materials on the safety of emergency contraception and its mechanism of action, which were requested at the June 5, 2002 briefing. (Tummino 30219-30235.) The memo stated, *inter alia*, that accidental use of emergency contraception has not been associated with adverse outcomes. (Tummino 30219-20.)

On April 22, 2003, WCC submitted its sNDA to the FDA to switch Plan B to OTC status. (Tummino 31020.)

B. Phase 1 OTC Switch Application: The FDA's May 2004 Not Approvable Letter

1. Advisory Committee Review

On June 9, 2003, review staff within the Office of Drug Evaluation III accepted the Plan B sNDA for review and set a Prescription Drug User Fee Act (PDUFA) goal date of February 20, 2004, to make a decision on the application. (GAO Rep. at 42.) On September 26, 2003, WCC participated in a conference call with FDA staff from the Offices of Drug Evaluation III and V, which included a discussion of the upcoming joint public meeting of FDA's Nonprescription Drugs Advisory Committee and Reproductive Health Drugs Advisory Committee. WCC also announced that on September 23, 2003, its board voted to sell the entire new drug application for Plan B to Barr Laboratories. (Tummino 30342-30345.)

On December 16, 2003, at a joint meeting of the Nonprescription Drugs Advisory Committee and Reproductive Health Drugs Advisory Committee, Advisory Committee members reviewed and made recommendations on how the FDA should respond to the application for OTC status for Plan B. They voted 23-4 in favor of the recommendation that Plan B be switched from prescription to OTC status. (Tummino 10792.) Advisory Committee members voted unanimously that Plan B is safe for use in a non-prescription setting. They voted 27-1 that the Actual Use Study data submitted by Barr were generalizable to the overall population of potential non-prescription users of Plan B. (Tummino 10754.)

These lopsided favorable votes occurred despite the fact that the Reproductive Health Drugs Advisory Committee was itself appointed in an unusual manner. (Houn Dep. 30:7-44:9; Kweder Dep. 28:10-14, Dec. 11, 2006; Griebel Dep. 14:14-21, 18:20-19, July 19, 2006). The

Office of the Commissioner of the FDA rejected the nominees proposed by CDER, claiming that the nominees lacked a "balance of opinion," a term for which CDER staff was unable to obtain further clarification. (Kweder Dep. 30:4-21, 28:16-29:3.) Instead, the Commissioner's office appointed several members of the Committee whom, according to Sandra Kweder, CDER's Deputy Director of the Office of New Drugs, CDER staff viewed as "not people [CDER] would normally have considered as the kind of people we would be looking for to be on the" Committee, because they had "very limited experience in product development, clinical trials. They were not well-published. They were not people who had the kind of stature in the community that we were seeking." (Kweder Dep. 35:3-12; *see also* Houn Dep. 38-8-12.) ("[T]he contention was over the constitution of the panel, the type of experts needed, and the lack of expertise in some of the nominees relevant to the function of the Reproductive Health Drugs Advisory Committee."). Kweder concluded that the Commissioner's office sought balance of *ideological* opinion (Kweder Dep. 36:12-21) because "[the appointees from the Commissioner's Office] were – these were people who were very active in the Right to Life antiabortion world, again with [one exception]." (Kweder Dep. 37:8-10.) According to Dr. Kweder, during her tenure as Deputy Director of Office of New Drugs, except around the time of the formation of this Committee, nominations have not come from Office of the Commissioner "before or really since." (Kweder Dep. 37:16-20.)

2. Reaction in the Commissioner's Office

Before even the date on which the FDA records having received the Plan B sNDA as being submitted, then Commissioner Dr. Mark McClellan on April 21, 2003 discussed the pending Plan B OTC switch application with White House domestic policy official Jay

Lefkowitz. (Tummino 509.) Contacts between McClellan and the White House about Plan B occurred periodically thereafter.[5] (McClellan Dep. 140:19-141:13, June 13, 2006.)

In late December of 2003 or early January of 2004, before scientific reviews of the OTC switch application had been completed, Acting Deputy Commissioner Woodcock, Acting CDER Director Galson, Director of the Office of New Drugs Jenkins, and Deputy Director of the Office of New Drugs Kweder met for lunch at a restaurant near the FDA's office in Rockville, Maryland. (Jenkins Dep. 17:16-18:2; 19:2-10; Kweder Dep. 44:16-20.) At that lunch, Galson and Woodcock informed Jenkins and Kweder that Commissioner McClellan had decided that the Barr OTC switch application would be rejected by the FDA. (Jenkins Dep. 17:6-11; 18:2-17; 20:7-10; Kweder Dep. 44:3-45:8, 46:2-8.) They were also told that this decision was made in collaboration with the White House. (Kweder Dep. 56:8-57:5.) Neither Galson nor Woodcock appeared satisfied with this decision by the Commissioner. (Jenkins Dep. 20:7-10; Kweder Dep. 48:16-49:5.) But Galson later expressed his concern that if he did not go along with the Commissioner's decision, his position at the FDA would be jeopardized. (Jenkins Dep. 51:7-8, 232:12-20; Wood Dep. 24:9-22, July 31, 2006.)

On January 15, 2004, Dr. Galson, then-Acting Director of CDER, informed members of the Offices of Drug Evaluation III and V and the Office of New Drugs that the Office of the Commissioner recommended a non-approval letter based on the need for more data to "more

[5] Because the Court has stayed proposed documentary discovery on the White House, Plaintiffs have been unable to test the veracity of McClellan's assertion that the purpose of this contact was to keep the White House updated about the Plan B process in order to respond to media inquiries and to inform the White House that the FDA was conducting scientific reviews. We note that McClellan was exceedingly unforthcoming in his 11-line non-response to the Government Accountability Office's detailed written questions (McClellan Dep. Ex. 1 at MBM01-03 (attached hereto at Ex. E)), and generally evasive during his deposition. Mr. McClellan also failed to respond to a letter dated November 17, 2005, from United States Senator Carl Levin, then-ranking minority member of the Permanent Sub-Committee on Investigations of the Committee on Homeland Security and Governmental Affairs, regarding Plan B. (McClellan Dep. 35:4-36:22, Ex. 1 at MBM11-12 (attached hereto at Ex. E).)

clearly establish appropriate use in younger women and/or the need to develop a restricted distribution plan" to address use in younger women. Representatives from Offices of Drug Evaluation III and V informed Dr. Galson that reviews of the Plan B OTC switch application were not yet complete and that there was additional data on the use of Plan B in adolescent girls. (Tummino 30666-70.) Scientific review staff later noted in their completed reviews that they were told at this meeting that the decision on the application would be made at a level higher than the Offices of Drug Evaluation, the normal locus of that decision under the CDER's policy manual. (GAO Rep. at 17.)

Within days after the January 15 meeting, Dr. Woodcock telephoned Dr. Houn, director of the Office of Drug Evaluation III which oversees reproductive health drugs. Dr. Houn had been upset after the January 15 meeting, and Dr. Jenkins had suggested to Dr. Woodcock that she speak with Dr. Houn. During a telephone conversation, Dr. Woodcock informed Dr. Houn that the Plan B process was unfolding as it was in order to appease the constituents of President Bush. (Houn Dep. 59:12-60:6; *see also* Jenkins Dep. 270:13-18 (confirming that he asked Woodcock to contact Houn).)

3. Review by the Professional Staff

Pursuant to FDA regulations, the FDA's professional staff continued with their review of the merits of Barr's OTC switch application. On January 9, 2004, Dr. Curtis Rosebraugh, Deputy Director of the Division of OTC Drugs, issued a review of Barr's Supplemental NDA (Tummino 30443-56), in which he recommended that the application be approved, concluding that "Plan B has an acceptable safety profile, low misuse and abuse potential and reasonable therapeutic index of safety…[W]hen used under non-prescription conditions the product is safe and effective." (Tummino 30454.) He went on to note that Plan B has the potential to decrease

unwanted teen pregnancies by 70% and would also likely result in a decrease in teen abortions. Based on these numbers, he stated that the "potential benefit of this for teen physical and mental health far outweigh the minor risks associate with Plan B use. (Tummino 30455.)

On January 21, 2004, Dr. Jonca Bull, Director of Office of Drug Evaluation V (which oversees nonprescription drugs), issued a memorandum stating that she was in agreement with an "overwhelmingly favorable assessment" of the Plan B OTC switch application by the FDA review staff and the majority votes by the Joint Advisory Committee. (Tummino 30651.) Dr. Bull reported that the sponsor "adequately demonstrated that women of reproductive potential across relevant age subgroups can use the product appropriately" and that "there is a compelling rationale that OTC availability is imperative to better ensure proper use of the product." (Tummino 30651.) She further noted that "the agency's regulatory mandate is not to regulate behavior or morality but to serve the public by ensuring that safe and effective products are made available for prescriber and patient choice." (Tummino 30650.)

On January 23, 2004, FDA staff from the Office of New Drugs and the Offices of Drug Evaluation III and IV met with representatives from Barr Laboratories and WCC. At that meeting, FDA officials informed Barr that while the Divisions were prepared to negotiate labeling, they had been told on January 15, 2004, that the decision on the Plan B OTC switch application would be made by CDER upper level management. They further informed Barr that a decision by upper level management "is not the usual or typical CDER process for determining the approvability of an NDA," and that the Divisions were in the process of completing their reviews of the application and would forward the reviews along with their final recommendations on the application to CDER upper management. (Tummino 30686-90.) FDA staff also conveyed to the sponsor that the Office of the Commissioner and the Acting Director

of CDER raised concerns about whether there was adequate data to establish that minors will use Plan B appropriately in the absence of a learned intermediary, even though reviews of the Plan B switch application had not yet been completed. (Tummino 30687.)

Despite this decision by the Commissioner, scientific review staff, all of whom were convinced that Plan B should be switched to OTC status without restriction, forged ahead with their scientific reviews in order to preserve a complete record of their scientific judgment. (Jenkins Dep. 27:17-30:2.) On February 18, 2004, review staff from the Offices of Drug Evaluation III and V presented additional data and analysis to Commissioner McClellan on the acceptability of the Plan B OTC switch application after reviewing numerous studies on adolescents. (Tummino 30719-44.) After reviewing the sponsor's Actual Use Study as well as additional data from four studies on the use of emergency contraception submitted after the December 2003 Advisory Committee meeting, with particular attention paid to use in adolescents, the Divisions concluded that "the benefits of timely access outweighed any risk for all women, including adolescents" and supported OTC availability without any age restriction. (Tummino 30720.)

Commissioner McClellan, who was not present for the entire meeting (Houn Dep. 49:20-50:7), stated that he was "not convinced" the studies had enough "power" to determine if there were behavioral differences between adults and adolescents. (Tummino 30721.) The Commissioner directed CDER to work with the sponsor on a marketing plan to limit OTC availability of Plan B and to consider the most appropriate age groups to be restricted from access to the product. *Id.*

On February 19, 2004, review staff in the Office of New Drugs and the Offices of Drug Evaluation III and V met with Dr. Janet Woodcock and Dr. Steven Galson. During the meeting

Dr. Woodcock re-iterated the Commissioner's and her concerns about adolescent use of Plan B. Dr. Woodcock expressed particular concern that OTC status of Plan B could lead to "extreme promiscuous behaviors" and that the medication could take on "'urban legend' status that would lead adolescents to form sex based cults centered around the use of Plan B." (Tummino 30745-46.) Dr. Galson stated that he shared those concerns. (*Id*.)

On March 24, 2004, Dr. Rosebraugh issued an addendum to his prior review memorandum, which was joined by Dr. Jonca Bull. In this memo, Dr. Rosebraugh reasserted his conclusion that Plan B meets the criteria for OTC marketing without restriction. He emphasized that adolescents would "derive great benefit" from OTC access to Plan B and that "[a]ny system that creates barriers to access, including restricted distribution or age restrictions, would defeat the purpose of this drug and lessen its public health potential. (Tummino 30757.) He also noted that Plan B was being held to a higher regulatory standard than other drugs, and suggested that "a natural progression" of the line of reasoning applied to Plan B regarding behavior concerns would result in the removal of OTC status for such drugs as laxatives (because of abuse by bulimics) and Tylenol (because of its use in suicide attempts). (Tummino 30757-58.) He concluded: "In terms of OTC switch applications, this drug has more information available to allow us to predict consumer behavior than any drug in recent memory. If this is not enough data upon which to base a decision, it is unclear what would constitute enough data or even if that is an obtainable goal. (Tummino 30757.)

On April 1, 2004, Dr. Donna Griebel, Deputy Director of the Division of Reproductive and Urologic Drugs, issued a lengthy review of the Plan B OTC switch application recommending approval for switch of Plan B to non-prescription status. (Tummino 30829-80.) Dr. Griebel found that the risk-benefit ratio of non-prescription access to Plan B supports its

approval for over-the-counter status. She also concluded that "it is unjustified to restrict access to the benefit of this product on the basis of age." (Tummino 30877.) On April 2, 2004, Dr. Julie Beitz, Deputy Director of the Office of Drug Evaluation III, recommended that Plan B be approved for OTC status with no age restriction based on her completed review of the Plan B OTC switch application. She found that there was sufficient data on the safety and effectiveness of Plan B to approve its use in an OTC setting with no restriction. (Tummino 30881-91.)

On April 22, 2004, Dr. John Jenkins, the Director of the Office of New Drugs, issued his review of the Plan B application. (Tummino 30897-900.) He concurred in the recommendations of the Offices of Drug Evaluation III and V that the sponsor provided adequate data demonstrating that Plan B can be used safely, effectively, and appropriately by women of childbearing potential. (Tummino 30898.) Dr. Jenkins recommended that Plan B be made available over-the-counter without any age restriction. (Tummino 30897-900.)

4. Issuance of the Not Approvable Letter

Despite the unanimous view of all the scientific reviewers, on May 5, 2004, Dr. Galson informed members of the Offices of Drug Evaluation III and V and the Office of New Drugs -- consistent with his statements at the late December/early January lunch and the January 15 meeting -- that the action letter on the Plan B OTC switch application would be a Not Approvable letter, and that the reason for the Not Approvable action was a lack of data in the under-16 age group. Dr. Galson asserted that non-medical or political views about the drug and sexual behavior did not factor into the decision. Dr. Galson further stated that the FDA staff's disagreement with the Not Approvable action would be acknowledged publicly. (Tummino 30912-14.)

Dr. Galson's internal memorandum justified this action in part on the view that adolescents have diminished capacity (compared with adults) to make rational decisions, a view for which he obtained cursory support in an e-mail exchange three days earlier. (Tummino 30908-11.) Accordingly, on May 6, 2004, FDA issued a Not Approvable letter on the Plan B OTC switch application based on a lack of adequate data regarding safe use by younger adolescents. The letter stated that the application cannot be approved until the sponsor either provides data demonstrating that Plan B can be used safely by women under age 16 without professional supervision, or provides additional information in support of a dual marketing plan that would sell Plan B as a prescription-only product for women under age 16 and as a nonprescription product for women age 16 and older. (Tummino 30904-07.)

C. Phase 2 Switch Application: The Dual Status Application

On July 21, 2004, Barr Laboratories submitted a revised OTC switch application that asked that Plan B be made available to women age 16 and older without a prescription while requiring women age 15 and younger to obtain a prescription for Plan B. (Tummino 30921.) Again, the FDA professional staff undertook to review the appropriateness of the application in light of the scientific evidence and the agency's statutory charge.

1. The Commissioner Pre-empts Approval of the Revised OTC Switch Application

On November 12, 2004, Dr. Hari Cheryl Sachs of the Division of Pediatric Drug Development at the FDA issued a review of the Plan B OTC switch application stating that the sponsor's submission fulfills the requirements of the Pediatric Research Equity Act of 2003 (PREA) for post-menarchal females. Dr. Sachs concluded that the sponsor submitted sufficient data to assess the efficacy of Plan B for its intended use, and that the sponsor sufficiently

demonstrated the safety of Plan B for use in adolescents. (Tummino 10939-10949.) Dr. Sachs observed, *inter alia*, that the age breakdown in the sponsor's actual use study was similar to the age breakdown of prescription users of Plan B. (Tummino 10941.) On November 16, 2004, Dr. Lisa Mathis, Acting Division Director of the Division of Pediatric Drug Development concurred with Dr. Hari Cheryl Sachs' conclusion that the PREA requirements for adolescents over age 14 were met. (Tummino 10949.)

All the FDA scientific reviews of the Plan B switch application other than Dr. Galson's recommended that the Barr application be rejected in favor of unrestricted OTC approval. Despite this unanimous view, which was based upon a review of scientific literature about Plan B that went far beyond the studies conducted by the manufacturer, in January of 2005, Dr. Steven Galson asked Dr. John Jenkins to draft an approvable letter for the Plan B OTC switch application approving Plan B for over-the-counter status for women age 17 and over. (Jenkins Dep. 145:18-147:15.) Before Galson could issue such a letter, however, Acting Commissioner Lester Crawford removed Dr. Galson's authority to make a decision on the Plan B application. (Crawford Dep. 46:1-49:20, 140:12-146:3, May 24, 2006; Galson Dep. 186:15-187:18, 205:1, 206:20, April 26, 2006.)

2. Continuing Scientific Review of the Barr Revised OTC Switch Application

Despite the removal of Galson's authority to issue a decision on the amended Plan B switch application, the scientific staff undertook reviews of the amended application and uniformly rejected the age restriction urged by upper management. On January 12, 2005, Dr. Daniel Davis, a Medical Officer in the Division of Reproductive and Urologic Drugs, issued a Review of Complete Response to the Not Approvable action on the Plan B OTC switch application. Dr. Davis concluded that "[t]here are no new safety findings that would preclude

the approval of changing Plan B from prescription status to over-the-counter status." (Tummino 31020.) He noted that the data submitted by the sponsor during the original review cycle showed that Plan B is "safe and efficacious when used in accordance with proposed labeling" and that it could be distributed over-the-counter without any age or distribution restrictions, and without the need for any additional clinical studies. (Tummino 31020.) Dr. Davis found that the sponsor's request that Plan B remain prescription-only for adolescents under age 16 was not "warranted or desirable." (Tummino 31020.)

On January 12, 2005, Dr. Curtis Rosebraugh, Deputy Director of the Division of Over-the-Counter Drug Products, issued a Division Director Memo-Addendum in response to the sponsor's amended application seeking over-the-counter approval for Plan B for consumers age 16 and over, which was also signed by Dr. Jonca Bull, Director of the Office of Drug Evaluation V, and Dr. Charles Ganley, Director of the Division of Over-the-Counter Drug Products. (Tummino 31026-30.) Dr. Rosebraugh concluded that: 1.) the Plan B application met the Durham-Humphrey Amendment criteria for over-the-counter marketing without restriction; 2.) any systems that created barriers to access to Plan B "would defeat the purpose of the drug and lessen its public health potential"; and 3.) implementation of an age restriction "for theoretical abuse by a small segment of the population" would have ramifications for how the FDA regulates other OTC drugs where known abuse by the population and by adolescents exists, such as dextromethorphan, laxatives, and analgesics. (Tummino 31026.) In his Memo Addendum regarding the amended Plan B OTC switch application, Dr. Rosebraugh stated that he has "many concerns regarding the regulatory precedent" that approval of a dual marketing plan based on age would set and the possible unintended consequences of such plan. He stated that he was "concerned that the regulatory precedent that would be set by requiring adolescents to obtain a

prescription to access an otherwise OTC contraceptive product may have implications for other OTC contraceptive products that are currently marketed which do not bear age restrictions and have not submitted adolescent data for OTC marketing. In the past when the Division [of Over-the-Counter Drug Products] has felt that there was insufficient data to warrant labeling for a particular age group, [the Division has] labeled the product with language that reflects that under a certain age, a physician should be consulted, but an age restriction for sale of the product was not part of the labeling." (Tummino at 31027.) Notably, Dr. Rosebraugh also concluded that, "It is unclear what additional data could be provided on adolescent use that would be sufficient to lift the age restriction in the future." (Tummino at 31027.)

On January 12, 2005, Dr. Donna Griebel, Deputy Director of the Division of Reproductive and Urologic Drugs, issued a Memorandum in response to Barr's amended Plan B OTC switch application affirming her April 1, 2004, Review of the Plan B OTC switch application and recommending full over-the-counter status for Plan B with no age restriction. Consequently, she did not recommend the amended Plan B switch application requesting dual status based on age for approval. (Tummino 31031-31084.) Dr. Griebel stated that she did not support the sponsor's split label application for two reasons: 1.) Labeling the product to require a prescription for consumers under age 16 sets a precedent that "could have negative consequences on current products sold as non-prescription products, including contraceptive products like condoms and spermicidal products."; and 2.) Creating an age restriction for over-the-counter sale of Plan B "could have the unintended public health consequence of limiting access to women of all ages." (Tummino at 31031-32.) Dr. Griebel expressed concern that enforcing an age restriction for a reproductive health drug could be viewed as an undesirable legal burden for pharmacies that may prompt pharmacies to cease carrying Plan B altogether. She further noted

that "there are multiple reported instances in the media and in the medical literature of pharmacists who refuse to fill prescriptions for the current prescription product because they believe it causes medical abortion." (Tummino at 31032.)

