



2 of 5 DOCUMENTS

ANNIE TUMMINO et al., Plaintiffs, -against- FRANK M. TORTI, * Acting Commissioner of the Food and Drug Administration, Defendant.

* Pursuant to Federal Rule of Civil Procedure 25(d), Acting Commissioner Frank M. Torti has been substituted for former Commissioner Andrew C. von Eschenbach as defendant in this case. Earlier in this litigation, Commissioner von Eschenbach was substituted for former Commissioner Lester M. Crawford, the original named defendant.

No. 05-CV-366 (ERK)(VVP)

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

603 F. Supp. 2d 519; 2009 U.S. Dist. LEXIS 23218

March 23, 2009, Decided

SUBSEQUENT HISTORY: As Corrected March 30, 2009. As Amended March 8, 2013. Reconsideration denied by, Motion denied by *Tummino v. Hamburg*, 260 F.R.D. 27, 2009 U.S. Dist. LEXIS 76585 (E.D.N.Y., Aug. 27, 2009)

PRIOR HISTORY: *Tummino v. Von Eschenbach*, 2007 U.S. Dist. LEXIS 35465 (E.D.N.Y., May 15, 2007)

COUNSEL: [**1] For Annie Tummino, in her individual capacity, as Vice-Chair of the Women's Liberation Birth Control Project, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception., Erin T. Mahoney, in her individual capacity, as Chair of the Women's Liberation Birth Control Project, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception., Carol Giardina, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception, Kelly Mangan, in her individual capacity, as President of the University of Florida Campus Chapter of the National Organization for Women, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception, Stephanie Seguin, in her individual capacity, as Chair of the Florida National Organization for

Women Young Feminist Task Force, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception, Lori Tinney, in her individual capacity, as President of the Gainesville Chapter of the National Organization for Women, as Coordinator [**2] of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception, Jennifer Brown, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of Women who need Emergency Contraception, Candace Churchill, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception, Francie Hunt, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception, Association of Reproductive Health Professionals, on its own behalf and on behalf of its members and women who need Emergency Contraception, National Latina Institute for Reproductive Health, on its own behalf and on behalf of women who need Emergency Contraception, Plaintiffs: Andrea H Costello, LEAD ATTORNEY, Florida Institutional Legal Services, Newberry, FL; Suzanne Ilene Novak, LEAD ATTORNEY, Janet Crepps, Sanford Cohen, Center for Reproductive Rights, New York, NY; Natalie N. Maxwell, Southern Legal Counsel, Inc., Gainesville, FL.

For Aurora DeMarco, Angelica Jaffe, Robert Jaffe, Aliza Lederer-Plaskett, Catherine Lederer-Plaskett, Gabrielle [**3] Marks, Jonathan Marks, Plaintiffs: Sanford Cohen, Suzanne Ilene Novak, LEAD ATTORNEYS, Bonnie Scott Jones, Janet Crepps, Center for Reproductive Rights, New York, NY; Natalie N. Maxwell, Southern Legal Counsel, Inc., Gainesville, FL.

For Lester M. Crawford, in his official capacity as acting commissioner of the Food and Drug Administration, Defendant: F. Franklin Amanat, LEAD ATTORNEY, United States Attorneys Office, Eastern District of New York, Brooklyn, NY; Michael L. Sturm, LEAD ATTORNEY, Wiley, Rein & Fielding LLP, Washington, DC.

For Dr. Andrew C. von Eschenbach, substituted in place and stead of Dr. Lester M. Crawford, Andrew C. von Eschenbach, in his official capacity as Acting Commissioner of the Food and Drug Administration, Defendants: F. Franklin Amanat, LEAD ATTORNEY, United States Attorneys Office, Eastern District of New York, Brooklyn, NY.

For State of Wisconsin, Intervenor: Richard Briles Moriarty, LEAD ATTORNEY, Nelle A. Rohlich, Wisconsin Department of Justice, Madison, WI.

JUDGES: Edward R. Korman, United States District Judge.

OPINION BY: Edward R. Korman

OPINION

MEMORANDUM & ORDER

[*522] KORMAN, J.:

Plan B is an emergency contraceptive that can be used to reduce the risk of unwanted pregnancy after sexual [**4] intercourse. When used as directed, it can reduce the risk of pregnancy by up to 89 percent. Plan B acts mainly by stopping the release of an egg from an ovary. It may also prevent sperm from fertilizing an egg that has been released or, if fertilization has already occurred, block implantation of the resulting embryo in the uterus. Plan B does not have any known serious or long-term side effects, though it may have some mild and short-term side effects, such as nausea or abdominal pain, in some users. The approved dosage of Plan B is two pills taken 12 hours apart, each containing 0.75 mg of levonorgestrel, a synthetic hormone similar to the naturally occurring hormone progesterone. Because the drug works best when taken within 24 hours of sexual intercourse, it is commonly referred to as a "morning-after

pill." Nevertheless, the drug is effective if the first dose is taken within 72 hours of sexual intercourse. Studies have shown that Plan B is equally effective if the two doses of levonorgestrel are taken less than 12 hours apart or at the same time.