On January 12, 2005, Dr. Julie Beitz, Deputy Director of the Office of Drug Evaluation III, issued a memorandum concurring with the Division of Reproductive and Urologic Drug Product's recommendation to approve Plan B for over-the-counter status with no age restriction. (Tummino 31085-87.) Dr. Beitz concluded that there is sufficient data illustrating the safety and effectiveness of Plan B to approve its use in an over-the-counter setting without any age restriction, and expressed concern about the sponsor's proposal to retain prescription status for Plan B for adolescents under age 16 based on "the regulatory precedent that would be set by requiring adolescents to obtain a prescription to access an otherwise OTC contraceptive product." (Tummino 31086.) She was concerned about the implications of such a precedent on other OTC contraceptive products that are not currently restricted by age. Dr. Beitz also noted the existence of products that are currently available to adolescents over-the-counter that, if misused, carry many more safety risks than would occur due to misuse of Plan B. (Tummino 31086.) She further noted the difficulty of enforcing an age restriction on Plan B in a retail pharmacy setting. (Tummino 31086.) Finally, like Dr. Rosebraugh, Dr. Beitz stated that "it is unclear what additional data Barr could provide on adolescent use of Plan B that would be sufficient to lift the age restriction in the future." (Tummino 31086.)

On January 14, 2005, Dr. John Jenkins, Director of the Office of New Drugs, issued a memorandum stating that he supported full over-the-counter access of Plan B with no age restriction, and that the sponsor's dual marketing plan should not be approved. (Tummino 31095-99.) Dr. Jenkins believed that the dual marketing plan should be rejected because there is

"no scientific basis for the differentiation in prescription and non-prescription status based on age and such an approach is inconsistent with well established FDA precedent with regard to labeling OTC products for use in adult and pediatric populations." (Tummino at 31096.) In response to Dr. Galson's previously stated concerns about the relatively small number of subjects under the age of 16 in the Label Comprehension and Actual Use studies, Dr. Jenkins stated that, "It is entirely reasonable to extrapolate the findings from the older women in these trials to adolescents given well established agency precedent for extrapolating data from studies in adults and older adolescents to younger adolescents and the fact that there was no suggestion based on the data from the sponsor's studies that younger women were less able to use the product correctly in a simulated OTC setting than older women." (Tummino 31096-97.) Dr. Jenkins noted that a decision to approve Plan B for both prescription and over-the-counter status for the same indication with the only difference being the patient's age "sets an important policy precedent that must be carefully considered and justified. In my opinion, such an approval for Plan B cannot be justified based on scientific data . . . and such an approval has the potential to raise other serious scientific and policy issues." (Tummino 31097.)

Dr. Jenkins additionally noted that concerns previously raised by Dr. Galson about the developmental differences between adolescents and older women "are more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse." (Tummino at 31097.) Dr. Jenkins concluded his memorandum in support of OTC status for Plan B without an age restriction with the following observation:

> Products 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 are derived 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. While acknowledging these concerns, I believe 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.

(Tummino 31098.)

3. The FDA Refuses to Act

On January 21, 2005, all of the professional staff remained unanimous that the age restrictions in Barr's revised OTC switch application should be rejected and that Plan B should be available over-the-counter to women of all ages. But apparently because Acting Commissioner Crawford removed Dr. Galson's authority to approve age-restricted OTC status for Plan B that Galson had instructed Dr. Jenkins to draft, the FDA missed the PDUFA deadline to issue a decision on the Plan B switch application. No further scientific reviews were conducted between January 14, 2005 (the date of the Jenkins Phase 2 memo) and Dr. Crawford's announcement of advanced notice of proposed rulemaking in August of 2005. Nobody at the FDA, including Deputy Commissioner Woodcock, knew what process Crawford was undertaking during this period. (Woodcock Dep. 68:20-22, April 26, 2006; Galson Dep. 202:4-9.)

The FDA's inaction moved members of the Senate to place a hold on the confirmation of Acting Commissioner Crawford. To remove the hold, Michael Leavitt, the Secretary of Health and Human Services on July 13, 2005, sent a letter to Senator Michael Enzi, Chairman of the Senate Committee on Health, Education, Labor and Pensions, assuring him that action would be taken on the Plan B application by September 1, 2005 (a letter that was used by the Government to obtain a stay of proceedings from this Court). (*See* Def's Ltr. Mot. to Chief Judge Korman, dated July 25, 2005 at 2 (Doc. 20).) On July 18, 2005, Crawford was confirmed by the Senate to

be FDA Commissioner. *See* 151 CONG. REC. S8438 (daily ed. July 18, 2005). Despite Secretary Leavitt's assurance, and despite a memorandum dated August 26, 2005 from Dr Galson stating that the sponsor's proposal to switch Plan B to OTC status meets the statutory standards for approval for women age 17 and older, (Tummino 31214-26), on August 26, 2005, the FDA announced that it was not going to make a decision on the Plan B OTC switch application by September 1, 2005, and instead announced that it would implement a 60-day public comment period on the enforceability of a dual marketing program. The FDA did not specify when a decision on the Plan B OTC switch application would be made. *See* FDA website at http://www.fda.gov/bbs/topics/news/2005/NEW01223.html (August 26, 2005 Crawford press release) (last checked on March 29, 2007).

The FDA's announcement moved Dr. Susan Wood, Director of the Office of Women's Health, to resign from her post on August 31, 2005 over the agency's handling of the Plan B OTC switch application. (Wood Dep. 13:17-14:17; *see also* Wood Dep. Ex. 2, July 31, 2006) (Deposition Exhibit is attached hereto at Ex. E). When Dr. Wood met with Dr. Woodcock to discuss her resignation, Dr. Woodcock discussed *her own concern* that the FDA's handling of Plan B could damage Woodcock's credibility if the FDA continued to delay action. (Wood Dep. 40:2-19.) On October 7, 2005, Dr. Frank Davidoff, a member of the FDA's Nonprescription Drug Advisory Committee resigned due to the FDA's delayed action on the Plan B OTC switch application. (Tummino 7509-10; Jenkins Dep. 258:20-260:11 (stating that he does not ever recall an Advisory Committee member resigning in protest prior to Dr. Davidoff)).

Dr. Crawford resigned as Commissioner of the FDA on September 23, 2005. Dr. Andrew von Eschenbach was named Acting Commissioner. On November 1, 2005, the 60-day public comment period on the enforceability of a dual marketing program for Plan B expired.

(Tummino 10820.) Review of the comments was outsourced to a private company, ICF International, which completed its final review of the comments on May 19, 2006. (Tummino 10816.) In the meantime, the FDA remained utterly silent.

4. Public Acknowledgment of the Denial of the Citizen Petition and the Adoption of the BTC Regime.

While the FDA continued its administrative stall, Plaintiffs continued their efforts to conduct appropriate discovery of the FDA's decision making process in this litigation. On June 9, 2006, while claiming that it had not rejected the Barr "dual status" application, the FDA acknowledged its denial of the Citizen Petition, stating that the petition failed to submit adequate data to satisfy the statutory requirements needed to approve Plan B for OTC status, and that the petitioners are not a party to the sNDA proceedings and may not therefore require the agency to render a decision on Barr's sNDA based on the information submitted by Barr to the FDA. (Cit. Pet. Denial Ltr. at 15-19.) This acknowledgment of the denial of the Citizen Petition came in the midst of Plaintiffs' discovery which began to reveal the degree to which the Office of the Commissioner of the FDA had steered the Plan B process for non-scientific reasons and as Plaintiffs began to compile evidence that high-level FDA officials sought to cover-up the non-scientific bases for the FDA's actions. In addition, it came weeks after Plaintiffs announced their intention to seek discovery of White House documents describing the White House's role in the FDA's handling of Plan B. (May 31, 2006 Hr'g Tr.) The Government quickly exploited the denial letter to once again purpose a halt to discovery. (*See* Def.'s Ltr. to Chief Judge Korman, dated June 28, 2006 (Doc. 160) at 4.)

On July 31, 2006, Acting Commissioner von Eschenbach, whose confirmation by the Senate was still outstanding, abandoned his predecessor's exploration of rulemaking as a means to resolve alleged regulatory issues raised by Barr's amended Plan B OTC switch application and

informed Barr that the FDA was proceeding with further evaluation of the Plan B application. (Tummino 10864.)

In the third phase of the review process, FDA scientific reviewers again rejected the propriety of an age restriction. Dr. Beitz, Acting Director of the Office of Drug Evaluation III, reiterated her view that no age restriction was appropriate "[i]n the absence of new data to support" such a restriction. (Tummino 10927.) Dr. Ganley, Director of the FDA's Office of Nonprescription Products, likewise stated "[n]o new data was provided to suggest the restriction based on age is necessary." (Tummino 10929.) Dr. Jenkins, Director of the Office of New Drugs, similarly reiterated his prior position adding, "I am not aware of any new data that supports the need for an age restriction." (Tummino 10931.) The Director and Deputy Director of FDA's Office of Surveillance and Epidemiology also observed that the BTC regime's program for "monitoring the compliance of the age restriction [by sending underage shoppers to try to purchase Plan B without a prescription and reporting pharmacists to state boards of pharmacy] is overly punitive and may have a negative impact on the availability of this product OTC. . . . For other products with restricted distribution plans, these types of findings are generally reported to the Agency, rather than professional licensing boards." (Tummino 11077.)

On August 23, 2006, Commissioner von Eschenbach issued a memorandum stating that he concluded that age 18, rather than age 17, is the "more appropriate cutoff point" for OTC Plan B, based on the "well-established state and private-sector infrastructures to restrict certain products to consumers 18 and older." (Tummino 10866.) On August 24, 2006, Dr. Galson issued a memorandum stating that the Plan B OTC switch application provided adequate information that Plan B is safe and effective for OTC use in women age 17 and older. Dr. Galson further stated that for the reasons outlined by Dr. von Eschenbach in his August 23, 2006,

memorandum, he determined that OTC Plan B should be restricted to women age 18 and older. (Tummino 10868-74.) FDA staff has indicated that the timing of the approval of Plan B was related in part to the pending Senate confirmation hearings of Dr. von Eschenbach. (Jordan Decl. ¶ 24.)

The August 24, 2006, action approved Plan B as a behind-the-pharmacy-counter nonprescription drug for women age 18 and older who have and are willing to produce government-issued photo identification. Women under 18 are required to provide a prescription to obtain Plan B. In announcing the BTC regime, von Eschenbach emphasized that it would continue to be illegal for women under 18 to obtain Plan B without a prescription. (Tummino 10866) ("Plan B® may not lawfully be made available without a prescription to [girls 16 and younger] under section 503(b) of the Food, Drug, and Cosmetic Act."). He also opined that "[l]everaging well-established state and private-sector infrastructures [for tobacco products and pseudoephedrine] will allow for comprehensive and effective enforcement of the age-based restrictions." (*Id*.)

Dr Galson's approval letter announcing the BTC regime described a surveillance program that Barr will implement which will utilize undercover shoppers to monitor compliance by pharmacies with the age-restriction. As a condition of the approval, Barr is required to:

> Conduct a "Point-of-Purchase Monitoring Program" to track how Plan B® is being sold at the time of purchase, including using anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. Using the data collected, you will document and analyze the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The program will be conducted twice in the first year and annually thereafter. The sponsor will report repeat violators to the relevant State Boards of Pharmacy.

(Tummino 10873.)

Evidently von Eschenbach and Galson viewed adopting state "infrastructures" for tobacco and pseudoephedrine and the decoy shopper program as the appropriate enforcement mechanism for the age restriction that provides a response to the prior Commissioner's enforcement concerns. (One year prior to announcement of the BTC regime, FDA Commissioner Crawford had identified enforcement as one of the chief justifications for considering general rulemaking regarding the FDA's authority to switch a drug to non-prescription status for one age group only. *See* August 26, 2005 Public Statement of Crawford (http://www.fda.gov/bbs/topics/NEWS/2005/NEW01223.html (last checked on March 28, 2007) ("And if FDA were to attempt to limit sale of an over-the counter product to a particular sub population, would FDA be able to enforce such a limitation as matter of law, and could it do so as a practical matter and then how?")).

IV. The Government Accountability Office Investigation

In November 2005, the United States Government Accountability Office, at the request of members of Congress, issued a report entitled "Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual" (hereinafter "GAO Rep."). The GAO Rep. made a number of findings relevant to this case, although the report considered only FDA actions prior to the May 6, 2004, Not Approvable letter and "did not consider any communications that may have occurred between FDA officials and other executive agencies." (GAO Rep. at 4.) The GAO found four aspects of the FDA's review process to be unusual:

> First, the Directors of the offices that reviewed the application, 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 not to approve the application was made before

> the reviews of the application were completed. Fourth, the rationale for the Acting Director's decision was novel and did not follow FDA's traditional practices. The Acting Director stated that he was concerned about the potential behavioral implications for younger adolescents of marketing Plan B OTC because of their level of cognitive development and that it was invalid to extrapolate data from older to younger adolescents. 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 previously has considered it scientifically appropriate to extrapolate data from older to younger adolescents.
>
> The Plan B decision was not typical of the other 67 proposed prescription-to-OTC switch decisions made by FDA from 1994 through 2004. The Plan B OTC switch application was the only one during this period that was not approved after the Advisory Committee's recommended approval. The Plan B action letter was the only one signed by someone other than the officials who would normally sign the letter. Further, there are no age-related marketing restrictions for any prescription or OTC contraceptives that FDA has approved, and FDA has not required pediatric studies for them. FDA identified no issues that would require age-related restrictions in review of the original prescription Plan B new drug application.

(GAO Rep. at 5-6.[6])

V. The FDA's Consideration of the Citizen Petition Was Heavily Intertwined With Its Consideration of the Barr OTC Switch SNDA

Because Preven was withdrawn from the market, the Citizen Petition and the sNDA as originally submitted by Barr both requested exactly the same action by the FDA. Clearly, then, the signatories of the Citizen Petition are within the zone of interests affected by the FDA's decision on the Barr sNDA. Conversely, Barr is within the zone of interests affected by the FDA's decision on the Citizen Petition. At the following meetings conducted by the FDA, FDA officials considered the Citizen Petition in tandem with the Barr sNDA: Office of the Commissioner Meeting re: Rx to OTC switch of Plan B (June 5, 2002) (Tummino 30166-74); Office of the Commissioner Meeting re: Rx to OTC switch of Plan B (Dec. 10, 2003) (Tummino

[6] The GAO observed that "The Acting Director [Galson] acknowledged to GAO that considering adolescents' cognitive development as a rationale for a not-approvable decision was unprecedented for an OTC application, and other FDA officials told GAO that the rationale differed from FDA's traditional practices." *Id.*

30393-420). In its letter acknowledging its denial of the Citizen Petition on June 9, 2006, the FDA reviewed extensively the evidence submitted by Barr in support of the sNDA, and specifically linked the denial of the Citizen Petition to asserted deficiencies in data provided in conjunction with the Barr sNDA. (Cit. Pet. Denial Ltr.) Indeed, the letter stated, "We made Dr. Galson's May 6, 2004 [Non-Approvable] letter to Barr available to the public. Thus, you were on notice that we did not believe that even the applicant had submitted sufficient data to support an OTC switch." (Cit. Pet. Denial Ltr. at 7 n.9.) Moreover, the letter relied in part on lack of data about "changes in sexual/contraceptive behaviors . . . due to Plan B," (Cit. Pet. Denial Ltr. at 16), the same impermissible factor relied upon by Dr. Galson in his rejection of unrestricted OTC status.

In addition, FDA officials charged with regulation of new drugs testified that the Citizen Petition was considered by the FDA together with the Barr sNDA. (Galson Dep. 28:7-16 ("In my mind, the issues is mixed of the citizens' petition and the application, similar issues were raised…"); Houn Dep. 17:10-14.) At an October Status Conference before the court, the Counsel for the Defendant agreed that the Citizen Petition would stand or fall with the Barr sNDA. (October 11, 2006 Hr'g Tr. 7.)

VI. The FDA's Treatment of the Plan B OTC Switch Radically Departs from the Manner In Which It Has Handled OTC Applications Concerning Other Drugs.

In denying the Citizen Petition and promulgating the BTC scheme, the FDA employed a decision process that treated Plan B in a discriminatory manner compared to its treatment of all other drugs.[7] In the past ten years, with the exception of Plan B, the FDA has never rejected an OTC switch that was recommended by an Advisory Committee. (Def.'s Chart, Rx Switches

[7] Indeed, the BTC regime discriminates against Plan B even among the smaller class of "products with restricted distribution plans." (Tummino 11077.)

(Proposed and Approved) to Nonprescription Status for the Last Ten Years, (*hereinafter* "10 Year Rx Switch Chart"), attached at Ex. E.)

The FDA does not routinely consult with the White House about an OTC switch application (McClellan Dep. 133:7-9) or decide OTC switch applications in a manner designed to appease the constituents of the President of the United States, but did both when it came to Plan B. (McClellan Dep.131:15-132, 127:10-15, 138:11-19, 140:19-141:13; Houn Dep. 59:12-60:6; Kweder Dep. 56:8-58:19.) In the past ten years, the Commissioner of the FDA has not made a determination on an OTC switch application before the reviews were complete except for Plan B. (GAO Rep. at 31.)

In the past ten years, no OTC switch application has been decided at the level of the Director of the Center for Drug Evaluation and Research (CDER). (GAO Rep. at 30; Galson Dep. 35:22-36:3, 36:14-19.) With the exception of one other drug and Plan B, the FDA has not received an Actual Use Study that included persons under the age of 18, even for numerous drugs that are available without age restriction. (Def.'s Resp. to Interrogs. 1-12 (indicating drugs approved for Rx to OTC switch between 1/1/01 and 12/31/05 (*hereinafter* "Interrog. 5 Year Chart") attached hereto at Ex. E; *see also* 10 Year Rx Switch Chart (indicating lack of FDA request for pre-marketing data on adolescents).) The FDA has approved numerous OTC switches without requiring or approving any Label Comprehension study from the sponsor. (Interrog. 5 Year Chart.) The FDA has never, prior to Plan B, required a non-prescription drug to be sold only at pharmacies. Many of these drugs that are available for sale in retail stores other than pharmacies are known to be abused both by minors and adults, including some such as aspirin, Ibuprofen, and Acetaminophen which cause hundreds of deaths each year in the U.S. (Tummino 30757-58, 31086; Jordan Decl. ¶ 21; Grimes Decl. ¶ 10(E).) Other OTC drugs, such

as dextromethorphan, are abused by taking higher than approved dosages in order to experience side effects of over dosage. (Rosebraugh Dep. 190:11-191:2, July 18, 2006.)

Nor in the last ten years has the FDA requested that a manufacturer provide data on adolescents in support of an OTC application.[8] (10 Year Rx Switch Chart.) Instead, FDA scientists routinely extrapolate from data about one age group to another age group as the professional staff of the FDA advocated in the case of Plan B. But the FDA refused to do so in the case of Plan B.

The FDA cannot identify another occasion in which it considered how its approval of a drug would effect on personal behavior of those who would use it. (GAO Rep. at 22; Tummino 31097-98; Jenkins Dep. 103:8-11, 105:5-107:13.) Indeed, the FDA did not consider the effects on sexual behavior of men when it approved Viagra and other erectile dysfunction drugs, and approved Plan B itself as a nonprescription drug for sale to men 18 and over without any data concerning, much less consideration of, the effect it might have on the sexual or contraceptive behavior of such men. (Jenkins Dep. 125:18-126:12; *see also* Jordan Decl. ¶ 20.)

The FDA has approved OTC switches for numerous prescription drugs and classes of prescription drugs which have greater toxicity than Plan B. (Grimes Decl. ¶ 10(E); *see also* Houn Dep. 120:18-121:17, July 20, 2006.) In other words, many OTC drugs could cause more severe side effects even when they are used according to approved directions than the correct or incorrect use of Plan B could ever cause. (Grimes Decl. ¶ (10)E; Tummino 31086; *see also* Houn Dep. 127:2-128:12.) Similarly, many OTC drugs pose special risks for certain populations (including certain age groups). (*See, e.g.,* Jordan Decl. ¶ 21) In no case have any of these OTC

[8] Although the 10 Year Rx Switch Chart indicates that FDA has on occasion requested adolescent data in the form of Phase IV studies, Phase IV studies are follow-up studies conducted *after the drug has been approved* and after it is being marketed and sold OTC. These are not studies that are required, or even possible to conduct, prior to approval.

drugs been approved with a specific restriction for such populations. (Jenkins Dep. 113:2-16.) Rather, the FDA has always addressed concerns about specific populations by requiring label warnings. (Jenkins Dep. 113:7-16; Tummino 31027, 31097.) For example, aspirin is not recommended for use by children or adolescents with viral infections, because of the risk of developing Reye's Syndrome – a potentially fatal illness. (Jordan Decl. ¶ 21.) Nevertheless, it is widely available to for unrestricted purchase, including by adolescents and by parents who intend to purchase it for their children. Before its action on Plan B, the FDA has never restricted a non-prescription drug product based on age but has always addressed concerns about inadequate data for younger ages by including an age warning on the drug label. (GAO Rep. at 30; Jenkins Dep. 113:6-16; Tummino 31027, 31031-32, 31086, 31097; Jordan Decl. ¶21.) Similarly, the FDA has approved OTC switches for numerous prescription drugs and classes of prescription drugs whose directions for approved use are far more complicated than the directions for Plan B. (Jenkins Dep. 101:5-18.)

As a further indication of the FDA's unprecedented treatment of Plan B, some FDA drug regulators are concerned that the BTC regime establishes a new precedent justifying similar age restricted non-prescription status for every drug for which actual use and label comprehension studies for younger ages are not submitted or are insufficient, as well as reexamination of both contraceptive and non-contraceptive OTC drugs and devices where age concerns are reflected currently in a warning label. (Tummino 30650, 31027, 31086, 31097, 31031-32; Jenkins Dep. 112:13-113:19.)

VII. The BTC Regime Reinforces Outmoded Stereotypes of Women.

Plan B is approved for use only by women. (Tummino 10876-84.) The FDA's rejection of unrestricted OTC status for Plan B and the structure of the BTC regime both perpetuate

outmoded stereotypes of women as less capable of making rational judgments than men and as incapable of following simple instructions. (DeMarco Decl. ¶¶ 9-10; Brown Decl. ¶¶ 8-9.)

Specifically, requiring adult women to obtain Plan B from behind the pharmacy counter by showing government-issued proof of age perpetuates the outmoded view that women's efforts to control their own fertility should be kept out of the public eye and are in some way shameful. (DeMarco Decl. ¶¶ 8-9; Mahoney Decl. ¶ 4; Tummino Decl. ¶ 5; Grimes Decl. ¶ 12.) Controlling the point of sale of Plan B as a non-prescription product for adults perpetuates the outmoded stereotype that adult women still require the guidance of pharmacy workers in order to be able to use Plan B effectively because they are less capable than adult men of following instructions. (DeMarco Decl. ¶¶ 8-9.)

Moreover, although Plan B was never tested or reviewed by the FDA in connection with the OTC switch for any use by males, the FDA nevertheless approved the product for men age 18 and over. Indeed, in the past ten years, no other product has been switched to non-prescription use for both males and females as to which the FDA required studies by the sponsor for one sex but not the other. (*See* 10 Year Rx Switch Chart). This reinforces stereotypes of women as uneducated and unintelligent by promoting the view that such adult men are so superior to women that they can be entrusted to use Plan B appropriately even though there is no approved use of Plan B for men. (DeMarco Decl. ¶ 9.) By requiring evidence that non-prescription availability of Plan B would not affect women detrimentally by changing their contraceptive behavior before approving it for women, while simultaneously approving non-prescription availability of Plan B for adult men without any studies showing how Plan B's availability affects men's sexual behavior,[9] the BTC regime reinforces an outmoded stereotype

[9] For example, perhaps the OTC availability of Plan B to adult men will discourage them from using condoms during sex.

of women as less capable than men of making their own sexual and contraceptive decisions. (DeMarco Decl. ¶ 10.) Furthermore, by rejecting as insufficient evidence that non-prescription availability of Plan B would not affect adolescent women detrimentally by changing their contraceptive behavior, while simultaneously approving non-prescription availability of Plan B for adult men without any studies showing how availability affects men's sexual behavior, the BTC regime reinforces an outmoded stereotype of women as less capable than men of making their own sexual and contraceptive decisions.

Indeed the BTC regime so strongly reinforces the stereotype of women as less capable than men of making sexual and contraceptive decisions that FDA officials who rejected full OTC availability were unable to state what evidence would suffice to meet their concerns about any younger women's sexual and contraceptive behavior. (Tummino 30649-51, 31027, 31086.) On the other hand, these same officials evidently viewed all adult men as so indisputably capable of making sexual and contraceptive decisions that no evidence at all is needed to make Plan B available to them. Consistent with the FDA's employment of sexual stereotypes in its treatment of Plan B, when erectile dysfunction drugs were approved by the FDA in 1998 no examination was undertaken whatsoever on these drugs' effects on men's sexual and contraceptive behavior. (Jenkins Dep. 125:18-126:11.)

APPLICABLE LEGAL STANDARD

Plaintiffs are entitled to summary judgment if the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-248 (1986). In

determining whether there is a genuine issue of material fact, the court must resolve all ambiguities, and draw all inferences in favor of the non-moving party. *United States v. Diebold, Inc.,* 369 U.S. 654, 655 (1962) (per curiam); *GlobalNet Financial.Com, Inc. v. Frank Crystal & Co., Inc.*, 449 F.3d 377, 382 (2d Cir. 2006). The party opposing summary judgment, however, "may not rest upon the mere allegations or denials of the adverse party's pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). *See also GlobalNet Financial.Com, Inc.*, 449 F.3d at 382. The non-moving party may not rely upon speculation, "but instead must offer some hard evidence showing that its version of the events is not wholly fanciful." *D'Amico v. City of New York*, 132 F.3d 145, 149 (2d Cir. 1998).

ARGUMENT

I. Plaintiffs Have Standing to Challenge the FDA's Rejection of Unrestricted OTC Status for Plan B.

It is well settled that persons who suffer injury-in-fact caused by government action have Article III standing to challenge that action, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992), and have standing to challenge administrative agency action so long as they are within the "zone of interests" of the relevant statute. "Qualified plaintiffs include not only those who are themselves the 'subject of the contested regulatory action,' *Clarke* [*v. Sec. Indus. Ass'n*], 479 U.S. [388,] at 399 [(1987)], but also those whose interests are 'not so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.' *Id*." *Amgen Inc. v. Smith*, 357 F.3d 103, 108 (D.C. Cir. 2004). Plaintiffs – all of whom seek unrestricted OTC status for Plan B for women of all ages in order to enhance their ability to make Plan B accessible to and more effective for women who need it, and some of whom seek OTC status to make Plan B more accessible for themselves – are

clearly within the "zone of interests" of the Food, Drug and Cosmetic Act. *See, e.g., Stauber v. Shalala*, 895 F. Supp. 1178, 1187 (W.D. Wis. 1995) ("The Food, Drug and Cosmetic Act creates legal rights or interests for consumers.").

In addition, Plaintiffs have standing not only in their own right, but also third-party standing to assert the constitutional rights of consumers of Plan B. *Eisenstadt v. Baird*, 405 U.S. 438, 446 (1972) (holding that a person distributing contraceptives to women had standing to assert women's constitutional right of access to contraception); *Carey v. Population Servs., Inc*., 431 U.S. 678, 684 (1979) (vendor of contraceptives had standing to assert rights of those to whom it sold contraceptives because it was among "'vendors and those in like positions [who] have been uniformly permitted to resist efforts at restricting their operations by acting as advocates for the rights of third parties who seek access to their market or function.'") (quoting C*raig v. Boren*, 429 U.S. 190, 195 (1976); *Craig*, 429 U.S. at 194-95 (beer vendor could assert rights of its customers to be free of gender-based discrimination).

A. Plaintiffs Have Standing in Their Own Right.

Each of the Plaintiffs has standing to bring claims under the APA because each has suffered injury-in-fact, because that injury is caused by the FDA's failure to approve Plan B for unrestricted OTC use, and because their injury will be redressed by an injunction requiring the FDA to make Plan B available OTC without any age restriction. Under the APA, any person is entitled to bring suit who is "suffering a legal wrong because of agency action." 5 U.S.C. § 702.

Specifically, each of the individual Plaintiffs who are coordinators of the Morning After Pill Conspiracy is injured because her ability to distribute Plan B to women under 18 is subject to criminal penalties. Because a prescription is required for dispensation of Plan B to women under

18, transfer of Plan B to a woman under 18 violates the misbranding prohibition of the Food, Drug, and Cosmetic Act, codified as 21 U.S.C. § 352,[10] as stated by the Commissioner of the FDA. (Tummino 10866.) ("Plan B® may not lawfully be made available without a prescription to ["girls 16 and younger"] under section 503(b) of the Food, Drug, and Cosmetic Act."). Given the FDA's expressed concern about enforcement of the age restriction, *see supra* at 38-39, Plaintiffs reasonably fear prosecution if they transfer Plan B to a woman under the age of 18.[11] These Plaintiffs are also injured because their own access to Plan B is contingent on their disclosure of name, address, and age to a pharmacist or pharmacy employee in order to obtain the product under the BTC regime. They are also injured because the BTC regime makes Plan B unavailable for purchase during hours when a pharmacist is not available to dispense it, despite the fact that as an "emergency" drug, Plan B is most effective when taken as soon as possible. (Jordan Decl. ¶ 4; Brown Decl. ¶¶ 3, 9; DeMarco Decl. ¶¶ 6-7.) The two organizational plaintiffs are injured because they are impeded in their missions of expanding access to emergency contraception. (*See, e.g.,* Jordan Decl. ¶ 17; *see also supra* at 15.) The individual young women Plaintiffs, and their Plaintiff parents who sue on their behalf, are injured because each young woman wants to be able to obtain Plan B, in the event that it would be needed, without a prescription and without restriction on its point of sale, in order to minimize her risk of unintended pregnancy.[12]

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[10] Misbranding is made a crime by 21 U.S.C. § 331 ("Prohibited acts"), for which fines and imprisonment are prescribed by 21 U.S.C. § 333(a).

[11] In addition, transfer of Plan B to a person who requires a prescription for it, including any woman under the age of 18 or any woman without sufficient proof that she is 18 or older, triggers criminal liability under state statutes which incorporate the prescription status of drugs. *See*, *e.g.*, 21 U.S.C. §§ 353(b)(1), 333(a), 333(b) (2005); § 465.015, Fla. Stat. (2004).

[12] It is undisputed that the risk of pregnancy increases the longer a woman waits to use Plan B. The BTC regime will cause some women to delay using Plan B. The increased risk of unwanted pregnancy is sufficient injury-in-fact to satisfy Article III standing requirements. *See Baur v. Veneman*, 352 F.3d 625, 633 (2d Cir. 2003) ("[T]he courts of appeals have generally recognized that threatened harm in the form of an increased risk of future injury may serve as injury-in-fact for Article III standing purposes.").

B. Plaintiffs Have Third-Party Standing to Assert the Rights of Women Who Need Plan B.

The Plaintiffs also have third-party standing to assert the rights of women for whom the Plan B prescription requirement is a barrier to their ability to use the drug in a timely and effective manner. This is because they have a sufficiently "close relationship" with such women, *see Eisenstadt*, 405 U.S. at 445 (holding that lay person who had given contraceptive to a woman had standing to assert equal protection and privacy rights of women seeking contraception: "And so here the relationship between Baird and those whose rights he seeks to assert is not simply that between a distributor and potential distributees, but that between an advocate of the rights of persons to obtain contraceptives and those desirous of doing so. The very point of Baird's giving away the vaginal foam was to challenge the Massachusetts statute that limited access to contraceptives."); *Craig*, 429 U.S. at 195 (licensed vendor of beer has standing to assert equal protection rights of those who wish to purchase beer in part because "vendors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function."), and because there are obvious hindrances to such women bringing their own litigation against the FDA. These hindrances include: 1) the same financial limitations that make it difficult for them to obtain a prescription for Plan B from a physician; 2) the short duration of time during which they need Plan B (Jordan Decl. ¶ 4), and therefore the limited period during which they have standing in their own right to seek injunctive relief;[13] and 3) the breach of confidentiality that

[13] A woman for whom the Plan B prescription requirement was a barrier who became pregnant as a result of the barrier might be able to bring a suit for damages against the FDA under, for example, the Little Tucker Act. 28 U.S.C. § 1346(a). But she would be unlikely to have standing to seek injunctive or declaratory relief because she would have difficulty asserting that her need for emergency contraception is sufficiently "capable of repetition," *Roe v. Wade*, 410 U.S. 113, 125 (1973). *See also Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983) ("Absent a sufficient likelihood that [the plaintiff] will again be wronged in a similar way, [the plaintiff] is no more entitled to an injunction than any other citizen . . . .); *Am. Postal Workers Union v. Frank*, 968 F.2d 1373, 1376 (1st Cir. 1992) (stating that even where past injury suffered by plaintiffs confers standing to bring an action for damages, "it is an insufficient predicate for equitable relief").

would be required for them to bring suit.

II. The District Court Has Jurisdiction over Plaintiffs' Claims and the Court of Appeals Lacks Such Jurisdiction.

On December 22, 2005, the Court reserved decision on the issue of whether this Court or the Court of Appeals is the appropriate forum for the cause of action based on the FDA's action on the Barr sNDA and sought clarification from Plaintiffs as to whether they would oppose transfer to the Court of Appeals. On January 27, 2006, Plaintiffs submitted to the Court a brief opposing transfer of this case to the Court of Appeals, and Plaintiffs now re-assert that this Court is the appropriate forum for all causes of action contained in Plaintiffs' Fifth Amended Complaint.

This Court has federal question jurisdiction under 28 U.S.C. § 1331 over Plaintiffs' Fifth Amended Complaint, which raises claims under the APA, including constitutional claims (5 U.S.C. § 706(2)(B)), a claim of arbitrary and capricious agency action (5 U.S.C. § 706(2)(A)), and a claim that the agency has exceeded its statutory authority (5 U.S.C. § 706(2)(C)). Judicial review is established by section 703 of the APA which provides that:

> The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction.

5 U.S.C. § 703. It is "well established" that Section 703 "does not confer upon a court of appeals any additional jurisdiction not expressly authorized by a statutory grant of power." *Noland v. U.S. Civil Serv. Comm'n*, 544 F.2d 333, 334 (8th Cir. 1976). *See also In re Sch. Bd. of Broward County, Fl.*, 475 F.2d 1117, 1119 (5th Cir. 1973) (holding that court of appeals is not appropriate initial forum "unless specially authorized by statutory grant of power.").

The Government has previously suggested that this case belongs in a federal appeals court, citing 21 U.S.C. § 355(h). That statute, contained in the Food, Drug and Cosmetic Act, states in relevant part:

> An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after entry of such order, a written petition praying that the order of the Secretary be set aside.

21 U.S.C. § 355(h). By its terms, section 355(h) confers jurisdiction on courts of appeals to review orders refusing to approve or withdrawing approval of "applications under this section." *Id.* "This section" means 21 U.S.C. § 355, which provides that "[a]ny person may file with the Secretary an application with respect to any [new] drug . . .". 21 U.S.C. § 355(b). Moreover, jurisdiction is conferred on courts of appeals only with respect to appeals filed "by the applicant" who filed the new drug application (NDA). Thus, only an applicant who has actually filed an NDA may appeal directly to a court of appeals from an adverse order regarding that NDA. Because none of the Plaintiffs is an applicant who has filed an NDA with the FDA that has been denied, jurisdiction does not lie under 335(h) in the United States courts of appeals.

This plain meaning of section 355(h) is reinforced by several court decisions that have examined whether cases related to actions taken by the FDA regarding drugs were properly before a district court or a court of appeals. The leading case is *Cutler v. Hayes*, 818 F.2d 879 (D.C. Cir. 1987). *Cutler* was "a challenge by consumers of over-the-counter (OTC) drugs to the program undertaken by the Food and Drug Administration (FDA) comprehensively to review these drugs for their safety and effectiveness." *Id*. at 882. The *Cutler* Court described review of FDA actions as follows:

> The FDC Act contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions. See, e.g., 21 U.S.C. § 355(h) (1982) (review by court of appeals of agency's disapproval of new-drug application); *id*. § 360g (review by court of appeals of regulations classifying devices); *id*. § 371(f) (review by court of appeals of orders issued pursuant to provisions enumerated in § 371(e)). Agency action taken under sections silent in this respect are directly reviewable in a district court under some appropriate head of its jurisdiction, for courts of appeals have only such jurisdiction as Congress has chosen to confer upon them. *Shaw v. United States*, 93 U.S. App. D.C. 300, 302, 209 F.2d 811, 813 (1954); *Diamond Shamrock Oil & Gas Corp. v. Commissioner*, 422 F.2d 532, 534 (8th Cir.1970).

Id. at 887 n.61 (emphasis added) (parallel citations omitted). Moreover, *Cutler* observes that:

> Section 355(h), however, authorizes review by a court of appeals only in cases challenging disapprovals of new-drug applications, and is therefore inapplicable [elsewhere]. Cf. *Weinberger v. Bentex Pharmaceuticals, Inc., supra* note 22, 412 U.S. at 651, 93 S.Ct. at 2493, 37 L.Ed.2d at 240-241 (interpreting § 355(h) narrowly and endorsing district-court jurisdiction to hear appeals from orders affecting new-drug status). We note, too, that the Supreme Court has implicitly approved the exercise of district-court jurisdiction over similar claims pertaining to FDA's enforcement duties under § 355. See *Heckler v. Chaney,* 470 U.S. 821, 824-825, 105 S.Ct. 1649, 1652, 84 L.Ed.2d 714, 719-720 (1985). We thus conclude that because in this case no statute commits direct review of FDA new drug regulations to this court . . . the District Court properly exercised jurisdiction.

Id. (parallel citations omitted). Here, as in *Cutler*, it is even arguable that the OTC switch application does not actually arise under section 355 *at all*, for it is 21 U.S.C. § 353(b)(3) that authorizes the Secretary "by regulation [to] remove drugs subject to section 355 of this title from the [prescription] requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health," and section 353 does *not* provide for direct court of appeals review of applications seeking such OTC switches.[14]

Following *Cutler*, courts have uniformly narrowly construed the scope of jurisdiction conferred on courts of appeals by section 355(h). For example, the First Circuit in *Bradley v.*

[14] It appears that OTC switch applications arise under both sections 353 and 355, and so it is unclear whether an OTC switch application would fall under section 355(h) for the purposes of establishing appellate court jurisdiction in a case where the applicant seeks to challenge the FDA's decision. *See* 21 U.S.C. § 353(b). *Cf.* 21 C.F.R. § 330 (indicating as sources of its regulatory authority sections 353 and 355 of Title 21 of the U.S. Code, among several other sections).

Weinberger, 483 F.2d 410 (1st Cir.1973), found that "[t]he right to petition the court of appeals for review under 21 U.S.C. § 355(h) is available *only to a drug-marketing applicant* after an order refusing or withdrawing approval of a drug application." *Id*. at 413 n.1 (emphasis added). As in this case, the controversy in *Bradley* involved a challenge by parties *other than the drug's manufacturer* to proposed changes in the drug's labeling. Similarly, in *Genentech, Inc. v. Bowen*, 676 F. Supp. 301 (D.D.C. 1987), the district court considered a challenge by certain drug manufacturers to the FDA's redesignation of the drug Humatrope (made by another manufacturer) as an "orphan drug." The court observed:

> [I]t is unlikely that a court of appeals would have jurisdiction under 21 U.S.C. § 355(h) to review the validity of the Humatrope designation. Subsection (d) of 21 U.S.C. § 355 enumerates seven grounds for denying a new drug application, and subsection (h) limits the courts of appeals' direct review jurisdiction to denials "under this subsection." A denial based on Humatrope's orphan drug exclusivity would be based on 21 U.S.C. § 360cc(a) (which is silent on the matter of judicial review), not on a ground enumerated in 21 U.S.C. § 355(d). Given the courts' narrow construction of jurisdiction under 21 U.S.C. § 355(h), it is likely that movants would be rebuffed if they attempted to challenge the Humatrope designation in a court of appeals.

Id. at 311 (internal citations omitted). Here, the August 24, 2006, approval of BTC status for Plan B for women over 18 and denial of non-prescription status for women 17 and younger, if it indeed falls under section 355 at all, rather than section 353, and regulations promulgated under section 353, was an *approval* of the sponsor's application for split label access. As the Agency's action was not a denial of the sponsor's application under 355(d),[15] as in *Genentech*, a court of appeals will likely "rebuff" an effort at direct review, even by the manufacturer itself. *See*

[15] Grounds for refusing an application under 21 U.S.C. § 355(d) include that studies have not demonstrated that the drug is safe for use, that the methods of studying a drug's safety are unpersuasive, that the manufacture and processing of a drug are inadequate to preserve its quality and purity, that a drug is not effective, and that the labeling is false or misleading. Moreover, if the enumerated clauses do not apply, the drug is to be approved. *Id.* The subsection also defines the term "substantial evidence" to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." *Id.*

generally Barnes v. Shalala, 865 F. Supp. 550, 555-56 (W.D. Wis. 1994) (third-party challenge to approval of bovine growth hormone does not implicate exclusive jurisdiction of court of appeals under 355(h), in part because challenge to approval is not equivalent to challenge to denial of approval or withdrawal of approval).

Therefore only the manufacturer of Plan B can invoke the jurisdiction of a court of appeals under section 355(h), and then only if the NDA it has submitted has been denied (which it has not been), *and* if it was denied for a reason enumerated in section 355(d), *and* if an OTC switch application arises under section 355 rather than under section 353 and regulations promulgated under it. But, as explained in more detail below, Plaintiffs do not and cannot stand in for Barr (and do not qualify as "applicants" under 355(h) by virtue of the Citizen Petition filed by one Plaintiff), and thus, even if Barr could surmount the several obstacles to court of appeals jurisdiction, Plaintiffs cannot. Jurisdiction should therefore remain with this Court, and the case should not be transferred.

A. Plaintiffs Cannot Assert the Rights of Barr and Thereby Invoke the Jurisdiction of the Court of Appeals.

It is well settled that, in order for a party to have standing to represent the interests of a third-party not before the Court, the party must establish its own standing, and then also establish the prudential components of third-party standing:

The determination whether a plaintiff has standing to assert the rights of third parties has constitutional and prudential components. *Singleton v. Wulff,* 428 U.S. 106, 112 (1976). First, as is the case with any plaintiff, she must meet the constitutional prerequisites of standing: (1) injury-in-fact, (2) causation, and (3) redressability. *Steel Co. v. Citizens for a Better Env't* 523 U.S. 83, 102-03 (1998) (identifying this triad as the "irreducible constitutional minimum of standing" (internal quotation marks omitted)). In addition, she must satisfy "prudential"

limitations on third-party standing: (1) a "close relation with the third party" and (2) "some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 411 (1991); *Sec'y of State v. Joseph H. Munson Co.,* 467 U.S. 947, 956 (1984); *Lewis v. Thompson*, 252 F.3d 567, 584 (2d Cir. 2001) (parallel citations omitted). *See also Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004) (requiring a party seeking third-party standing to make two showings in addition to demonstrating Article III standing: "First, we have asked whether the party asserting the right has a 'close' relationship with the person who possesses the right. *Powers*, 499 U.S. at 411. Second, we have considered whether there is a 'hindrance' to the possessor's ability to protect his own interests. *Ibid*.") (parallel citations omitted).