Plan B was approved for prescription-only use in the United States in 1999 and is the only emergency contraceptive drug currently available [**5] in the United States. Plan B and other emergency contraceptives with the same active ingredient are available without a prescription or age restriction in much of the world, including virtually all major industrialized nations. Plaintiffs - individuals and organizations advocating wider distribution of and access to emergency contraceptives, as well as parents and their minor children seeking access to the same - brought this action challenging the denial of a Citizen Petition, [*523] which requested that the Food and Drug Administration ("FDA") make Plan B available without a prescription to women of all ages.

The FDA considered the Citizen Petition in tandem with a number of proposals - referred to as supplemental new drug applications ("SNDA") - submitted by Women's Capital Corporation, the drug's original manufacturer. Women's Capital Corporation sold its right to market Plan B to Barr Pharmaceuticals, Inc. during the course of the proceedings described below. I refer to them collectively as the "Plan B sponsor." The first SNDA, like the Citizen Petition, sought non-prescription access to Plan B for women of all ages. After the FDA denied such access, the Plan B sponsor submitted a [**6] second SNDA, seeking non-prescription access for women 16 and older. The FDA rejected that application too despite nearly uniform agreement among FDA scientific review staff that women of all ages could use Plan B without a prescription safely and effectively. The Plan B sponsor then submitted a third SNDA, which proposed making Plan B available without a prescription to women 17 and older. While FDA scientists and senior officials found that 17 year olds could use Plan B safely without a prescription, the FDA Commissioner determined that, because of "enforcement" concerns, Plan B would be available without a prescription only to women 18 and older. Putting aside for the moment the specifics of the many claims brought by plaintiffs and the details of each of the FDA's decisions, the gravamen of plaintiffs' claims is that the FDA's decisions regarding Plan B - on the Citizen Petition and the SNDAs - were arbitrary and capricious because they were not the result of reasoned and good faith agency decision-making.

Plaintiffs are right. The FDA repeatedly and unreasonably delayed issuing a decision on Plan B for suspect reasons and, on two occasions, only took action on Plan B to facilitate [**7] confirmation of Acting FDA Commissioners, whose confirmation hearings had been

held up due to these repeated delays. The first occasion involved the confirmation of then-Acting FDA Commissioner Lester M. Crawford, who froze the review process for seven months in 2005. In order to overcome a hold that had been placed on his nomination by two Senators, the Secretary of Health and Human Services promised that the FDA would act on Plan B by September 2005. After Dr. Crawford was confirmed by the Senate in July 2005, however, he reneged on the promise and, instead, delayed action another eleven months to pursue, and then abandon, a rulemaking with respect to Plan B. There is also evidence that when the FDA finally decided to approve non-prescription use of Plan B for women 18 and older, it did so to facilitate the confirmation of Commissioner Crawford's successor, then-Acting FDA Commissioner Andrew C. von Eschenbach, whose confirmation certain Senators had vowed to block because of the continued delays on Plan B.

These political considerations, delays, and implausible justifications for decision-making are not the only evidence of a lack of good faith and reasoned agency decision-making. [**8] Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use, referred to as a "switch application" or an "over-the-counter switch." For example, FDA upper management, including the Commissioner, wrested control over the decision-making on Plan B from staff that normally would issue the final decision on an over-the-counter switch application; the FDA's denial [**524] of non-prescription access without age restriction went against the recommendation of a committee of experts it had empanelled to advise it on Plan B; and the Commissioner - at the behest of political actors - decided to deny non-prescription access to women 16 and younger before FDA scientific review staff had completed their reviews.

In light of this evidence, the FDA's denial of the Citizen Petition is vacated and the matter is remanded to the FDA for reconsideration of whether to approve Plan B for over-the-counter status without age or point-of-sale restrictions. While the FDA is free, on remand, to exercise its expertise and discretion regarding [**9] the proper disposition of the Citizen Petition, no useful purpose would be served by continuing to deprive 17 year olds access to Plan B without a prescription. Indeed, the record shows that FDA officials and staff both agreed that 17 years olds can use Plan B safely without a prescription. The FDA's justification for this age restriction, that pharmacists would be unable to enforce the prescription requirement if the cutoff were age 17, rather than 18, lacks all credibility.

I now proceed to outline the statutory and regulatory framework for the FDA's consideration of over-the-counter switch applications in general, detail the FDA's evaluations of and decisions regarding Plan B, and recount the procedural history of this action. I then turn to the merits of plaintiffs' claim that the FDA's denial of the Citizen Petition was arbitrary and capricious.

I. Background

A. Statutory and Regulatory Background

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, no new drug product may be sold in the United States unless the Secretary of Health and Human Services ("Secretary") first approves a new drug application ("NDA") submitted by the drug's sponsor. *Id.* § 355. Congress [**10] delegated primary responsibility over drug regulation to the Commissioner of the FDA ("Commissioner"). *Id.* § 393(d). As part of the NDA, the drug sponsor must submit, *inter alia*, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" to the FDA. *Id.* § 355(b)(1)(A). An NDA will be denied if "the investigations ... do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions," or there is "insufficient information to determine whether such drug is safe for use under such conditions." *Id.* §§ 355(d)(1),(2),(4).

A drug must be dispensed by prescription if, "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 such [**11] drug." *Id.* § 353(b)(1)(A). A drug may be moved from prescription-only to non-prescription status when the Secretary deems that the prescription requirement is not necessary for the protection of the public health. *Id.* § 353(b)(3). Specifically, the applicable regulation provides that:

Any drug limited to prescription use ... shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful [**525] effect, or the method of its use, or the col-

lateral 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). Many new drugs are initially approved for prescription-only status and then later considered for non-prescription status, i.e., an over-the-counter or OTC switch. A drug is suitable for OTC use when found to be safe and effective for self-administration and when its labeling clearly provides directions for safe use and warnings regarding unsafe use, side effects, and adverse reactions. *See id.* § 330.10(a)(4). These regulations [**12] were promulgated following the adoption of the Durham-Humphrey Amendment to the FDCA in 1951. The amendment was intended, in part, "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." S. Rep. No. 82-946 (1951), as reprinted in 1951 U.S.C.C.A.N. 2454, 2454; H.R. Rep. No. 82-700 at 2454 (1951).

There are various means by which the FDA can switch a prescription-only drug to non-prescription status. *See* 21 U.S.C. § 353(b)(3). Such a switch can be initiated by the Commissioner, 21 C.F.R. § 310.200(b), by any interested person who files a citizen petition. *Id.* § 10.25(a). or by the request of a drug sponsor, *Id.* § 310.200(b) Within 180 days of receipt of a citizen petition, the Commissioner must either approve or deny the petition or provide "a tentative response [to the petitioner], indicating why the agency has been unable to reach a decision on the petition." [**13] *Id.* § 10.30(e)(2)(iii). If a drug sponsor seeks a switch in prescription status, it must file a supplemental new drug application (SNDA). All of the rules and procedures applicable to new drug applications, discussed above, apply to SNDAs. *Id.* § 314.71(c).

The Commissioner delegated authority over OTC switch applications to the FDA's Center for Drug Evaluation and Research ("CDER"). FDA Staff Manual Guidelines ("SMG") 1410.30(1), 1410.104(1). OTC switch applications are reviewed by two offices within CDER: the Office of Drug Evaluation ("ODE") V, which reviews all OTC switch applications, and, in this case, the ODE 111, which includes the Division of Reproductive and Urologic Drug Products ("DRUDP"). CDER may seek scientific advice from outside experts by empanelling an advisory committee to provide a recommendation on an application. After reviewing the OTC switch application and the advice of the advisory committee, the directors of the two ODEs make a decision. If the Director of CDER disagrees with that decision, the

Director may change the decision. Pls.' Ex. B at 9 (General Accountability Office, *Food and Drug Administration: Decision Process to [**14] Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual*, GAO Doc. No. GAO-06-109 (November 2005), hereinafter "GAO Report").

B. Factual Background

In February 1997, the FDA announced that certain combined oral contraceptives are safe and effective for emergency use, and requested sponsors to submit new drug applications for that use. On July 28, 1999, the FDA approved an NDA for Plan B submitted by the Plan B sponsor. Plan B then became available to consumers in the United States on a prescription-only basis.