Here, none of the Plaintiffs can assert third-party standing to represent the interests of Barr as an applicant for the OTC switch for Plan B because (1) they lack a "close relationship with" Barr; and (2) they are unable to present evidence of any hindrance to Barr's ability to protect its own interest. First, Plaintiffs have no relationship with Barr, let alone a close relationship, different than the relationship that any member of the public has to Barr. Such an attenuated relationship has not been considered by courts to be legally sufficient to establish third-party standing.

For instance, in *Kowalski*, the plaintiffs were attorneys who sought, unsuccessfully, to assert the rights of future, hypothetical clients – clients who they intended to represent in the future. *Kowalski*, 543 U.S. 130. The Supreme Court found that the attorneys in *Kowalski* did not have a sufficiently "close relationship" with future clients to establish third-party standing: "The attorneys before us do not have a 'close relationship' with their alleged 'clients'; indeed, they have no relationship at all." 543 U.S. at 131. Here, Plaintiffs have even less of a "close relationship" to Barr than the attorneys in *Kowalski* had with their future clients. Like the

attorneys in *Kowalski*, Plaintiffs have no commercial, financial, or associational relationship to Barr, and certainly no fiduciary or confidential relationship tantamount to that of an attorney and her client.[16] Indeed, the Protective Order filed in this case designed to protect Barr's confidential commercial information demonstrates the distance between Plaintiffs and Barr. Under *Kowalski*, Plaintiffs have no hope of establishing the requisite "close relationship" to Barr. *Kowalski*, 543 U.S. at 130-31.

Second, Plaintiffs do not have third-party standing to represent Barr because they cannot demonstrate that there is any hindrance to Barr asserting its own interests and rights concerning the denial of Barr's initial request to switch Plan B to unrestricted OTC status. Indeed, Barr has submitted a declaration to the Court declining to specify its reasons for failure to sue the FDA over its actions regarding Plan B. (*See* Carole Ben-Maimon, M.D., Decl. dated January 23, 2005 (Doc. 92A) (attached to Pls.' Mem. in Opp. to Transfer to Ct. of Appeals (Doc. 92).) But Barr has sued the FDA before, *see, e.g.*, *In re Barr Labs., Inc.*, 930 F.2d 72 (D.C. Cir. 1991); *Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236 (D.D.C. 2002); *Barr Labs., Inc. v. Harris*, 482 F. Supp. 1183 (D.D.C. 1980), so Plaintiffs (and the Court) are left to infer that Barr has financial or commercial reasons for avoiding litigation about Plan B. In any event, there is absolutely no evidence, and none is available to Plaintiffs, that some factor other than a strategic decision not to sue the FDA "hinders" Barr from asserting its own rights and interests. Such a strategic decision not to litigate cannot possibly form the basis for "hindrance" sufficient for third-party standing, else "hindrance" would exist any time the third party chooses not to bring suit itself.

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[16] In fact, it would inconsistent for the FDA to argue that Plaintiffs do have a close relationship with Barr, given that in their letter dated June 9, 2006 denying approval of Plaintiffs' citizen petition, the FDA wrote: "As you lack any commercial, financial, associational, fiduciary, or confidential relationship with Barr, you are not privy to Barr's legal, business, or scientific concerns, and therefore cannot represent its interests, which may well be in conflict with your own." (Cit. Pet. Denial Ltr. at 17.)

Accordingly, Plaintiffs cannot assert third-party standing to represent Barr, the sNDA applicant for Plan B.

B. Plaintiff and Citizen Petitioner Association of Reproductive Health Professionals (ARHP) Is Not an "Applicant" under Section 355 and Therefore Cannot Invoke the Jurisdiction of the Court of Appeals.

Plaintiff ARHP is a signatory of the Citizen Petition seeking unrestricted OTC status for Plan B. The FDA acknowledged denial of the Citizen Petition on June 9, 2006. However, because Plaintiff ARHP's Citizen Petition does not constitute an application under section 355 of the Food, Drug and Cosmetic Act, the jurisdiction explicitly granted to courts of appeals under subsection 355(h) is inapplicable to ARHP. (*See Henley v. F.D.A.*, 873 F. Supp. 776, 779-80 (E.D.N.Y. 1995) (district court exercising jurisdiction over denial of citizen petition), *aff'd,* 77 F.3d 616 (2d Cir. 1996). Thus, jurisdiction over denial of a Citizen Petition does not lie in the court of appeals because a Citizen Petition is not an "application" under 21 U.S.C. § 355. Rather, the Citizen Petition exists by virtue of the APA, not the Food, Drug and Cosmetic Act: "APA § 553(e) requires every agency to 'give an interested person the right to petition for the issuance, amendment, or repeal of a rule.' The FDA regulation that grants this right is found at 21 C.F.R. § 10.30." *Id*.

Moreover, citizen petitions also can request a much broader range of agency actions than action on a drug or set of drugs. The relevant FDA regulation, 21 C.F.R. § 10.30, authorizes any person, whether that person is a U.S. citizen or not, to request the FDA Commissioner to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30 (a), (b) (1994). The Citizen Petition requesting OTC status for emergency contraceptive drugs initially asked the FDA to order such status *for all such*

drugs – not only Barr Labs' product, Plan B. This is hardly the type of application that would ever be filed by a drug manufacturer.

In addition, the entire FDA citizen petition process is differently structured than the NDA process described in section 355. For example, as to a citizen petition:

> Within 180 days of receipt of the petition, the Commissioner must respond by 1) approving the petition, 2) denying the petition, or 3) providing a tentative response indicating the reasons for postponing a final response (e.g., more time or more information is needed). While there is *no* requirement that the Commissioner hold hearings with regard to the petition, the Commissioner must consider the petition and must give written notice of the decision accompanied by an explanatory statement.

Id. (emphasis added). In contrast, an applicant under section 355 must, within 180 days after the filing of an application, receive either approval or an opportunity for a hearing. 21 U.S.C. § 355(c)(1). Similarly, while the grounds for approval or denial of a citizen petition are framed quite broadly, *id.* ("The Commissioner must grant the petition upon a determination that the following factors are all present: 1) relevant information was not adequately considered; 2) the position is not frivolous; 3) sound public policy grounds support reconsideration; 4) public interests do not outweigh reconsideration."), the grounds for denying an NDA submitted under section 355 are quite detailed and specific, including, for example, failure to include "patent information prescribed by" 355(b). *See generally* 21 U.S.C. § 355(d) (specifying seven distinct and specific grounds for failure to approve an NDA). Likewise, the application processes delineated in 21 C.F.R. § 10.30 with regard to a Citizen Petition and under 21 U.S.C. § 355(b) for a new drug application require completely different types of supporting information and materials. *Compare* 21 C.F.R. § 10.30 *with* 21 U.S.C. § 355(b).

For all the foregoing reasons, Plaintiff ARHP's standing as a signatory of the Citizen Petition does not arise under section 355 of the Food, Drug and Cosmetic Act, and hence the

special jurisdiction conferred on courts of appeals by subsection 355(h) is unavailable. *See also Henley*, 873 F. Supp. 776 (exercising jurisdiction over denial of citizen petition).[17]

III. Plaintiffs Are Entitled to Summary Judgment on Their Four Constitutional Claims.

In the Fifth Amended Compliant, Plaintiffs assert that the BTC regime violates four constitutional mandates.[18] First, it violates the right to decisional privacy by imposing unjustified barriers on women's access to Plan B. Second, it violates the right to equal protection of the law by classifying and discriminating on the basis of the fundamental right to use contraceptives by unjustifiably treating the contraceptive drug Plan B in a discriminatory and invidious manner. Third, it violates equal protection of the law because it discriminates on the basis of sex by unjustifiably treating a drug approved for use only by women differently from other drugs and in a manner that reinforces outmoded stereotypes of women. Fourth, it violates women's right to informational privacy by unjustifiably requiring disclosure of private information in order to obtain Plan B. In each instance, the government must come forward, at a minimum, with an "exceedingly persuasive" or "compelling" justification for the violation. No such justification can be found in the record before the Court. Accordingly, Plaintiffs should be granted summary judgment on each of these claims.

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[17] All the Plaintiffs have standing to sue based on their own injury caused by the FDA's failure to approve Plan B for unrestricted OTC use, and which will be redressed by an injunction requiring the FDA to make Plan B OTC without an age restriction. (*See supra* at 48-49) The Plaintiffs also have third-party standing to assert the rights of women for whom the Plan B prescription requirement is a barrier to their ability to use the drug in a timely and effective manner. (*See supra* at 50). Consumers of drugs, however, are in no sense "applicants" for drug approval under section 355 of Title 21; they have filed no application under section 355, and indeed could not. Accordingly, they cannot invoke the special jurisdiction of the courts of appeals conferred by section 355(h).

[18] Ordinarily, a court should avoid constitutional rulings if alternative grounds for decision are available. *Jean v. Nelson*, 472 U.S. 846, 854 (1985). Here, however, two factors militate in favor of reaching Plaintiffs' constitutional claims. First, because the standard of review applicable to Plaintiffs' constitutional claims is far less deferential than the standard applicable to "arbitrary and capricious" claims (absent a finding of bad faith), adjudication of these claims is much less dependent on matters of scientific evidence and judgment about which the Court may find that genuine factual disputes exist. Second, given the Court's repeated finding of agency bad faith, reaching Plaintiffs' constitutional claims will serve to demonstrate the gravity of the FDA's malfeasance, for it is rare that agency action so blatantly violates fundamental constitutional rights.

As to all of Plaintiffs' constitutional claims, the FDA's actions are not entitled to any deference. First, it is clear the Congressional intent in authorizing the federal courts to undertake review of the constitutionality of agency actions via section 706(2(B)) of the APA was to authorize plenary and de novo review of constitutionality. *Webster v. Doe*, 486 U.S. 592, 603 (1988) ("[W]here Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear. . . . We require this heightened showing in part to avoid the 'serious constitutional question' that would arise if a federal statute were construed to deny a judicial forum for a colorable constitutional claim.") (citations omitted). Second, the FDA has no special expertise that would entitle its findings on the constitutionality of the BTC scheme to any deference. *See Porter v. Califano*, 592 F.2d 770, 781 (5th Cir. 1979) (finding no statutory reason for courts to defer to agency findings in reviewing constitutional claims). Third, it is axiomatic that only matters actually and properly considered by an agency are due any deference, and then only if such matters are within the agency's expertise. *See Rydeen v. Quigg*, 748 F. Supp. 900, 906 (D.D.C., 1990) ("When reviewing constitutional challenges to agency decisionmaking, courts make an independent assessment of the facts and the law. . . . [W]e need not accord deference to the agency's decisions in regard to plaintiff's constitutional challenges because the courts, not agencies, are experts on constitutional issues.") (citations omitted). Indeed, there is no indication from the administrative record that the FDA itself even considered the constitutionality of its actions regarding Plan B. Thus, even if it had considered the constitutionality of its actions, such consideration would be due no deference because the FDA has no expertise in constitutional law.

A. The BTC Regime Violates the Right to Decisional Privacy.

The right to obtain and use contraceptives has been protected as part of the fundamental constitutional right to privacy beginning with *Griswold v. Connecticut*, 381 U.S. 479 (1965) (right of married persons to use contraceptives), and continuing with *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (right of unmarried persons to use contraceptives), and *Carey* (right of minors to use contraceptives). A restriction on the sale or use of contraceptives affecting adults must be justified by a compelling state interest. As the Court wrote in *Carey*:

> Both types of regulation [of abortion and contraception] "may be justified only by a 'compelling state interest' . . . and . . . must be narrowly drawn to express only the legitimate state interests at stake."

431 U.S. at 688 (quoting *Roe v. Wade*, 410 U.S. 113, 155 (1973)). Although the Court later abandoned the "compelling state interest" standard for regulation of abortion, it has not done so with respect to regulation of contraception, and indeed the reasons for changing the standard in the abortion context are inapplicable in the contraception context. *See Planned Parenthood v. Casey*, 505 U.S. 833, 871 (1992) (altering standard to accord greater importance to state interest in potential life of the fetus); *Carey,* 431 U.S. at 694 (plurality) ("The State's interests in protection of the mental and physical health of the pregnant minor, and in protection of potential life are clearly more implicated by the abortion decision than by the decision to use a nonhazardous contraceptive."); *cf. Roe*, 410 U.S. at 159 ("The pregnant woman cannot be isolated in her privacy. She carries an embryo, and, later, a fetus, if one accepts the medical definitions of the developing young in the human uterus. The situation is therefore inherently different from marital intimacy, or bedroom possession of obscene material, or marriage, or procreation, or education, with which *Eisenstadt* and *Griswold* . . . were respectively concerned." (citation omitted)). Thus, the Government in its initial motion to dismiss properly observed that

decisions of the United States Supreme Court "applied strict scrutiny to laws broadly restricting access to contraception." (Def.'s Mem. at 46.) The BTC regime is not narrowly drawn to serve any compelling state interest and is therefore unconstitutional.

In addition, a restriction on the right of minors to use contraceptives must be justified by a "'significant state interest . . . that is not present in the case of an adult.'" *Carey*, 431 U.S. at 693 (quoting *Planned Parenthood v. Danforth*, 428 U.S. 52, 75 (1976)). As set forth in more detail below, the BTC regime is not justified by any significant state interest, and certainly not one "that is not present in the case of an adult," and is therefore also unconstitutional because it violates the rights of minors to use contraceptives.

Under *Carey*, even a government restriction on adults' access to contraception short of a "total ban" on contraception must be analyzed under strict scrutiny. Indeed, the *Carey* court struck down a state law requirement much like the "point of sale" restriction of the BTC regime, reasoning as follows:

> Limiting the distribution of nonprescription contraceptives to licensed pharmacists clearly imposes a significant burden on the right of the individuals to use contraceptives if they choose to do so. The burden is, of course, not as great as that under a total ban on distribution. Nevertheless, the restriction of distribution channels to a small fraction of the total number of possible retail outlets renders contraceptive devices considerably less accessible to the public, reduces the opportunity for privacy of selection and purchase, and lessens the possibility of price competition.

Id. at 689 (citations and footnotes omitted). It cannot genuinely be disputed that the BTC regime's restriction on the sale of Plan B to licensed pharmacists and health clinics likewise imposes "a significant burden" on the right of adult women to use contraceptives. Not only do Plaintiffs assert this in their own Declarations (DeMarco Decl. ¶ 6; Brown Decl. ¶ 9; Mahoney Decl. ¶ 4), the administrative record is replete with recognition of this fact. *See, e.g.,* Tummino 30755 ("Any system that creates barriers to access, including restricted distribution or age

restrictions would defeat the purpose of this drug and lessen its public health potential."); Tummino 30748 ("After Washington state reduced barriers to Plan B access, the data demonstrates decreased pregnancies and abortions for adolescent age groups, and STD rates national averages."); Tummino 30648-51; 31026-30; 31031-32; 31095-99; Jenkins Dep. 114:7-116:13. Indeed, in general the FDA recognizes that elimination of a prescription requirement enables consumers to have easier access to a drug. Tummino 10080-81. Because the BTC regime restricts adult women's right to use contraceptives, it must be analyzed under strict scrutiny. It fails this standard.

The only possible compelling interest the government could claim for the BTC regime is protection of public health, and as to this interest, the government's claim must be restricted to the health of persons under the age of 18. There are several reasons that any asserted interest in the health of minor women is not compelling.

First, where the division of scientific authority, both within and outside the FDA, is so lopsidedly in favor of OTC access for women of all ages, the Court should find that scientific authority simply does not support any age-based restriction on OTC access to Plan B. Surely the scientific support for an age restriction cannot be "compelling" when every major public health organization, all the internal usual decision makers at FDA, and one of the world's leading experts on Plan B all agree that the scientific justifications for the age restriction are spurious. Moreover, to the extent that the reasons for the age restriction relate to speculation about how OTC access to Plan B would affect the sexual and contraceptive behavior of young women, the very fact that FDA does not consider the effects on personal behavior of drug approvals and OTC switches renders this speculation far from compelling. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490 (1995) ("The Government's brief submits anecdotal evidence and educated

guesses to suggest that . . . [the ban on listing alcohol content on beer labels] has constrained strength wars that otherwise would burst out of control. These various tidbits, however, cannot overcome the irrationality of the regulatory scheme and the weight of the record."); *Hodgson v. Minnesota*, 497 U.S. 417, 451 (1990) (finding that a two-parent notification requirement of a minor's abortion was "not merely ineffectual…but actually counterproductive" to achieving the State's goal of assisting and protecting minors in making reproductive choices). Importantly, even this speculation is unsupported by the agency record, and, given Plaintiffs' expert declaration, should not be credited by the Court, because the speculation is false. Lastly, even assuming *arguendo* the legitimacy of the FDA's speculation about impact on personal sexual behavior, any such speculative impact is equally present in the case of adults, and hence unjustified even under the more lenient standard applicable to minors.

Second, even if the government could come forward with evidence supporting a compelling interest advanced by the BTC regime, the BTC regime is not (at all) narrowly tailored to serve such an interest.[19] It uses the age of 18 as a cutoff even though the FDA's entire recalcitrant upper management endorsed the age of 17 as the appropriate age restriction. It restricts the sale of Plan B to licensed pharmacists based on "state and private-sector infrastructures" (Tummino 10866) for tobacco and pseudoephedrine products, even though tobacco is extremely widely available, not, of course, sold only by pharmacists, and infinitely

[19] In its letter acknowledging denial of the Citizen Petition, the FDA stated that one of the issues that would need to be addressed by data regarding use of Plan B is the following: "Could sexually active girls under age 18 effectively comprehend the labeling of the product and appropriately use Plan B both in terms of timing and selection, *even in the absence of parental or other adult involvement in the procurement and use of the drug*?" (Cit. Pet. Denial Ltr. at 16 (footnote stating that age 17 was used as the cutoff instead of 18 omitted).) The implication that the FDA has any role in assessing the value of parental involvement in contraceptive decisionmaking by adolescents simply confirms that the FDA was acting in blatant disregard of constitutional rights of adolescents to use contraceptives, for mandating parental involvement in contraceptive decisionmaking is unconstitutional. *Planned Parenthood v. Planned Parenthood Ass'n of Utah v. Matheson,* 582 F. Supp. 1001 (D. Utah 1983*)*; *see also Carey*, 431 U.S. at 694 (plurality opinion).

more dangerous than Plan B,[20] and even though restrictions on pseudoephedrine were mandated by Congress in light of widespread evidence of abuse whilst there is absolutely no evidence of abuse of Plan B anywhere on Earth. Finally, allowing men 18 and over to buy Plan B without a prescription, while simultaneously restricting the availability of Plan B so severely for women of all ages, as the BTC regime does, is so hopelessly unrelated to any scientific evidence or other possible justification that it renders the entire regime a travesty. Thus, far from being *narrowly* tailored to serve legitimate interests, the BTC regime appears to be tailored to serve only the irrational caprice of the FDA Commissioner and the White House which has directed the FDA's process regarding Plan B from the outset. *See Rubin*, 514 U.S. at 490-91 (finding the government's regulation of speech not sufficiently tailored to its stated goal).

Because the BTC regime burdens women's right to use contraceptives without being narrowly tailored to serve a compelling state interest, it is unconstitutional under the Due Process Clause of the Fifth Amendment.

B. The BTC Regime Violates Equal Protection of the Law.

1. The BTC Regime Discriminates Based on Sex Without Serving an "Exceedingly Persuasive Justification."

The BTC regime affects access to a drug used *exclusively* by women, and which could be needed by almost any woman at some point in her life. (Jordan Decl. ¶ 6.) The FDA's action is gender-based because the class of people who use Plan B consists of only women. Only women are burdened by the FDA's action; no men are burdened by it at all, because no men are potential

[20] Since there are no deaths from Plan B, and hundreds of thousands from tobacco, we have the ratio: $\frac{100{,}000s}{0} = \infty$.

users of Plan B.[21] *See Saks v. Franklin Covey Co.*, 316 F.3d 337, 348 (2d Cir. 2003) (distinguishing "cases involv[ing] a distinction based on the capacity to become pregnant and on the exclusion of oral contraceptives, *both of which disadvantage women only*") (emphasis added). Thus, the Court should infer that the FDA's action is gender-based. Indeed, federal district courts have reached just this conclusion in the context of an employment discrimination case under Title VII:

> [T]he law is no longer blind to the fact that only women can get pregnant, bear children, or use prescription contraception. The special or increased healthcare needs associated with a woman's unique sex-based characteristics must be met to the same extent, and on the same terms, as other healthcare needs. Even if one were to assume that Bartell's prescription plan was not the result of intentional discrimination, the exclusion of women-only benefits from a generally comprehensive prescription plan is sex discrimination under Title VII.

Erickson v. Bartell Drug Co., 141 F. Supp. 2d 1266, 1271 (W.D. Wash. 2001). The same reasonable inference should be made here: because the FDA's action relates to a drug tied directly, and solely, to the capacity of women to become pregnant, its action is gender-based.

Even if the BTC regime did not discriminate on its face based on sex, there is ample evidence supporting a finding that, in adopting the BTC regime, the FDA acted with an intent to discriminate on the basis of gender. First, the FDA's action is rooted in gender-biased views about the proper sexual conduct and reproductive decision-making of young adolescent women. For example, Drs. Galson and Woodcock agreed that OTC status for Plan B might cause the formation of "sex-based cults." (Tummino 30745-46; Jenkins Dep. 67:20-68:3; 143:3-144:1.)

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[21] That the FDA's treatment of Plan B is disadvantageous to women is obvious. Indeed, the BTC regime for Plan B is unprecedented in its imposition by the FDA of point-of-sale restrictions on a nonprescription drug, and this unprecedented regime comes across as especially invidious when compared to the numerous OTC products available without age or point-of-sale restrictions that carry established adverse side effects as well as risks of abuse. (*See, e.g.*, Grimes Decl. ¶ 10(E); Woodcock Dep. at 155:11-19 ("Similarly, dextromethorphan, which is an ingredient in over the counter cough and cold remedies is particularly used as a recreational drug in the 13 to 16-year-old age group. And I, in my wildest dreams, could not imagine misusing cough and cold medicines, but these young teenagers call them skittles, they use the internet to disseminate this sort of cult status of using, misusing this drug."); *see also* Tummino 31026.)

The entire opposition to unrestricted OTC status (reflected primarily in documents written by Dr. Galson) is based on the view that young women will act irresponsibly and that special evidence (of an unknown sort) is required to refute this view. (Tummino 30649-51, 30897-900, 30648-51, 31086, 31027; Jenkins Dep. 27:9-16; Rosebraugh Dep. 47:15-18; Woodcock Dep. 161:19-163:13, April 27, 2006; Bull Dep. 50:18-52:9, June 21, 2006.) Such views impermissibly "perpetuate the legal, social, and economic inferiority of women," *United States v. Virginia*, 518 U.S. 515, 534 (1996), and are direct evidence of purpose to discriminate.

Second, the BTC regime's authorization for men 18 and over to obtain Plan B without a prescription in the absence of *any* evidence of safe or even *possible* use by men is compelling evidence of sex discrimination because at the same time the FDA denied nonprescription access to women under 18 for whom there was voluminous evidence of safe and proper use and indeed of significant public health benefits. (Tummino 30648-51, 30745-83, 30784-828, 30881-91, 30897-900, 31026-28.) This feature of the BTC regime specifically promotes the stereotype that all younger women are incapable of properly using Plan B without the benefit of a "learned intermediary," while *every* man 18 and over can serve as a "learned intermediary" for *any* woman (or himself), regardless of age, to whom he transfers a purchased dose of Plan B. Adult men as a class are, under the FDA's BTC regime, fully capable of (1) using Plan B themselves for some presumably experimental purpose; (2) knowing *not* to use Plan B and instead transferring Plan B (possibly illegally) to any woman of any age for her use and guiding her as her personal "learned intermediary" or *ad hoc* pharmacist, and as such: (3) inhibiting women through their erudition from ever using Plan B "inappropriately"; and (4) single-handedly preventing all the alleged harm to adolescent women that FDA upper management asserts might befall them if they used Plan B without a physician's guidance. Meanwhile, all women under 18

are deemed incapable of using Plan B safely without the guidance of a learned intermediary despite clear-cut and overwhelming evidence that they can do so and that their sexual and contraceptive behavior is not compromised. As Dr. Grimes testifies in his Declaration, allegations to the contrary "are scientifically groundless and demeaning to women." (Grimes Decl. ¶ 10(D).)

Third, the FDA's discriminatory purpose may be inferred from the foreseeable impact of its action. *E.g., Washington v. Davis*, 426 U.S. 229, 241-42 (1976); *Goldberg v. Whitman*, 743 F. Supp. 943 (D. Conn. 1990). Here, the impact of the FDA's action will be a diminution in the ability of women to prevent unwanted pregnancies. (Tummino 30650, 31098.) Causing women to become pregnant by denying them wider access to EC clearly perpetuates outmoded stereotypes of women as childbearers, something government is barred from doing. *J.E.B. v. Alabama ex rel. T.B.*, 511 U.S. 127, 131 (1994). Because the BTC regime has no medical or scientific basis, *see infra* Section IV D and *see generally* Grimes Decl., the Court should infer that the intended purpose of the FDA's action is to disadvantage women.

Impermissible purpose may also be inferred from departures from the normal procedural sequence the agency followed. *Village of Arlington Heights v. Metro. Housing Dev. Corp.*, 429 U.S. 252, 267 (1977) ("Departures from the normal procedural sequence also might afford evidence that improper purposes are playing a role. Substantive departures too may be relevant, particularly if the factors usually considered important by the decisionmaker strongly favor a decision contrary to the one reached."). These are extensive and occurred at nearly every step of the FDA's process. (*See infra* Section IV C; *see also* Jenkins Dep. 16:9-17:11, 33:8-17; Houn Dep. 20:5-22:9, 30:7-31-15.) These departures from normal agency process are also strong indications of invidious purpose.

In sum, the BTC regime is sex-based. As such, it must have an "exceedingly persuasive" justification, and the burden of meeting this justification "rests entirely on the state." *Virginia*, 518 U.S. at 532-33. As set forth below at 90-108, the overwhelming scientific evidence supports unrestricted OTC status for Plan B. Accordingly, there can be no "exceedingly persuasive" scientific justification for the BTC regime. Nor is the possible justification of deterring or penalizing the sexual behavior of minors an "exceedingly persuasive justification," for it is doubtful that it is legitimate. *See Carey*, 431 U.S. at 695 (plurality opinion of Brennan, Stewart, Marshall & Blackmun, JJ.) (expressing reluctance to attribute to state goal of inflicting pregnancy and childbirth as "punishment for fornication"); *id.* at 715-16 (Stevens, J., concurring) (rejecting such "government-mandated harm" as "a deprivation of liberty without due process of law."). If the government has some other justification for the FDA's sex-based action, the burden falls squarely on it to come forward with it.

2. The BTC Regime Discriminates Against the Exercise of the Fundamental Right to Use Contraception.

The undisputed record before the Court demonstrates that Plan B has been treated differently both from all other drugs recently considered for OTC status, and indeed from all other drug applications to the FDA. Singling out a contraceptive drug for application of an unprecedented standard discriminates on the basis of the fundamental right to contraception and subjects the FDA's actions to strict scrutiny. *Mass. Bd. of Retirement v. Murgia*, 427 U.S. 307, 312 (1976) ("equal protection analysis requires strict scrutiny of a legislative classification . . . when the classification impermissibly interferes with the exercise of a fundamental right"); *Ramos v. Town of Vernon*, 353 F.3d 171, 175 (2d Cir. 2003) ("A heightened level of review—strict scrutiny—applies when [government action] . . . burdens a group's exercise of a

fundamental right."). As set forth above at 64-66, the BTC regime does not survive strict scrutiny.

Evidence of the FDA's singling out of Plan B for harsher review is legion. We describe some of the more egregious examples. First, the FDA refused, as is its normal practice, to extrapolate from evidence of safe use and label comprehension by adults to younger women. (Jenkins Dep. 86:10-17, 94:17-95:21, 111:2-22, 118:13-119:9.) This normal practice is reflected in the fact that during the past 10 years, the FDA has never required actual use or label comprehension studies of adolescents in any OTC switch application, and has approved numerous such switches. It is also reflected in the administrative record, which discloses that the FDA informed Plan B's manufacturer that such extrapolation was permissible. (Tummino 30100-02.) Second, the FDA required evidence that OTC status for Plan B would not change adolescents' sexual and contraceptive behavior; the FDA has not elsewhere considered effects on personal behavior of drug approvals.[22] Third, where the FDA in the past has not been confident of the applicability of manufacturers' studies in OTC switches to younger consumers, it has always provided a label warning, rather than an age restriction, in approving such switches. (Jenkins Dep. 91:11-19, 113:7-16, 118:13-119:9.) Fourth, the FDA has never in the past 10 years acted on an OTC switch against the recommendation of its Advisory Committees. (*See* 10 Year Rx Switch Chart, attached at Ex. E.) Fifth, no other OTC switch application has been made at the level of the Director of CDER or higher. (GAO Rep. at 30.) Sixth, the White House has not been involved in deliberations on any other OTC switch application. Seventh, FDA has

[22] For example, in approving erectile dysfunction drugs, the FDA did not consider whether such drugs would have an effect on sexual behavior. (Jenkins Dep. 125:18-126:11.) In approving drugs that treat lung cancer caused by smoking, the FDA does not consider whether approval of such drugs will encourage smoking. In approving pain-relief drugs for OTC use such as Tylenol and Advil, the FDA does not consider whether such approval will cause people to engage in riskier pain-causing behavior. In approving various OTC drugs for acid indigestion, the FDA does not consider whether such approval will cause risky over-eating behavior.

never imposed a point-of-sale restriction on any other OTC drug,[23] even where there have been subpopulations of the public for which specific OTC drugs pose special dangers, and even where there is a demonstrated record of abuse of OTC drugs.[24] Eighth, no other OTC switch application was rejected prior to the completion of scientific reviews.

All of the above differential and harsher handling of Plan B establish that the FDA applied a discriminatory standard to the Plan B OTC switch application. Such discriminatory treatment of a drug which is the unique drug approved as a post-coital contraceptive triggers strict scrutiny. Because, as demonstrated above at 65-66 the BTC regime is not narrowly tailored to serve any compelling state interest, it violates the "fundamental rights" strand of equal protection of the law.

C. The BTC Regime Violates Adult Women's Right to Informational Privacy.

In order to obtain Plan B as an OTC drug, women 18 and over must present government identification showing their age. (Tummino 10864-67.) This is not the case for any other OTC drug product (except pseudoephedrine, which is subject to special federal legislation enforced by the Drug Enforcement Agency because it has a demonstrated record of abuse in the manufacture of illegal drugs, *see* http://www.fda.gov/cder/news/methamphetamine.htm). The FDA's requirement of disclosure of identifying information to pharmacies violates the right to informational privacy, both because such disclosure itself is unjustified and because it provides pharmacies with strong indicators that the woman seeking Plan B has experienced unprotected sexual intercourse and needs Plan B to minimize the risk of pregnancy. (*See generally* Brown Decl. ¶¶ 6-8; *see also* Grimes Decl. ¶ 12 ("the novel requirement to show a government

[23] Indeed, the FDA does not even have authority to impose a point-of-sale restriction on Plan B or any other drug. *See* Point V, *infra*.

[24] A good example is dextromethorphan, which is available as an OTC drug without age restriction but has an established record of abuse. (Tummino 31026.)

identification before provision of Plan B erases the potential for privacy of OTC provision").) The latter information is at the core of information as to which all citizens have a high expectation of privacy. *See Doe v. City of New York,* 15 F.3d 264, 267 (2d Cir. 1994) ("Extension of the right to confidentiality to personal medical information recognizes there are few matters that are quite so personal as the status of one's health, and few matters the dissemination of which one would prefer to maintain greater control over."); *Bloch v. Ribar*, 156 F.3d 673, 685 (6th Cir. 1998) (noting that publicly revealing information about sex exposes an aspect of life we regard as highly personal and holding that rape victims have a right of privacy in preventing gratuitous disclosure of the details of the rape); *Eastwood v. Dept. of Corr.*, 846 F.2d 627, 631 (10th Cir. 1988) ("This constitutionally protected right [to privacy] is implicated when an individual is forced to disclose information regarding personal sexual matters."); *Thorne v. City of El Segundo*, 726 F.2d 459, 468 (9th Cir. 1983) (the interest in keeping sexual activity private is within the zone of privacy protected by the Constitution); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980) ("Information about one's body and state of health is a matter which the individual is ordinarily entitled to retain within the private enclave where he may lead a private life." (internal quotation marks and citations omitted)); *In re Labady*, 326 F. Supp. 924, 927 (S.D.N.Y. 1971) ("[I]t is now established that official inquiry into a person's private sexual habits does violence to his constitutionally protected zone of privacy.").

The right to informational privacy has been recognized at least since *Whalen v. Roe*, 429 U.S. 589, 599-600 (1977). Under the Second Circuit's opinion in *Doe*, the government must meet "[s]ome form of intermediate scrutiny," in order to justify its mandated disclosure of highly personal information. 15 F.3d at 269, citing *Barry v. City of New York*, 712 F.2d 1554, 1559 (2d Cir. 1983). Specifically, the government must demonstrate a "substantial" interest in mandating

the disclosure. *Doe*, 15 F.3d at 269. As set forth above, the asserted justification for the requirement -- *viz*., concerns about OTC availability to women under 18 -- is not "substantial," because it goes against the overwhelming weight of scientific evidence and indeed is so vague that even scientists at the FDA did not know what evidence would convince FDA upper management that the concern was invalid. Accordingly, the Court should find that the BTC regime violates women's right to informational privacy.

IV. The FDA's Denial of Unrestricted OTC Status for Plan B is Arbitrary and Capricious.

Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc., v. Drug Enforcement Admin*., 259 F.3d 731, 736 (D.C. Cir. 2001). When inquiring as to whether an agency decision was arbitrary or capricious, the reviewing court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation and citation omitted). *See generally Henley*, 77 F.3d at 620 ("An agency rule may be deemed arbitrary, capricious or an abuse of discretion if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'") (quoting *Motor Vehicle Mfrs. Assoc. of the United States, Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)). The inquiry must "be searching and careful," although "the ultimate standard of review is a narrow one." *Marsh*, 490 U.S. at 378.

While a court's task is to assess whether the agency's determination is arbitrary, "[a]gency deference has not come so far that [a court] will uphold regulations whenever it is possible to conceive a basis for administrative action." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986) (plurality opinion) (citing *Motor Veh. Mfrs. Ass'n*, 463 U.S. at 43) (internal quotations omitted). Indeed, the "presumption of regularity afforded an agency in fulfilling its statutory mandate is *not* equivalent to the minimum rationality a statute must bear in order to withstand analysis under the Due Process Clause." *Id.* at 626-27 (citing *Motor Veh. Mfrs. Ass'n*, 463 U.S. at 43) (internal quotations omitted). *See also Paradyne Corp. v. United States*, 647 F. Supp. 1228, 1236 (D.D.C. 1986) (noting that the level of rationality required for an agency's action "must be greater than that necessary to extend analysis under the Due Process Clause of the Constitution"). The "mere fact that there is some rational basis within the knowledge and experience of the [regulators] . . . under which they might have concluded that the regulation was necessary to discharge their statutorily authorized mission . . . will not suffice to validate agency decision making." *Bowen,* 476 U.S. at 627 (internal quotations and citations omitted). Thus, absent a logical basis to support an agency decision, it must be held invalid. Additionally, an agency rule is arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider." *Motor Veh. Mfrs. Ass'n*, 463 U.S. 29 at 43. *See also N.R.D.C. v. Muszynski*, 268 F.3d 91, 97 (2d Cir. 2001).

In assessing whether agency action is arbitrary and capricious, an important test is whether the agency has adhered to its normal practice. "The dominant law clearly is that an agency must follow its own precedents or explain why it departs from them." Richard J. Pierce, Administrative Law Treatise §11.5 (4th ed. 2002). Thus, the United States Supreme Court has held that an agency has a "duty to explain its departure from prior norms." *Atchison, Topeka, &*

Santa Fe Ry. Co. v. Wichita Bd. of Trade, 412 U.S. 800, 808 (1973) (plurality opinion). In *I.N.S. v. Yang*, 519 U.S. 26 (1996), the Supreme Court elaborated on the consequences of departing from agency norms, stating that "if [an agency] announces and follows—by rule or by settled course of adjudication—a general policy by which its exercise of discretion will be governed, an irrational departure from that policy (as opposed to an avowed alteration of it) could constitute action that must be overturned as 'arbitrary , capricious, [or] an abuse of discretion" within the meaning of the Administrative Procedures Act." *Id.* at 32.

Accordingly, it is axiomatic that an agency may not treat similar products differently absent a rational basis. "Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005). As the court in *Bracco Diagnostics v. Shalala*, 963 F. Supp. 20, 28 (D.C.D.C. 1997) put it, "the FDA is not free to . . . treat [similar products] dissimilarly and to permit two sets of similar products to run down two separate tracks, one more treacherous than the other, for no apparent reason." Indeed, "*the disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious." Id.* (emphasis added). *See also El Rio Santa Cruz Neighborhood Health Ctr. v. Dep't of Health & Human Servs.*, 300 F. Supp. 2d 32, 42 (D.C. Cir. 2004) (holding that HHS's inexplicable inconsistency is sufficient to allow the court to reverse its determination). *See also Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996); *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996).

Furthermore, where the FDA considers a factor or factors that it has not previously considered when determining an application, and that are not articulated in its own review

regulations, its action may be found to be arbitrary and capricious. In *Rhodia, Inc. v. F.D.A.*, 608 F.2d 1376 (D.C. Cir. 1979), the court decided an appeal from an FDA denial of Plaintiff's supplemental new animal drug application (NADA). The court found that the FDA improperly considered whether changes in the supplemental NADA would increase available quantities of a new animal drug on the market as a factor in determining drug safety. The court found that there was "no indication that the FDA has previously considered changes in a NADA that will increase available quantities of a new . . . drug to bear on the safety of the drug. Indeed, the contrary appears to be the case." *Id.* at 1379. The court noted that the FDA's own regulations "affirmatively exclude from the approval requirement . . . changes that appear to possess a potential for increasing quantities on the market." *Id.* The court vacated the FDA order denying the supplemental NADA, stating:

> [t]he FDA has the authority, and it has the responsibility, to define those changes that bear on safety so as to invoke the full safety and effectiveness review required by its supplemental NADA policy. Thus far, the FDA has not structured its regulations to define quantity as a factor triggering invocation of the safety review. Once it channels its discretion in a certain manner . . . the agency should follow that course consistently or articulate reasons for departure. In view of its previous course, bypassing quantity as a determinative criterion, the FDA may not now latch onto this factor as the basis for rejecting an otherwise-unobjectionable supplemental NADA.

Id. The Second Circuit in *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325 (2d Cir. 1977), similarly held that where the Commissioner of the FDA made a determination of a drug classification on the basis of factors that are not relevant to the statutory criteria, such a determination is arbitrary and capricious. The court was clear to state that the determination that an article is properly regulated as a drug "is not left to the Commissioner's unbridled discretion." *Id.* at 334.

Under the governing law described, the FDA's denial of OTC status for Plan B is arbitrary and capricious.

A. This Court's Repeated Findings that the FDA Engaged in "Improper Behavior or Bad Faith" In Its Review of the Plan B Application Mandate a Finding that the FDA's Actions are Per Se Arbitrary and Capricious.

The Court should set aside the FDA's decision to deny over-the-counter access to women under 18 as arbitrary and capricious because the decision was made in bad faith. In reviewing an administrative agency action, courts must judge the action on the actual basis of the agency's decision. *See S.E.C. v. Chenery Corp.*, 332 U.S. 194, 196 (1947) (holding that "a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency."). If the agency's underlying reason for acting was the product of bad faith, the decision is rendered arbitrary and capricious because bad faith in the decision-making process denies the petitioner the opportunity for their application to be given full and fair consideration. *See Latecoere Int'l, Inc. v. U.S. Dept. of Navy*, 19 F.3d 1342, 1356 (11th Cir. 1994), *citing Keco Indus., Inc. v. United States*, 492 F.2d 1200, 1203 (Ct. Cl. 1974) ("[P]roof of subjective bad faith…depriving a bidder of fair and honest consideration of its proposal, generally constitutes arbitrary and capricious action.").

In this case, the FDA's egregious treatment of the Plan B OTC-switch applications has moved this Court repeatedly to remark that its actions "reek" of bad faith. (*See* Oct. 11, 2006 Hr'g Tr. 20; July 26, 2006 Hr'g Tr. 9:1; Dec. 22, 2005 Hr'g Tr. 95). After reviewing the conclusions reached by the Government Accountability Office and evidence from the administrative record demonstrating departures from the agency's usual process for handling OTC switch applications, the Court found that Plaintiffs had made a strong preliminary showing

of bad faith or improper agency behavior. *See Tummino*, 427 F. Supp. 2d at 231-32. This conclusion was based in part on the Court's concern that the FDA's unreasonable delay in issuing its original non-approvable letter to Barr was a "calculated 'filibuster' to avoid making a decision subject to judicial review." *Id.* at 231. The Court also indicated that it viewed the June 9, 2006, letter announcing the FDA's denial of the Citizen Petition as showing bad faith (July 26, 2006 Hr'g Tr. 30:23-33:8; 36:18-24), no doubt in part because the letter is written as a litigation document and designed as an attempt to defeat the Court's jurisdiction.

In addition to unreasonable delay, the Magistrate Judge found at least five other indications of bad faith on the part of the FDA:

> 1) Involvement in the Plan B OTC-approval process by high-level FDA officials who, historically and statutorily, do not generally participate in OTC-switch proceedings;
>
> 2) Inappropriate (non-scientific) considerations by FDA officials imported into the Plan B OTC-switch process, including those brought to the FDA's attention by third parties;
>
> 3) Indications of efforts to chart an unusual course in dealing with the OTC-switch applications, including veiled attempts to delay reaching a final decision;
>
> 4) Indications that a decision had already been made or that efforts were made to steer the application towards a specific result under the direction of higher level officials before completion of the scientific process;
>
> 5) Indications of potential retaliation by upper management against FDA employees who disagree with management's views that Plan B OTC-access be restricted.

November 6, 2006 Magistrate Judge Decision and Order at 18. We show below that the record contains more than mere indications of each of these indicia of bad faith by the agency but abundant evidence that leads inescapably to the conclusion that the FDA's decision-making process was contaminated by each of those improper characteristics.