[*526] 1. Filing of the Citizen Petition and First OTC Switch Application

On February 14, 2001, one of the named plaintiffs, the Association of Reproductive Health Professionals ("ARHP"), and sixty-five other organizations (together the "petitioners") filed a Citizen Petition, asking the FDA to switch Plan B, and all emergency contraceptives like it, from prescription-only to over-the-counter status without age or point-of-sale restrictions. The petition included affidavits from Dr. David Grimes, the chair of the World Health Organization task force that had conducted the largest and most definitive trials on Plan B to date, and Dr. [**15] Elizabeth Raymond, who conducted the label comprehension and actual use studies which the Plan B sponsor would ultimately submit in support of its SNDA. Numerous national organizations, including the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Public Health Association, endorsed the petition. Def.'s Ex. 1 at CP020-28.

Upon receipt of the Citizen Petition in February 2001, the FDA noted that (1) "[t]he petition clearly outlines how ... Plan B[] meet[s] all the criteria for OTC availability," (2) the statements in the petition "are supported by scientific data and the cited literature," and (3) "DRUDP [Division of Reproductive and Urologic Drug Products] agrees with much of the scientific information presented in the supporting statements." Def.'s Ex. 3 at T-30004. Nevertheless, Dr. Andrea Leonard-Segal of the Division of the Over-the-Counter Drug Products ("DOTCDP"), who reviewed the Citizen Petition in April 2001, identified a number of safety concerns which needed evaluation through an actual use study. *Id.* at Tummino ("T") 30023. Among these concerns were whether consumers would use emergency contraception instead of more [**16] effective forms of birth control, whether adolescent girls could comprehend and use

emergency contraception, and whether the availability of emergency contraception would dissuade consumers from being tested for sexually transmitted diseases. Dr. Segal noted that the sponsor of Plan B "expressed a willingness to work with the Agency to address the[] concerns" raised by the petition. *Id.*

On September 6, 2001, the FDA advised the petitioners that it had not yet resolved the issues raised in the Citizen Petition, but that it would respond "as soon as we have reached a decision on your request." Def.'s Ex. 1 at CP029. The FDA did not respond for nearly five more years, when it announced, on June 9, 2006, that it had denied the petition. *Id.* at CP001-19. During this period, however, the FDA communicated regularly with the Plan B sponsor about its anticipated SNDA. Indeed, in February 2001, shortly before the Citizen Petition had been filed, FDA staff met with the Plan B sponsor to discuss a development plan for an over-the-counter switch application, including the details for a proposed actual use study and label comprehension study. Def.'s Ex. 3. at T-30005-17. Specifically, the FDA made [**17] a number of recommendations regarding the age composition of participants in a proposed actual use study and the importance of enrolling young adolescents. The sponsor indicated that it would seek to enroll at least 50 participants aged 17 years of age or younger. *Id.* at T-30047. The FDA did not disapprove of this figure or recommend a larger number. *See id.* at T-30254. Indeed, in subsequent meetings prior to the filing of the SNDA, FDA staff assured the sponsor that the actual use study, the study the FDA considered "pivotal" to the application, "appear[ed] to be adequate for filing." *Id.* Moreover, as early as April 2002, the FDA informed the Plan B sponsor that results from trials in [*527] the adult population could be extrapolated to the postmenarcheal pediatric population. Pls.' Ex. F-1 at T-30100. The Director of the Office of New Drugs ("OND"), Dr. John K. Jenkins, noted that "the Agency has a long history of extrapolating findings from clinical trials in older patients to adolescents." Pls.' Ex. A-3 at T-30898.

On April 21, 2003, over two years after it had begun discussions with the FDA, the Plan B sponsor submitted an SNDA formally requesting that Plan B be switched from prescription- only [**18] to OTC status without age or point-of-sale restriction. On June 9, 2003, the FDA accepted the SNDA for review and set a goal date of February 20, 2004 to render a decision on the application. Def.'s Ex. 3 at T-30284.

2. Review of First OTC Switch Application: OTC Access Without Age Restriction

As discussed above, while the Plan B sponsor did not formally submit the SNDA until April 2003, the FDA was aware of and anticipated the application well in

advance. Indeed, at an Office of the Commissioner's meeting in June 2002, FDA officials - including then Deputy Commissioner Dr. Lester Crawford - and review staff discussed the "political sensitivity" of a potential switch to OTC status for Plan B. Pls.' Ex. A-1 at T-30167. These discussions regarding the political implications of the switch applications were not limited to intra-agency meetings: On the very same day that the Plan B sponsor first formally requested OTC status, then-FDA Commissioner Dr. Mark McClellan discussed the pending application with Jay Lefkowitz, the Deputy Assistant to the President for Domestic Policy at the White House. *Id.* at T-509. Commissioner McClellan testified that he had provided several updates on the Plan [**19] B application to relevant policy staff at the White House. Pls.' Ex. D-2 at McClellan Dep. 140:19-141:13.