The FDA's final decision to deny OTC access to women under 18 is marked by bad faith for several additional reasons. First, von Eschenbach testified at his August 1, 2006, confirmation hearing that his decision to make Plan B available without a prescription to women 18 and over was based on Dr. Galson's finding that data regarding use of Plan B by women under 18 was inadequate. Yet Dr. Galson, in his August 26, 2005, memo, stated that there was adequate data to support OTC access to Plan B for women 17 and over, and that his support for the age 18 cutoff was in turn based on von Eschenbach's (non-scientific) reasons for choosing 18. Thus, von Eschenbach's statement that his decision was based on a lack of adequate data for use of Plan B by women under age 18 is belied by Dr. Galson's findings to the contrary, made public a year prior. The shell game played by von Eschenbach and Galson in their effort to justify the arbitrary age 18 cutoff is redolent of bad faith agency action. Second, while von Eschenbach misleadingly claims to adopt the "infrastructure" of tobacco sales (Tummino 10866-67) to justify limiting OTC Plan B sales to people over 18 (von Eschenbach's arbitrary choice), the Plan B BTC regime restricts the sale of Plan B far more stringently than tobacco products by making it available only at pharmacies. This is ironic, given that tobacco products kill hundreds of thousands of Americans each year, *F.D.A. v. Brown & Williamson Tobacco*, 529 U.S. 120, 127-28 (2000), and Plan B has no serious side effects whatsoever. (Houn Dep., 127:11-12, 134: 12-19.) Third, the FDA has approved the sale of Plan B without a prescription to men 18 and older even though there is absolutely no approved male use for Plan B, and certainly no evidence

in the agency record supporting its safe and effective use as a nonprescription drug by men. By contrast, Acting Commissioner von Eschenbach refuses to approve nonprescription status for *any* women under 18 -- including those who are 17 years of age whom his predecessor, Commissioner Crawford, publicly stated could use Plan B safely as an OTC product.

In addition, the FDA has continued to act in bad faith throughout the course of this litigation. Most notably, it has asserted the deliberative process privilege in order to block discovery of documents that Magistrate Judge Pohorelsky upon *in camera* review determined to include evidence of bad faith. The FDA selectively invoked the deliberative process privilege even though it had waived that privilege by turning over numerous other documents revealing agency deliberations and failed to object to two prior rulings by the Magistrate Judge permitting Plaintiffs to explore agency process with FDA employees. The FDA's selective withholding of information based on that privilege, which violates the "fairness doctrine," *see In re von Bulow*, 828 F.2d 94, 102 (2d Cir. 1987) ("From that has grown the rule that testimony as to part of a privileged [attorney-client] communication, in fairness, requires production of the remainder."), was plainly an attempt to limit this Court's review to those documents that show the FDA's deliberative process in a favorable light.

Proof that any one of those factors delineated above, and described below in more detail, infected the FDA's decision requires this Court to enter judgment reversing the agency action as arbitrary and capricious. In combination, they demonstrate that the Plan B OTC decision was not simply arbitrary and capricious but one that is the product of an agency determined to reach a improper result. In light of its demonstrated pattern of improper and evasive bad faith action, there is little likelihood that FDA will ever engage in fair consideration of OTC status for Plan B. For that reason, the appropriate remedy is not only to vacate the decision as arbitrary and

capricious but also to enjoin enforcement of the BTC regime and direct the FDA to remove all restrictions on OTC availability of Plan B.

B. The FDA Relied on Factors Congress Did Not Intend It to Consider.

In 1951, when Congress amended the Food, Drug, and Cosmetic Act by the Durham-Humphrey amendment, Congress determined that the default status of drugs is over-the-counter status. Since enactment of the Durham-Humphrey amendment, the FDA has reviewed numerous OTC switch applications under it and under regulations and internal criteria. These agency interpretations of the federal statute have, with the exception of Plan B, been applied uniformly. Under them, in assessing OTC switch applications, the FDA considers drug toxicity and the capacity of individuals to use a drug safely without the guidance of a prescribing health care provider, including an individual's ability to understand instructions for proper use. The Durham-Humphrey amendment and the regulations interpreting it do not permit the agency to consider political acceptability of an OTC switch or impact of an OTC switch on personal behavior.[25] In this case, the FDA affirmatively asserts that it considered impact on personal behavior as a factor in its decision on Plan B, and the evidence shows that the political acceptability of OTC status of Plan B, particularly for younger women who are now excluded from OTC access by the BTC regime, has been considered as a controlling factor throughout the

[25] In numerous depositions conducted in this case, the government has sought to elicit from FDA officials their own interpretation of the statutory and regulatory phrase "other potentiality for harmful effect." (*See, e.g.*, Woodcock Dep. 177:14-180:6.) Specifically, the government has sought to elicit testimony that this regulatory phrase includes harmful effects on personal behavior. However, these FDA employees' interpretations of the regulatory phrase are entitled to no deference whatsoever, and are contradicted by more specific testimony from FDA drug regulators stating that personal behavior has not, other than in the case of Plan B, ever been used as a factor in deciding an OTC switch application, and should not be considered in the determination of an OTC switch application. (*See, e.g.,* Jenkins Dep. 187:2-188:10.)

agency's process.[26] Because the FDA relied on two factors which Congress has not intended it to consider, the agency's action is arbitrary and capricious.

1. The FDA Impermissibly Considered Personal Behavior.

The FDA's entire justification for its denial of unrestricted OTC status is that such status for Plan B might have an impact on the personal behavior of younger women, which in the FDA's view, is not adequately refuted by scientific evidence.[27] As set forth below at 92-96, there is overwhelming evidence that OTC access to Plan B would cause no change in the sexual and contraceptive behavior of women under 18. Even in the absence of such evidence, however, the FDA's consideration of the impact OTC access on personal behavior is unprecedented and not authorized by the FDA's regulatory framework. (Jenkins Dep. 105:5-106:22; Grimes Decl. ¶ 10(D).) There is uncontroverted evidence that the FDA has never previously considered impact on personal behavior in making an OTC determination. (Tummino 30757-58, 31098; Rosebraugh Dep. 105:18-106:13; Jenkins Dep. 105:5-106:22.) The FDA has utterly failed to explain why, in the case of Plan B, it has departed from that uniform practice. The departure is particularly unwarranted because Plan B is among the safest, easiest-to-use drugs the FDA has ever considered for OTC status. (Tummino 31086; Houn Dep. 120:18-121:15; Jenkins Dep. 101:5-22.) Indeed, consideration of impact on personal behavior has never been considered

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[26] The government made no effort in eliciting interpretations of the regulatory phrase "other potentiality for harmful effect" to obtain testimony interpreting the harmful effect to include harmful political effects.

[27] Thus, Dr. Jenkins testified:

> I read [Dr. Galson's] explanation about his concern about developmental differences in adolescents, and as I thought through the consequences of those issues, I couldn't see how they related to decisions about appropriately using Plan B. They seemed to be more applicable to the question of making appropriate decisions about engaging in sexual intercourse . . . . I didn't see those as relevant for the ability of adolescents to safely and effectively use Plan B without a doctor's involvement. . . .
>
> . . . [W]hat I'm trying to say again is that the data that we had available from the Application, I felt and others felt, had adequately demonstrated that the adolescent age group could safely and effectively use the product without a physician's intervention in the over-the-counter setting.

(Jenkins Dep. 108:15-109:7, 111:2-8.)

when other contraceptive drugs were reviewed and approved for OTC use. (Tummino 30648-52; 31026-30; 31031-32; 31095-99; Jenkins Dep. 105:5-106:22, 125:18-126:11.) If there is anything peculiar about Plan B that justifies consideration for the first time in the agency's history of a drug's impact on personal behavior, it cannot be discerned from the administrative record. Moreover, were impact on personal behavior a factor that Congress intended the FDA to consider, even a cursory review of approved OTC switch applications shows the morass that the FDA would enter if it made those assessments. For example, in approving OTC switches of antacid medications, must the FDA consider impact on individuals' eating behaviors? In approving OTC switches of pain medications such as ibuprofen or naproxen, must the FDA consider impact on pain inducing behavior? In approving OTC switches of vaginal anti-fungal creams, must the FDA consider impact on personal sexual and hygiene behavior? (Jordan Decl. ¶ 20.) The possibility that Congress intended the FDA to consider these impacts on personal behavior is so far-fetched, and indeed so offensive to the numerous personal liberties that protect each of these behaviors, that the Court cannot attribute such an intent to Congress. *See, e.g.*, *Carey*, 431 U.S. at 695.

2. The FDA Impermissibly Considered the Political Acceptability of the Plan B OTC Switch Application.

The uncontroverted evidence shows that beginning very early in the FDA's consideration of Plan B, the FDA consulted with the White House and charted a course for Plan B designed to appease the constituents of President Bush opposed to OTC availability. Indeed, one witness testified that the view was and remains "fairly widespread" within CDER that "non-medical and political views" factored into the FDA's decision to reject unrestricted OTC status for Plan B. (Houn Dep. 101:9-102:1; *see also* Kweder Dep. 58:13-19.) Thus, for example, the original

decision to issue a Not Approvable letter for the Plan B OTC application in May 2004 was made in consultation with the White House and implemented by then Commissioner McClellan well before scientific reviews of the application were complete.[28] (Jenkins Dep. 17:6-11; 18:2-17; 20:7-10; Kweder Dep. 44:3-45:8; 46:2-8; 56:8-57:5). Further, testimony that high-ranking FDA officials involved in denying unrestricted OTC status were concerned about their future at the agency and about damage to their credibility (Jenkins Dep. 232:12-20; Wood Dep. 40:2-19.) compels the inference that political rather than scientific factors played a predominant role in the FDA's handling of the Plan B application.[29] Moreover, the agency's asserted justification for denial of unrestricted OTC status has throughout related to asserted concerns about OTC use of Plan B by adolescents, the very same "justification" that was produced in collaboration with the White House in late 2003 or early 2004. Finally, Commissioner McClellan's stonewalling of the Government Accountability Office investigation into the Plan B Not Approvable letter provides another basis for inferring consideration of impermissible political factors. *See supra* n.3. In sum, there is direct evidence and evidence from which the court may infer that political factors which Congress did not intend for the agency to consider were considered during, and indeed were determinative of, the Plan B application review process.[30] (Oct. 11, 2006 Hr'g Tr. 25:2-25; 27:21-28:3.)

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[28] It is well-settled that the White House has no proper role in agency adjudicatory and quasi-adjudicatory decision-making. *Sierra Club v. Costle,* 657 F.2d 298, 407 (D.C. Cir. 1981) (finding "no inherent executive power to control the rights of individuals" concerning adjudicatory or quasi-adjudicatory proceedings.)

[29] Indeed, Dr. Houn, former head of the office within CDER that deals with reproductive health drugs, who feared retaliation from the FDA for her testimony in this case, (Houn Dep. at 230:18-231:1,) testified that she was told by two other FDA officials that if CDER leadership decided to approve an Plan B as an OTC drug, the leadership that was involved in such a decision "may not be able to stay on" at the FDA. *Id*. at 102:22.

[30] The Bush administration is no stranger to improper political influence over the work of scientific agencies. *See* Adam Clymer, *U.S. Revises Sex Information, and a Fight Goes On,* NEW YORK TIMES (Dec. 27, 2002) (change in language on National Cancer Institute's Web site to indicate a link between abortion and breast cancer on the basis of "newer scientific information" failed to reference the largest and most reliable study to date that concluded abortions had no effect on breast cancer); Andrew C. Revkin, *NASA's Goals Delete Mention of Home Planet*, NEW YORK TIMES (July 22, 2006) (deletion of the phrase "understand and protect our home planet" from NASA's mission statement without consulting NASA employees in advance alarmed NASA researchers); Michael Specter,

C. The FDA's Numerous Departures From Its Own Policies For Deciding OTC Switch Applications Render the Rejection of OTC Status for Plan B Arbitrary and Capricious.

The FDA's actions on the Plan B OTC switch application and the Citizen Petition depart dramatically from agency practice and precedent. The lengthy list of departures establishes beyond any serious dispute that the FDA's rejection of unrestricted OTC status for Plan B was arbitrary and capricious, in particular because none of the departures has ever actually been justified for such a safe and easy-to-use drug with such far-reaching potential health benefits for American women. While one or another of these departures in isolation might not rise to the level of arbitrary and capricious action, taken together they provide a text book example of an agency cavalierly setting aside its own well-established "prior norms." *Atchison,* 412 U.S. at 808 (plurality opinion). Indeed, some of the departures – such as the FDA's "consultation" with the White House or its rejection of unrestricted OTC status before scientific reviews were complete –standing alone render the FDA's entire process regarding Plan B arbitrary and capricious:

- the Office of the Commissioner placed individuals on the Reproductive Health Drugs Advisory Committee who were not well-published or of the stature normally held by such appointees in order to bring ideological "balance" to the Committee, namely a number of persons associated with the anti-abortion movement. (Kweder Dep. 36:12-21; 37:8-10.)
- the Commissioner of the FDA, who contacted the White House about the Plan B OTC switch application within days after it was filed, decided in consultation with the White House that the OTC switch application could not be approved.

Political Science: The Bush Administration's War on the Laboratory, The New Yorker (Mar. 13, 2006) (removal of a fact sheet about condoms from the Centers of Disease Control website for one year and replacement with language denigrating the effectiveness of condoms and promoting abstinence represented "the most horrific examples of manipulating science" that one senior CDC official had ever seen).

The record before this Court contains no evidence that the FDA has ever contacted the White House about any other OTC switch application. (McClellan Dep. 131:15-132, 127:10-15, 128:11-19, 140:19-141:13; Kweder Dep. 56:8-58:19.)

- the OTC switch application for Plan B represents the only example in at least the last decade in which the FDA has acted against the recommendation of its Advisory Committees voting in favor of the application. (GAO Rep. at 29.)
- the Plan B OTC switch application was decided in a manner directly contrary to the ordinary process prescribed in the FDA's own policy manuals, which delegate authority to decide such applications to the level of Office Director within CDER. (GAO Rep. at 17.)
- Plan B is the only OTC switch application in the last ten years which the FDA has demanded additional data as to adolescents and indeed almost all other approved OTC switch applications have been accompanied by no data on adolescents at all. (Tummino 31098.)
- Plan B is the only OTC switch application that was decided at the level of the CDER Director or higher within the memory of any of the FDA employees deposed by plaintiffs. (GAO Rep. at 30; Galson Dep. 35:22-36:3, 36:14-19.)
- the Plan B OTC switch application resulted in a nearly year-long advanced notice of proposed rulemaking process allegedly implemented because the FDA doubted its authority to approve an age restriction on an OTC drug, and then abandoned in part to expedite the confirmation of the President's appointee as Commissioner. (Jordan Decl. ¶ 24.)

- the FDA notified the United States Senate that it would take action on the Plan B OTC switch application by a certain date (in part in order to secure the confirmation of another Presidential appointee) and then failed to take any action by that date. (Def.'s Ltr. Mot. To Chief Judge Korman, dated July 25, 2005 at 33 (Document 20).
- even assuming arguendo that the FDA did not have adequate data to support OTC use by adolescents, Plan B is the only drug in which age restriction has been imposed contrary to the agency's longstanding practice of simply including an age warning on an OTC drug label. (Jenkins Dep. 113:2-16; Tummino 31097.)
- Plan B is the only OTC application as to which the FDA based its decision on adolescents' cognitive development, *see* n.6 *supra*.
- Plan B is the only OTC drug whose sale is restricted to pharmacies and health clinics. *Von Eschenbach Promotes Behind-the-Counter Drug Class,* The Pink Sheet (Mar. 16, 2007) (attached hereto at Ex. E).
- Plan B is the only non-prescription drug for which the FDA requires an individual to produce identification to purchase. (Tummino 10864-67; Grimes Decl. ¶ 12.)
- Plan B is the only drug whose conditions of sale have been justified even in part by the manner in which states regulate tobacco products. (Jordan Decl. ¶ 12; Grimes Decl. ¶ 13.)
- the FDA's rejection of the Citizen Petition was clearly timed not to reflect the crystallization of some scientific judgment, but instead to impede Plaintiffs' discovery efforts and defeat Plaintiffs' unreasonable delay claim. *See* 36, *supra*.

Perhaps the most dramatic arbitrary and capricious action regarding Plan B is that Commissioner McClellan, in consultation with the White House, decided that the FDA would reject unrestricted OTC status for Plan B and that this decision was made (1) before the scientific reviews of the OTC switch application by FDA scientists was complete, (2) without consultation with FDA scientists, and (3) shortly after the joint advisory committees overwhelmingly recommended unrestricted OTC status at a meeting which the Commissioner did not attend. This decision by Commissioner McClellan, which he asserted was based on "concerns" about data about adolescent women, has remained to this day the justification for rejecting unrestricted OTC status and for the FDA's August 2006 BTC regime. Although various memoranda written by Dr. Galson have sought to express these concerns in scientific jargon, career scientists at the agency have stated that the concerns were so vaguely expressed and nonspecific that they viewed the concerns as insurmountable by any amount of evidence or data. *See, e.g.,* Tummino 30649-51, 31027, 31086. In addition, in the more than three years since Commissioner McClellan made his decision to reject unrestricted OTC status, no evidence supporting any legitimate concerns about adolescents' OTC access has ever been identified either by the Office of the Commissioner or by CDER Director Galson.[31] Moreover, the evidence establishes that Dr. Galson's irrational efforts to justify the Commissioner's concerns were the product of his fear that if he did not tow the Commissioner's line, his position at the FDA would be in jeopardy.

An agency charged to make decisions on the basis of scientific evidence surely engages in arbitrary and capricious action when, as here, it bases its decision on vague and nonscientific

[31] The arbitrary and capricious nature of the FDA's entire process regarding Plan B is dramatically compounded and confirmed by the details of the August 2006 BTC regime in which the Commissioner of the FDA raised the minimum age OTC access to 18 despite Dr. Galson's own finding that as a scientific matter, women 17 and older should have OTC access. Notably again, Dr. Galson played the same obsequious role that he played previously in the process by endorsing this change in the age limit, this time without even attempting to provide a scientific justification.

views that are the product of consultations between the head of the agency and the White House. Indeed, if the FDA's decision on OTC status for Plan B is not arbitrary and capricious then the Commissioner of the FDA at the behest of the White House or on his own whim could reject any new drug or OTC switch application for any reason simply by announcing that he has "concerns" about the application. As we set forth in the next section, the record does not support any of the Commissioner's ostensible concerns about adolescents having access to Plan B without prescription. That evidentiary lacuna confirms that extreme arbitrariness and caprice animated the denial of unrestricted OTC status.

D. The FDA's Justification for Denial of Unrestricted OTC Status for Plan B Runs Counter to the Evidence Before It and Is So Implausible That It Cannot Be Ascribed to a Difference in View or the Product of Agency Expertise.

The FDA has produced written justifications for its denial of unrestricted OTC status for Plan B in each of the three "phases" during which it took public action on Barr's OTC switch application, as well as in its denial of the Citizen Petition. The first phase culminated in the May 2005 Not Approvable letter denying unrestricted OTC status. The second phase culminated in the August 2005 announcement denying unrestricted OTC status and announcing an advanced notice of proposed rulemaking. The third phase culminated in the FDA's denial again of unrestricted OTC status and its promulgation of the BTC regime in August of 2006, preceded by its litigation-driven letter in June of 2006 admitting that it had denied the Citizen Petition. The "scientific" justifications are detailed in memoranda by CDER Director Dr. Steven Galson, the only FDA employee to write detailed reviews of the Plan B OTC switch application who opposed approval of the unrestricted OTC switch. (The non-scientific justifications for the BTC regime are contained in memoranda by Commissioner von Eschenbach.)

As set forth below, two purportedly "scientific" concerns emerge from Dr. Galson's memoranda. First, he stated his speculation that unrestricted OTC status could have an impact on the sexual and contraceptive behavior of adolescents. This concern is illegitimate because the FDA is not authorized to regulate such behavior (for either adolescents or adults). *See supra* at 82-85. Even assuming *arguendo* that the FDA could within its mandate begin to regulate the personal sexual behavior of American citizens via its drug approval decisions, every available piece of scientific evidence contradicts Galson's speculation about behavioral effects of unrestricted OTC status of Plan B. *See infra* at 92-96.

Second, Dr. Galson expresses the concern that the data does not establish that Plan B will be safely and appropriately used by adolescents under 17 as an OTC drug. But this concern is based on his unwillingness to extrapolate from data for older age groups to younger adolescents, a concern he in turn bases on adolescents' diminished capacity to rein in impulsive behavior (*see* Tummino 31218) and his analysis of the available evidence is in any event wrong.[32]

Third – and without any scientific justification – Galson and FDA Commissioner von Eschenbach, in adopting the BTC regime, raised the age of safe OTC use from 17 to 18.

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[32] In any event, Dr. Galson has demonstrated through his slipshod assertions that he is not qualified to draw conclusions about safe and appropriate use of Plan B in an OTC setting. For example, in seeking to distinguish Plan B from other OTC drugs for which the FDA has not required special adolescent data, Galson claims as one "critical fact" that Plan B has:

> specific risks . . . which differ from most other OTC drug products. Plan B is a form of oral contraceptive that is currently available Rx-only because of the serious side effects that may be associated with long-term regular use. . . . Other non-contraceptive, OTC products, such as antacids, are indicated for uses that are normally associated with risks much less serious than unprotected sexual intercourse, unwanted pregnancy, and the risk of stroke. . . . More information are [sic] needed demonstrating whether OTC use of Plan B by women under the age of 17 would . . . present serious health risks (e.g., stroke and blood clots) from frequent use of a high-dose oral contraceptive.

(Tummino 31220.) In fact, Plan B, which is a progestin-only contraceptive, has no known risk of stroke, blood clot, or other serious adverse effects. *(*Grimes Decl. ¶ 10(F)) ("Plan B carries no increased risk of any cardiovascular disease."); (Houn Dep. 121:1-15 ([W]ith respect to toxicity, there is no established cardiovascular risk with progesterone. And this is also documented in the post-marketing review of over a million and a half uses of Plan B. . . . In fact, during the vote [by the Advisory Committee on Plan B] . . . it was unanimous that there wasn't a safety concern.") Dr. Galson's confusion (purposeful or not) of Plan B with contraceptives containing estrogen (which do carry such risks) is emblematic of his scientific acumen and integrity.

1. Galson's Speculation About Impact on the Sexual and Contraceptive Behavior of Adolescents is Refuted by the Available Evidence.

Even if Galson's stated concerns about such an impact were within the legitimate purview of the FDA, those concerns are amply refuted by the available scientific evidence. As FDA scientist Dr. Rosebraugh wrote:

> The data reviewed . . . is quite compelling to dispel any potential concerns regarding adolescent use or changes in sexually behaviors associated with plan B use. . . . In terms of OTC switch applications, this drug has more information available to allow us to predict consumer behaviors than any drug the Division has approved for switch in recent memory. If this is not enough data upon which to base a decision, it is unclear what would constitute enough data or even if that is an obtainable goal.

(Tummino 30755-57.) In addition, as Plaintiffs' expert Dr. Grimes explains: "[A] Cochrane systematic review of the world's randomized controlled trials of advance provision of emergency contraception demonstrated no increase in risky sexual behavior or undermining of ongoing contraceptive use." (Grimes Decl. ¶ 10(D).)[33]

All the other reviewers that commented on this concern echoed the tenor of these opinions. For example, Dr. Daniel Davis, Medical Officer in the Division of Reproductive and Urologic Drug Products, wrote:

> 7.5.2 Adolescent Use Data
>
> In addition to the AUS, data from 3 other randomized controlled studies that enrolled adolescents was submitted by the Applicant with the original supplemental NDA (see Table 6). These studies involved advance provision of ECPs (varying from 1 to 3 packs) to a generally high-risk group of sexually active women age 14 to 24 yr. All subjects were provided with similar minimal information about the indication and correct dosing for ECPs. Subjects were then randomized to receive ECPs by either advance provision (AP) or standard access ([SA], i.e., needed a prescription and had to go to a pharmacy or clinic to obtain ECPs). Subjects were followed over a 6-12 month period (much longer than in the AUS.)

[33] Dr. Grimes explains that "Cochrane reviews are published, peer-reviewed syntheses of randomized controlled trials and reflect the highest level of evidence concerning the safety and efficacy of medical interventions." *Id*.

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- *The above studies greatly expand the number of adolescents for whom we have data concerning the use of emergency contraception and its impact on "risky behavior." There were over 1,000 adolescents age ≤ 16 yr., and almost 2,000 age ≤ 17 yr. When possible, this group of young adolescents (17 yr. and younger) was compared to the older adolescents age 18-20 yr.*
- *The statewide DIAL EC Project in North Carolina mimicked an OTC setting in many ways. Women did not have to go to a clinic or health care provider to get a prescription; they had to self-determine that they needed emergency contraception, make a phone call to the coordinating center, and then pick up the ECPs at a local pharmacy or Planned Parenthood Clinic (PPC). As in the OTC setting, they had to pay for the pills and more often chose to go to a local pharmacy than to a PPC. More than 9,700 prescriptions were issued to the 7,756 participants over a 29-month period . . .*

. . . There is evidence to suggest that the OTC availability of emergency contraception will not increase sexual activity among young adolescents. A randomized controlled trial in the U.K. of a teacher led intervention in schools with 1,974 boys and 1,820 girls, all 14-15 yr. of age, demonstrated that education about emergency contraception did not increase sexual activity among this group of young adolescents. The intervention increased levels of knowledge about emergency contraception, but there were no differences observed in sexual activity or in frequency of emergency contraception use at a 6-month follow-up. (n29. Graham A, et al. Improving teenagers' knowledge of EC: cluster randomized controlled trial of a teacher led intervention. *British J Medicine* 18 May 2002;324;1179-84.)

(Davis, 3/25/04 Medical Officer's Safety Review of Supplemental NDA, Tummino 30809-10.)

Dr. Rosebraugh (Deputy Director of the Division of OTC Dug Products) and Dr. Bull (Director of the FDA Office that handled nonprescription drugs) reviewed several of the other studies of Plan B in some detail, and reached the same conclusion:

Below is a table of behavioral studies similar to that reviewed with the Commissioner. This table demonstrates that there is data available on over 1900 adolescents 17 years old and younger.

In reviewing these studies, adolescent use and contraceptive behavioral trends were similar to those in older age groups and had the same trends as those demonstrated in the AUS study. In prior discussions, upper level management was concerned that the extent that these studies can be used in decision making may be limited because these studies included healthcare provider intervention (counseling) that was not available in the actual use study and would not be available for an OTC drug. However, for the two behaviors

of interest, timing of dose and contraceptive behaviors, the AUS provides data that health care provider intervention does not impact on timing of dose or contraceptive behaviors beyond what the label provides by itself (data presented below). . . .

. . . In Table 3, the data from the AUS demonstrate that the frequency of sexual intercourse during the study and contraception use were comparable between different age groups except that the 14-17 year old age group tended to use more effective contraception after receiving Plan B.

Previous health care provider intervention also does not appear to impact upon contraceptive behaviors. If we compare behavioral changes with subjects that had prior experience with Plan B to novice users as seen in table 4, we see similar percentages of contraceptive behaviors between groups. This would again support that prior intervention of a health care provider did not influence subsequent contraceptive behaviors associated with the use of this product compared to no intervention of a health care provider. . . .

. . . The Gold study demonstrates that advanced provision of ECP 1) does not increase promiscuous sexual behavior in 15-17 y/o adolescents compared to current methods of access, 2) is more likely to lead to use of the product earlier after unprotected sex, and 3) is more likely to lead to use of the product after unprotected sex compared to current methods of access. . . .

. . . This study had 476 females aged 15-17 y/o and 1,614 aged 18-24 y/o. At baseline, the adolescents had similar prior emergency contraceptive use and frequency of unprotected sex as the older group, but had fewer prior pregnancies, abortions and STDs. This would be expected because the younger subjects would have been sexually active for a shorter duration than the older group. At study end, the 15-17 y/o compared to the 18-20 y/o had no significant differences in emergency contraception use on study, emergency contraception use a second time, unprotected sex, or STDs as seen in table 10.

The behavioral data comparing the adolescents in the advanced provision group (n=194) compared to the pharmacy access group (n=189) revealed no differences in frequency of sex/month, number of sex partners or failure to use a contraceptive method as listed in the table 11. This suggests that ready access to a 3 month supply of emergency contraceptive in the house (advanced provision) did not alter the sexual or contraceptive behaviors of adolescents compared to pharmacy access. . . .

. . . Overall, the data from Washington State would speak against the concerns that access to Plan B would increase promiscuity or that females may not be able to use the drug correctly. Since the State introduced reduced barriers to Plan B access, the data demonstrates decreased pregnancies and abortions for adolescent age groups, and STD rates below national averages. In fact, the State has decreased their National STD ranking over this time period for two common STDs. Also during the six plus years that

Plan B has had pharmacy availability, there have no reports from Washington State that Plan B has led to an increase in promiscuity among teenagers. In regard to the possible abuse of Plan B, it must also be remembered that Plan B does not have any significant CNS effects and has a high rate of non-serious adverse events, such as nausea in over 23% of subjects and menstrual irregularities that would prohibit recreational use of this drug. Finally, as noted earlier, in Washington State, health care provider (pharmacist) input into women's decisions regarding Plan B use is minimal and consists of initialing a check list that highlights tabling concepts. This demonstrates that all ages of females seem able to use this drug with minimal health provider intervention. . . .

. . . A summary of the data reviewed demonstrates that:

- The Actual Use study demonstrated that users not receiving previous health care provider counseling had similar timing of dose and contraceptive behaviors compared to those users having had received prior health care provider counseling.
- The Dial study demonstrated that females 18 y/o and younger used ECP for the same reasons and had similar timing of medication and repeat use frequency as older females.
- The Gold study demonstrated that 15-17 y/o had the same sexual and contraceptive behaviors as older females. 15-17 y/o with advanced provision had the same sexual behaviors as 15-17 y/o obtaining the medication from a clinic and the advanced provision group started the medication 10 hours sooner on average.
- The Raines study demonstrated similar contraceptive behaviors between 15-17 y/o compared to 18-24 y/o and similar sexual behaviors in adolescents obtaining advanced provisions compared to adolescents using pharmacy access.
- The Washington State data demonstrated that since pharmacy access has been granted to Plan B in 1997:
    - Adolescents pregnancy rates have decreased
    - Adolescent abortion rates have decreased
    - The total number of adolescent abortions have decreased
    - STD rates have remained below national averages
    - The national ranking for Chlamydia has decreased from 31st to 35th
    - The national ranking for gonorrhea has decreased from 39th to 40th

There is compelling data evidencing that Plan B fulfills regulatory requirements for OTC marketing. An overwhelming majority of members comprising two advisory committees, with 12 out of 13 NDAC members and 12 out of 15 ACRHD members, voted for full OTC approval. There is a rich body of literature demonstrating appropriate and safe use of Plan B under decreased restrictions to access conditions. This memorandum reaffirms my previous recommendation that Plan B should be approval for OTC marketing without restriction.

(Rosebraugh & Bull, 3/23/04 Division Director Memo-Addendum, Tummino 30748-59.)

Dr. Jenkins' overall summary shows that Dr. Galson's concerns were utterly unfounded, and indeed were completely refuted by the studies he was unwilling to consider:

> [I]n addition to the studies submitted by the sponsor, there exists a substantial body of data from recently completed published and unpublished studies on emergency contraception that have enrolled a substantial number of adolescent women. While none of the studies directly mimic the OTC setting for access to Plan B, I believe that these data are relevant and help to address whether adolescents can use Plan B in the OTC setting. Taken together, these additional studies do not support a concern that adolescent women are less able to understand the label directions or less likely to appropriately use the product than older women. Further, these studies found that increased access for adolescents to emergency contraception did not result in inappropriate use of Plan B as a routine form of contraception, an increase in the number of sexual partners, an increase in the frequency of unprotected intercourse, or an increase in the frequency of sexually transmitted diseases.

(Jenkins, Mem. 4/22/04, Tummino 30898.)

Because the evidence overwhelmingly refutes Galson's concern about impact on adolescent behavior, this basis for rejecting unrestricted OTC status is arbitrary and capricious even if it is assumed to be a factor within the agency's statutory mandate.

2. Galson's Statements About Adolescent Impulsivity Have No Link to Safe and Appropriate Use of Plan B as an OTC Product and Are Refuted by the Scientific Evidence.

As demonstrated below, the findings of FDA scientific staff with actual expertise at the FDA, *see* Grimes Decl. at ¶10(G) (Galson appears to lack relevant scientific expertise), reveal that Dr. Galson's justifications are arbitrary and capricious for several reasons. First, he provides no scientific explanation for his unwillingness to extrapolate from available data from older age groups to younger age groups, despite the fact that the FDA does this routinely and, in fact, earlier told the manufacturer that such extrapolation was appropriate for Plan B as well. (Tummino 30100, Jenkins Dep. 111:17-22, Tummino 30898.). Dr Galson's generalized concern about the capacity of adolescents to engage in mature decision making would of course be applicable to any drug, including the many drugs which the FDA switched to OTC status without

any adolescent data. Moreover, there is no evidence that links reported deficiencies in adolescent reasoning abilities to any inability to understand the extremely simple instructions for using Plan B, nor does Dr. Galson cite such evidence. (*See* Jenkins Dep. 61-62, 63:11-19.)

Second, as Dr. Grimes observes, Dr. Galson's concerns about lack of data both in May 2004 and later in the process simply confuse the validity of the statistical evidence with its precision. (Grimes Decl. at ¶ 10(A-B).) This confusion is particularly arbitrary because of the many OTC switch decisions approved by the FDA for which adolescent data had zero precision because no such data was ever even submitted or requested.

Dr. Galson asserted that his decision to reject unrestricted OTC status for Plan B was based on developmental differences between younger adolescents and older age groups, which in turn led him to assert that more data for younger age groups was needed. For example, in the May 2004 memorandum justifying his Not Approvable letter, he wrote:

> In making decisions about pediatric use, it is often possible to extrapolate data from one age group to another, based on knowledge of the similarity of the condition. However, in this case, adolescence is known to be a time of rapid and profound physical and emotional change. For example, during early adolescence (10-13), this age group experiences the emergence of impulsive behavior without the cognitive ability to understand the etiology of their behavior. During mid-adolescence (14-16), youth begin to develop the capacity to think abstractly; however, their ability to integrate their emerging cognitive skills into their real-life experiences is immature and incomplete. The capacity to understand complex concepts, which develops during middle adolescence, allows adolescents to modulate their impulsive behavior (n2. *Rudolph's Pediatrics,* 21st edition, Chapter 3.1, Growth and Development, Psychological Development During Adolescence.).

(Tummino 30901-02.) He reiterated his speculation in his August 2005 memorandum:

> Finally, with regard to the characteristics of a younger population in general, extrapolation of the actual use and labeling comprehension data to this group could be inappropriate because data in the pediatric literature on younger age groups suggest potentially significant differences from older adolescents with regard to cognitive abilities and risk taking behaviors. The less developed cognitive abilities of women under age 17 could lead to inappropriate use of Plan

> B and the potential for younger women engaging in risky sexual behavior, behaviors which carry significant safety and efficacy concerns.

(Tummino 31218-19.)

But Dr. Galson *never provides any explanation of the mechanism by which such developmental differences would affect the ability of younger adolescents to use Plan B safely and appropriately without a physician's guidance*, or why such differences would not also affect their ability to use any of hundreds of other OTC drug products appropriately and safely.

Dr. Jenkins explained why Galson's stated concern about adolescents' cognitive ability is irrelevant to the assessments about the safety and efficacy of their use of Plan B:

> Dr. Galson has cited developmental differences between adolescents and older women in support of his concern about extrapolation of findings from older to younger women. In my opinion, the concerns Dr. Galson raises are more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse. The Plan B regimen in very simple (one tablet as soon as possible after unprotected intercourse and another tablet 12 hours after the first) and in many ways easier to follow than many other OTC products that are labeled for use by adolescents and younger children (e.g., some OTC products require a decision about the proper dose to be taken based on age or weight, require frequent repeat dosing, and contain multiple warnings and "Do not use if" statements). Further, levonorgestrel, the active ingredient in Plan B, has a very high margin of safety. This high margin of safety combined with the packaging, makes it very unlikely that a serious adverse event would occur if an adolescent incorrectly dosed the product.

(Tummino 31096-31098.)[34] In the absence of an explanation of how risk-taking behavior would interfere with adolescents' capacity to use Plan B safely and appropriately, Galson's refusal to extrapolate from older age groups is patently arbitrary (or just another version of his impermissible foray into regulation of personal behavior).

[34] In fact, as Dr. Jenkins testified, "We did not see any evidence that their behavior or their ability to use the product correctly and safely and effectively was different from the older age group, so bringing in the developmental differences, I didn't understand its relevance, because we had data in front of us that seemed to refute that those developmental differences were consequential." (Jenkins Dep. 111: 9-116.)

Even if the Government were for the first time now to offer some link between adolescents' purported risk-taking behavior and their capacity to use Plan B safely and appropriately as an OTC drug, the scientific evidence demonstrates that those concerns are entirely unfounded, because, as set forth below, adolescents of all ages have been repeatedly shown to be capable of using Plan B correctly.

A. "Inadequate Data on Adolescents"

Dr. Galson erroneously asserted that there was a "lack of available data" for adolescents 16 and under. Specifically, in two of his memoranda he wrote:

> - My decision is based on the lack of available data relevant to OTC use of the product by adolescents younger than 14 and very limited data in the 14-16 age group. Without data in the application on OTC use in this age group, and lacking confidence that data from older adolescents can be confidently extrapolated to this age group, I find the proposal to switch Plan B from Rx to OTC use—thus making it available to very young adolescents—to be unsupported.

(Galson, 5/06/04 Memorandum Re: Plan B, Tummino 30901-02.)

> In reviewing a proposed switch from Rx to OTC status, FDA assesses the actual use and labeling comprehension studies submitted by the applicant to support the switch. As described in my May 6, 2004 Not Approvable letter, the April 2003 supplement contained very limited actual use data on women ages 14 and 15, and no actual use data on women under age 14. Similarly, the label comprehension study also included few women ages 16 and under (n=76) (n.4. Plan B, Label Comprehension Study, Table 9, page 31.). Moreover, as described below, what little data were in the supplement raised questions about whether the product can be used safely and effectively by younger adolescents.

(Galson, 8/26/05 Memorandum Re: Plan B, Tummino 31216.)

The concern about limited adolescent data is scientifically unjustified. As Dr. Jenkins wrote in January of 2005:

> Dr. Galson is correct in noting that a relatively small number of subjects less than 16 years of age were included in the label comprehension and actual use studies conducted by the sponsor. As I noted in my previous memorandum, given the setting in which these

> studies were performed it is likely that the observed age distribution is reflective of the age distribution of the population of women who will use Plan B if approved for non-prescription marketing. Further, I believe that it is entirely reasonable to extrapolate the findings from the older women in these trials to adolescents given well established agency precedent for extrapolating data from studies in adults and older adolescents to younger adolescents and the fact that there was no suggestion based on the data from the sponsor's studies that younger women were less able to use the product correctly in a stimulated OTC setting than older women. There is no pharmacologic or safety issue for the use of levonorgestrel at the dose found in Plan B in younger adolescents compared to older women, and the approved prescription labeling for Plan B and other oral contraceptives that contain levonorgestrel make no distinction based on age.

(Jenkins, 1/14/05 Mem. Re: Review of Resubmitted NDA for Rx to OTC Switch for Plan B, Tummino 31096-97.)[35]

Plaintiffs' expert Dr. Grimes renders a similar opinion about Dr. Galson's justification:

> Dr. Galson stated in his memorandum of August 25, 2005, that "what little data were in the supplement raised questions about whether the product can be used safely and effectively by younger adolescents." This claim was false. The data on women aged 16 years and younger were less extensive than for older women, reflecting the typical ages of those who use the product. However, the data for women aged 16 years and younger demonstrated that they used the product as appropriately as older women did. Stated alternatively, the data for women 16 years and younger were 1) valid, 2) consistent with those of older women, and 3) less precise due to smaller numbers. To imply that less statistical precision "raised questions" about study validity was incorrect and misleading. No evidence suggested inappropriate or unsafe use.

(Grimes Decl. ¶ 10(B).

Moreover, Dr. Galson, as set forth below, improperly excluded from consideration other studies with much larger numbers of adolescent subjects, some of which are reflected in the following table:

[35] In fact, the FDA's office that reviews pediatric drugs found that the age breakdown for prescription use of Plan B included less than 0.5% of persons 8-14 years of age, and a detailed breakdown by age shows that the percentage of 14-year olds ranged between 0.2% and 0.4% in the period 2002-June 2004. (Tummino 10947.) Thus, for example, Barr's Actual Use Study, which included would have matched the prescription use age breakdown if it had included *one* (1) adolescents under aged 14. In fact, it included 22 adolescents 14-16 years of age, and of these exactly *one* (1) was 14.

Table 16. Studies Assessing Patient Behavior in Response to Facilitated Access to Plan B

Study	Age Range	Total N	Age		
			≤16 years	≤17 years	≥18 years
Actual Use	14-44	540	22	46	494
Dial EC	8-51	7756	613	1225	6531
Gold	15-20	301	115	187	114
Raine*	15-24	2090	254	476	1614
Jackson	14-?	370	15	21	349
Belzer	14-20	160	NA	NA	NA
Total		11,217	1019	1955	9012
*2004, unpublished study					

(Griebel, 4/1/04 Deputy Division Dir. Summary Review of New Drug App., Tummino 30868; *see also* Tummino 30867-77 (providing detailed analysis of "Adolescent OTC Access Issues" including adequacy of numbers of adolescents included in studies, correct dosing, value of learned intermediary, advisory committee reaction to age restriction, benefits to OTC access for adolescents, and risks to adolescents).)

B. Label Comprehension Studies

Dr. Galson also offered as a reason for his decision his observation that younger adolescents performed less well than older adolescents in the manufacturer's label comprehension studies. He asserted:

> First, when compared to older adolescents (>17 years) and adults, early adolescents (ages 12-16 years) were less likely to specifically comprehend Plan B's labeling instructions. In the label comprehension study (N=656), adolescents (ages 12-16 years, n=76) did not understand certain key directions in the labeling. For example, women ages 12-16 did not understand as often as women 17 years and older that Plan B's indication is to prevent pregnancy after unprotected sex (86% for ages 12-16, 93% for ages 17-25, 95% for ages 26-50), that Plan B is not for routine use (57% for ages 12-16, 67% for ages 17-25, 71% for ages 26-50), that the first pill should be taken within 72 hours after intercourse (77% for ages 12-16, 86% for ages 17-25, 87% for ages 26-50), and that the second pill should be taken 12 hours after the first pill (77% for ages 12-16, 90% for ages 17-25, and 82% for ages 26-50) (n5. Plan B, Label Comprehension Study, Table 9, page 31.).

(Galson, 8/26/05 Mem. Re: Plan B, Tummino 31216.)

That reasoning is invalid and in fact is a scientific abuse of the studies. The label comprehension studies are designed to test the quality of the manufacturer's proposed labeling, not the ability of consumers to use the product properly. Moreover, as Dr. Rosebraugh made clear, this selective use of irrelevant differences in the label comprehension study gave greater than appropriate weight to the label comprehension study, because the actual use study (as indicated by its name) provides much more valuable information:

> By way of prioritizing the importance of this study in the review of this application, it is important to consider that in applications that include both a label comprehension and actual use study, the actual use of the product as determined in the Actual Use study is the basis to decide whether a concept of use is adequately conveyed. As expressed in Dr. Leonard-Segal's secondary review, the purpose of the label comprehension study in this application was to enable the sponsor to test if their label adequately relayed information that would allow proper use of the product in the Actual Use study and if not, to allow the sponsor to make changes in the label prior to initiating the Actual Use study. When label concepts demonstrate poor results, it can be either because the label language is difficult to comprehend, or because the question evaluating the concept is poorly constructed. . . . . . In regard to #1, #2 and #3 above, the actual use study (to be discussed next) demonstrated that:
>
> 1) Routine contraception use and effective contraception use was not affected during the study.
> 2) Over ninety percent of subjects in the actual use study demonstrated dosing within 72 hours.
> 3) Over ninety percent of subjects took the 2nd pill between 6-18 hours after the 1st pill.
> 4) There were not any important differences across age demographics.
>
> Therefore, concepts in the label comprehension study were either scored at a high level, or those concepts not scoring at the higher level had high levels of appropriate use during the Actual Use study.

(Rosebraugh, 1/9/04 Division Dir. Mem., Tummino 30445-46)

Furthermore, detailed analysis of the label comprehension study shows that Galson accorded special weight to certain data differences while he ignored other, more important data. As Dr. Griebel wrote:

> *1.2.1 Young Age Group Performance.*
> The youngest age group had scores that were reportedly statistically significantly different from other age groups on 3 study objectives. These statistical analyses were not adjusted for multiple comparisons, however, and on one the youngest age group scored significantly better (side effects objective). On another (doesn't prevent HIV/AIDS), the youngest group scored similar to the oldest age group, but lower than the 17-25 year olds. In only one objective (#6), the youngest age group scored both lower than the other age groups and less than 86%--the objective evaluating understanding of timing of the second dose at 12 hours post the first. The youngest age group scored 77% on this compared to 90% in the 17-25 year olds and 82% in the 26-50 year olds. This objective was assessed with a single question, a direct question that asked when a woman should take the second tablet. The score for the overall population on this question was 86%. The literacy analysis found 82% of the lower literate and 93% of the higher literate participants answered the question correctly. The division reviewers believe the youngest age group's 77% correct score for the 12 hour dose interval is still acceptable, and as will be discussed later in this review, the younger age group performed similarly to the older age group in taking the second dose at 12 hours in the actual use study.

(Griebel, 4/1/04 Deputy Division Dir. Summary Review of New Drug App., Tummino 30833.)

In addition, adolescents' score on the timing of the second dose of Plan B is almost entirely meaningless given that, as Dr. Houn testified, taking the two doses less than 12 hours apart does not affect Plan B's effectiveness. (Houn Dep. 122:15-123:2; *see also* Jordan Decl. ¶ 3 (stating that studies have found that Plan B (or its equivalent) remains effective regardless of whether the second pill is taken at the same time as the first pill, 12 hours after the first pill, or 24 hours after the first pill, and that timing of the second dose does not increase side affects or create a health risk)). As Dr. Jenkins summarized: "The data I saw from the Actual Use Study and the Label Comprehension Study did not suggest to me that there was any substantial difference between the older women and the younger women, and I continue to hold that view." (Jenkins Dep. 95:16-22.)

C. Actual Use Studies

Dr. Galson also selectively exploited data from the manufacturer's actual use study to justify his rejection of OTC status:

> [T]he data from the actual use study, which enrolled very few women under 17 years, also raise concern about the safety of OTC Plan B for young women. For instance, they show that adolescents under age 17 were less compliant with the 4 week follow-up period specified in the study protocol when compared to the older women (ages ≥17 years). Fifty-five percent of the subjects aged 14-16 had two or more follow-up contacts, while 89% of the older subjects (ages 17-44) had two or more follow-up contacts (n.6 Plan B, Actual Use Study, Final Report Tables, Table 1.4c, page 16.). These differences in follow-up undermine the ability of the actual use study to support safe use of OTC Plan B in this age group (n.7 See also, page 23 of January 12, 2004 sNDA review by OTC Division (Jin Chen).). Furthermore, of the 29 14-16 year olds enrolled, most of them were 16 year olds (20 of 29 or 69%) (n.8 January 11, 2005 email from Joseph Carrado to Tia Frazier.).

(Galson, 8/26/05 Mem. Re: Plan B, Tummino 31216)

But no other FDA scientist viewed the data in this skewed manner. For example, Dr. Bull, the Director of Office of Drug Evaluation V, the Office within CDER that reviewed nonprescription drugs wrote:

> As to the findings of the actual use study, it is noted that the actual use data submitted is consistent with prior Agency findings of acceptability for OTC switch determination. Specific to Agency concerns on teenagers, the findings of the study did provide a sufficient representation of subjects in the lower age groups of women of childbearing potential who are sexually active. It is noted that incorrect use was lower among subjects 16 and younger (13.6%) than in those 17 years and older (26.4%). There was also a higher percentage of subjects in this age group who changed to a more effective contraception (28.6% vs. 10.5%). Although a difference was found in taking of the protocol specified timing for the second dose (75.9% vs. 93%) there was no evidence that the difference in timing of the second dose adversely impacted efficacy and the reduction of the risk of pregnancy in the study population for this subgroup.

(Bull, 1/21/04 Office Dir. Mem. Re: NDA 21-045, Plan B (levonorgestrel) proposing Rx to OTC switch, Tummino 30650-51.)

Other FDA reviewers described adolescents' performance in the actual use studies in nearly glowing terms. Dr. Leonard-Segal stated:

> At the request of the agency. the sponsor submitted a reanalysis of data on teenage use of Plan B from the Actual Use Study. The actual use data is predictive that teenagers 14-17 years of age would use OTC Plan B no less properly than those 18-44 years of age. This reanalysis lends further support to my view that the application to switch Plan B from prescription to over-the-counter marketing should be approved. *Id.* at 30691.

(Leonard-Segal, 3/5/04 Medical Review, Tummino 30691-92.)

Similarly, Dr. Davis found :

- *There was excellent compliance with the labeled dosing regimen among subjects < 18 yr. of age. Compliance was at least as good as that in the subjects 18 yr. and older.*

(Davis, 3/25/04 Med. Officer's Safety Review of Supplemental NDA, Tummino 30800. *See also* Griebel, 4/1/04 Deputy Division Dir. Summary Review of New Drug App., Tummino 30840 ("2.4.1 Age Analysis: Subgroup analyses by age, educational level and previous experience with EC did not reveal significant differences in correctness of dosing across subgroups."); Houn Dep. (143-46 - confidential).)

D. Other Studies

Dr. Galson also managed to reject *all* other studies and literature reviewed by his subordinates:

- The additional studies cited in the Office of New Drugs reviews do not approximate actual OTC use sufficiently to support approval. Although the studies are relevant, none tests the hypothesis that typical adolescent consumers with no extra information will use the product correctly. The studies are either not conducted in the general population or they provide product education assistance beyond what adolescents would receive in an OTC situation, where no contact with a health care professional is expected. Likewise, the literature review submitted to address questions of important potential behavioral changes associated with availability of an emergency

> contraceptive (e.g., substitution of the product for routine and more effective contraception, or increased medically risky sexual behavior) did not contain studies that mimic what would be actual OTC availability.

(Galson, 5/6/04 Mem. Re: Review of NDA for Rx to Over the Counter Switch for Plan B, Tummino 30901-02.) This sweeping rejection of numerous other studies in which Plan B was made more readily available than by a physician's prescription is utterly without scientific or common-sense rationale, and appears to be designed simply so that Galson could delete from his consideration the wealth of scientific evidence that actually refutes all his stated concerns about adolescents.

Thus, several FDA scientists described the great value of these other studies:

> *Studies of Plan B Use in Adolescents*
> Other concerns are that there are insufficient numbers of adolescents that participated in the actual use study (AUS) limiting any conclusions for this demographic. OTC switches can be based on a variety of data including randomized trials or historic use of similar products. It is important to remember that "actual use" is just a title indicating that the study is used to analyze a product for OTC use. There are currently no study designs that can *exactly mimic* the OTC setting. Other studies that aren't titled "Actual use" can contribute data in the determination of OTC appropriateness. For plan B, there exists a large body of data supporting the actual use study including randomized clinical trials evaluating a variety of distribution mechanisms for emergency contraceptive pills (ECP) and a large study of women who accessed emergency contraception via telephone. These data give more adolescent information on timing of dose, self-selection, repeat use, diverse populations, clinic and non-clinic settings, behavioral changes over time and follow-up over several months.

(Rosebraugh & Bull, 3/23/04 Division Dir. Memo-Addendum, Tummino 30748 (emphasis added).)

Other scientists summarized the other studies in a similar manner, and with far greater attention to actual analysis of the studies than Dr. Galson's cursory rejection of them. Dr. Griebel explained:

> In summary, the actual use study is supported by large randomized controlled trials and a sizeable single arm study that closely mimicked the OTC setting in terms of self-selection

and minimal interaction with an intermediary. These supportive studies enrolled large numbers of adolescents, and showed no increase in unprotected intercourse. Impact on contraceptive use varied. Jackson showed no change in condom use, Raine 2004 and Gold 2004 showed an increase in condom users, while Raine 2000 showed a concomitant decrease in condom users with an increase in oral contraceptive (OC) users. Changes in OC use on the other studies also varied. It increased in the Raine 2004 study and increased relative to the control arm in the Gold 2004 study. It remained stable on the advanced provision arm of that study compared to the first month of the study, and was also stable on the Jackson study. Pregnancy rates and STI acquisition were similar between comparators in the studies that reported these endpoints. EC use was higher in the advanced provision arms of these studies and repeat use was higher in the advanced provision arms, but ranged from less than 10% to 15%. The Dial EC study showed a similar rate of repeat use.

Data specific to adolescents less than age 18 were provided in exploratory analyses in 3 of the large studies. Raine 2004 data show that the unprotected sex patterns of the adolescents echo those of the older age group on study and do not increase with advanced provision of EC. Never [*sic*] use of condoms also showed a similar pattern between the younger adolescents and those 18 and older in that study. Oral contraceptive use demonstrated a greater increase in the adolescent group. Gold's study also showed similar patterns of unprotected intercourse between the older and younger age groups. Condom use was highest in the youngest age group, while OC use was higher in the older age group, with a similar pattern in comparisons to control arms. . . .

. . . The Divisions do not believe these data support concern for adolescent access. They don't show substitution for regular contraceptives and incorrect timing of use in those studies that collected these data. The review divisions consider the data from the studies discussed in this section relevant and supportive for evaluation of Plan B for distribution in the over the counter setting. With the exception of the North Carolina DIAL EC study, the randomized controlled trials evaluated advance provision of emergency contraception. The Divisions believe that studies of advance provision are relevant to assessing the behavioral impact of the facilitated availability of emergency contraception through non-prescription distribution. Advance provision of EC is a form of access that makes the product more available to a woman than even OTC access, since the product is kept on hand at home for a woman to self-select when it is indicated for her. Given that the product use with advance provision is remote from the time that it is dispensed, the woman must rely on the package labeling and any written information provided to her to guide use at the time that she decides to take it. Senior CDER management has argued that the presence of an educational component in these studies, which varied amongst trials, negates the applicability of these studies to assessing the behavioral impact of improved access to EC. The Divisions disagree. They do not concur that the education provided in these trials would significantly counteract the <u>behaviors most feared</u> to result from easy access to an emergency contraceptive in a high risk adolescent population, a well-described age group known for risk-taking and inconsistent use of contraception... .

(Griebel, 4/1/04 Deputy Division Dir. Summary Review of New Drug App., Tummino 30860-61.)

Dr. Beitz agreed. She wrote:

Study Strengths

- Taken together, the sponsor's Labeling Comprehension and Actual Use studies along with the other behavioral studies described here represent a large experience on the use of EC by women at high risk for pregnancy who have been observed in a variety of clinical settings. Findings from behavioral studies that evaluated women who obtained EC in advance of need, or women who had had a prior pregnancy are very relevant to the OTC setting.
- Over a thousand adolescents aged ≤ 16 years have been evaluated, with over half participating in the Dial EC Project in North Carolina. Results from this study are very relevant to the OTC setting given that subject eligibility was not restricted, there was no interaction with a healthcare provider at an office/clinic visit, and callers had to pay for their prescriptions.
- Findings regarding the use of EC, frequency of unprotected sex, and frequency of pregnancy and STDs are remarkably consistent across studies, clinical settings, and age strata.

(Beitz, 4/2/04 Mem. Re: NDA 21-045 Levonorgestrel; Plan B Barr Research, Tummino 30888.)

3. The BTC Regime's Age Cutoff Has No Scientific Justification.

The eleventh-hour shift of the age restriction to age 18 is arbitrary and capricious on its face, being based on nothing more than the presumed incompetence of pharmacists to verify any age other than 18. In rejecting unrestricted OTC status in favor of the BTC regime, Drs. Galson and then Acting Commissioner von Eschenbach justified the agency's action as follows:

> In an August 26, 2005 memo written by Dr. Steven Galson, the Director of the Center for Drug Evaluation and Research (CDER), CDER found that for women 17 and older the existing Rx dispensing requirements for Plan B® are not necessary to protect the public health and that an Rx-only to non-prescription switch for those consumers is authorized under 21 U.S.C. 353(b)(3) and 21 CFR 310.200. CDER also determined, however, that Barr had not established that Plan B® could be used safely and effectively by young adolescents—girls 16 and younger—for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug. As a result of this scientific conclusion (with which I concur), Plan B® may not lawfully be

> made available without a prescription to this group under section 503(b) of the Federal Food, Drug, and Cosmetic Act.
>
> In considering the difficulty of enforcing an age-based restriction on the availability of this oral hormonal contraceptive, I have concluded that 18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health. The state-regulated pharmacies that will be dispensing Plan B® under Barr's voluntary CARE℠ program (as well as society as a whole) are more familiar with 18 as a cutoff age. I understand that in all 50 states, 18 is the age of majority (i.e., the legal delineation between minor and adult), and retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products. With regard to drug products, for example, the legal age to purchase FDA approved non-prescription nicotine replacement therapy products is 18. Moreover, I also understand that as a matter of state law many products routinely sold by pharmacies, e.g., tobacco products and non-prescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older.

(Tummino 10866.)

Thus, the agency has put forth not a shred of scientific or medical support for the age restriction being raised to age 18. Moreover, given that distribution is restricted to pharmacists and health care professionals at clinics – professionals who are responsible for understanding and educating consumers and patients about highly complex dosing instructions, allergic reactions to drugs, multiple drug interactions, drug contra-indications, all of which may have life-threatening consequences – it is particularly insulting – not to mention absurd – to suggest that those professionals would be incapable of discerning from government identification that a person is 17, as opposed to 18. In addition, restriction of point-of-sale to pharmacies also has no scientific justification or plausible enforcement justification, because numerous products, including tobacco, liquor, beer and lottery tickets, may not legally be sold to minors, and those age restrictions are implemented by all business entities – even convenience stores – that sell such products. Indeed, as set forth below, the FDA lacks statutory authority to restrict the distribution of OTC products.

V. The FDA's Rejection of Unrestricted OTC Status for Plan B and Its Promulgation of the BTC Regime Exceed the FDA's Statutory Mandate.

As this Court has written:

> The APA authorizes reviewing courts "to hold unlawful and set aside agency action . . . in excess of statutory . . . authority. . . ." 5 U.S.C. § 706(2). "It is 'central to the real meaning of "the rule of law," [and] not particularly controversial' that a federal agency does not have the power to act unless Congress, by statute, has empowered it to do so." *Transohio Sav. Bank v. Director, Office of Thrift Supervision,* 967 F.2d 598, 621 (D.C. Cir. 1992) (citations omitted); *Chrysler Corp. v. Brown,* 441 U.S. 281, 302 (1979). Agency actions that do not fall within the scope of a statutory delegation of authority are *ultra vires* and must be invalidated by reviewing courts. *Id. See also SEC v. Sloan,* 436 U.S. 103, 118-19 (1978); *Civil Aeronautics Bd. v. Delta Air Lines, Inc.,* 367 U.S. 316, 334 (1961); 5 U.S.C. § § 701, 706(2)(C) (1988) (authorizing judicial review of agency actions "in excess of statutory jurisdiction, authority, or limitations").

Haitian Ctrs. Council, Inc. v. Sale, 823 F. Supp. 1028, 1047 (E.D.N.Y. 1993). The FDA's actions regarding Plan B exceed its statutory authority in two respects. First, as described above at 83-84, the FDA's statutory mandate does not include regulation of personal (including sexual) behavior, and its reliance, even in part, on possible changes in the behavior of adolescents stemming from easier access to Plan B, therefore exceeds that mandate. Second, the FDA's restriction on the sale of Plan B as a nonprescription product to pharmacies exceeds its statutory authority because, as the agency itself has conceded, there is no provision in the Food, Drug and Cosmetic Act for an intermediate class of drugs between OTC and prescription products.

First, the Food Drug and Cosmetics Act itself as well as the FDA's regulations implementing the FDCA contemplate only two categories of drugs: 1) non-prescription drugs and 2) those drugs which are limited to dispensation upon a prescription. There is no statutory or regulatory provision for limiting the sale of non-prescription drugs to particular business entities, such as pharmacies.

Second, case law holds that "nowhere is FDA empowered to approve an NDA upon the condition that the drug be distributed only through specified channels." *Am. Pharm. Assoc. v. Weinberger*, 377 F. Supp. 824, 829 n.9 (D.D.C. 1974), *aff'd sub nom. Am. Pharm. Ass'n v. Mathews*, 530 F.2nd 1054 (D.C. Cir. 1976) (per curiam). In *Weinberger*, the District court rejected an FDA regulation seeking to restrict "the distribution of methadone to certain specified outlets as set forth in the regulation. In effect, it prohibits virtually all licensed pharmacies from dispensing this drug when lawfully prescribed by a physician . . . ." 377 F. Supp. at 825. Although *Weinberger* involved an attempt to restrict the distribution of a prescription drug, rather than a non-prescription drug, its holding that the FDA lacks authority to regulate the manner in which approved drugs are distributed applies with equal or greater force to the distribution of nonprescription drugs. Indeed, more recent legislation by Congress confirms that authority to regulate the distribution of nonprescription drugs that are deemed dangerous in some manner does not lie with the FDA. Since *Weinberger* was decided, the FDA itself has stated that, "The agency believes it is questionable whether the distribution of lawfully marketed OTC drugs can be restricted [to a pharmacist-only class of drugs] under current statutory provisions." FDA Response to Citizen Petitions filed by American College of Apothecaries and the National Association of Retail Druggists. FDA Docket No. 84P-0028/CP (Dec. 3, 1984) (attached hereto at Ex. E). In fact, just two weeks ago, FDA Commissioner von Eschenbach was reported to say that establishing a "behind-the-counter" class of drugs would require determining whether the FDA has authority to create it. *Von Eschenbach Promotes Behind-the-Counter Drug Class,* The Pink Sheet (Mar. 16, 2007) (Ex. E). Under *Weinberger* and the FDA's own admissions of its lack of authority to establish a new class of "behind the pharmacy counter" drugs, the BTC regime exceeds the FDA's statutory mandate. To paraphrase *Haitian Ctrs. Council*, the process

to which Plan B has "been subjected is 'extra-statutory,' and a 'third thing' nowhere authorized by" Congress. *Id*. 823 F. Supp at 1047.[36]

[36] Any argument by the FDA that Barr "voluntarily" accepted the BTC regime is belied by von Eschenbach's letter to Barr insisting that its revised application must limit access to pharmacies:

> [W]e would like to learn more about your proposal to restrict distribution of Plan B® to certain pharmacies, i.e., *the OTC version of Plan B® would not be available at gas stations, convenience stores, etc.,* but only to those pharmacies agreeing to (1) keep the OTC version of the drug behind the pharmacy counter and (2) dispense the drug only upon the production of a valid photo identification card establishing the age of the consumer. In particular, we would like to learn more about your plan to routinely monitor these pharmacies to make sure they comply with the restricted distribution plan. In addition, we are very interested in learning how you plan on enforcing the restrictions if a pharmacy fails to comply with them, *e.g.,* whether the restrictions will be incorporated into the terms of a formal contract and, if so, what the terms of that contract (particularly those terms related to a breach) look like. *If after our discussions we conclude that the CARE^{SM} Program isn't sufficiently rigorous to prevent the OTC version of Plan B® from being used by young girls who can't safely use the product without the supervision of a practitioner licensed by law to administer the drug, Plan B® will remain Rx-only for women of all ages.*

(Tummino 10864-65.)

CONCLUSION

For all the foregoing reasons, and in furtherance of restoring the scientific integrity of the FDA's drug evaluation process, this Court should enter judgment for Plaintiffs on each of the causes of action pled in the Fifth Amended Complaint and order the FDA to approve Plan B as an over-the-counter drug product without age or point-of-sale restriction.

Dated: March 31, 2007.

Respectfully submitted,

/s Simon Heller
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