Moreover, deposition testimony of several FDA senior staff members reveals that political and ideological factors played a determinative role in the nomination and selection process for membership on the Advisory Committee for Reproductive Health Drugs, which, along with the Advisory Committee for Nonprescription Drugs (together the "Advisory Committee"), was empanelled by the FDA to make recommendations as to how the FDA should respond to the OTC switch applications. *See 68 Fed. Reg. 66113 (Nov. 25, 2003).*

The common procedure for selecting members of such committees was for the offices and divisions within CDER to "put together a panel of nominees and send those up [to the Office of the Commissioner] for clearance. [However, i]n this case names were sent down." Pls.' Ex. D-1 at Houn Dep. 30:16-18; Pls.' Ex. D-2 at Kweder Dep. 37:16-20. According to Dr. Jenkins, "[i]t wasn't as if names were being floated for internal vetting. These names were being sent down as these are new people who will be on the Committee." Pls.' Ex. D-2 at Jenkins Dep. 258:12-15. The Deputy Director of the [**20] Office of New Drugs (OND), Dr. Sandra Kweder, who had been involved in the formation of many advisory committees, *id.* at Kweder Dep. 37:12-15, testified that the Office of the Commissioner appointed several individuals to the committee "who would [not] normally [be] considered as the kind of people we would be looking for to be on the panel." *Id.* at 35:3-5. These people had "very limited experience in product development, clinical trials. They were not well-published." *Id.* at 35:8-10; Pls.' Ex. D-1 at Houn Dep. 31:13- 15, 39:13-40:4. Dr. Florence Houn, Director of the ODE III, testified that the individuals appointed by the Office of the Commissioner did not have "[e]xpertise recognized on a regional or national level or specialty field [*528] that would help our deliberations." Pls.' Ex. D-1 at Houn Dep. 39:1-3.

The Office of the Commissioner appointed members to the Advisory Committee not for their expertise, but to achieve what the Office of the Commissioner called a "balance of opinion" on the panel. Pls.' Ex. D-2 at Kweder Dep. 30:2-22. Indeed, Dr. Kweder testified that the Commissioner's office rejected many qualified nominees proposed by CDER in favor of individuals who shared a common [**21] ideological viewpoint. *Id.* at 30:4-21, 28:16-29:3. Specifically, "the backgrounds of many of the candidates that were forwarded [by the Commissioner's office] ... had an ideological commonality.... They were ... people who were very active in the Right to Life antiabortion world." *Id.* at 37:4-6, 8-10. According to Dr. Kweder, the CDER is "not . . . looking for people who have an opinion coming in [to their participation on the committee]. That's exactly what we don't want. We want people who can look at what's before them and render an assessment and recommendation on the basis of that." *Id.* at 30:13-18.

In preparation for the Advisory Committee meeting, which would consider whether to recommend approval of the Plan B sponsor's switch applications, review staff met with and informed Commissioner McClellan that "[t]he results of the AUS [actual use study] demonstrated that the frequency of unprotected sex did not increase, condom use did not decrease, and the overall use of effective contraception did not decrease [with use of Plan B]." Def.'s Ex. 3 at T-30394. Staff noted that while only 5 percent of subjects recruited for the actual use study were in the 16 and younger age group, [**22] the Plan B sponsor supplemented the actual use study data with reports and behavioral studies from the medical literature. *Id.* These studies enrolled more than 1,000 subjects ages 16 and younger, Pls.' Ex. A-3 at T-30868; Pls.' A-2 at T-30809, and lent further support to a finding that young adolescents can use Plan B safely in an OTC setting.

On December 16, 2003, the Advisory Committee voted 23 to 4 in favor of the recommendation to approve Plan B for over-the-counter status without age or point-of-sale restrictions. Def.'s Ex. 2 at T-10792; it voted unanimously that Plan B is safe for use in a non-prescription setting, and voted 27 to 1 that the actual use study data submitted by the Plan B sponsor could be generalized to the overall population of potential non-prescription users of Plan B, i.e., data from older age groups could be extrapolated to younger ones. *Id.* at T-10754. Only a few panel members raised questions concerning the quality of the supporting data regarding young adolescent use and possible substitution of Plan B for other forms of contraception. See *id.* at T-10753-56, 10763-67, 10776-78, 10789, 10792. And, significantly, at least two of those raising such concerns [**23] appear to have been appointed by the Commissioner's of-

fice to achieve ideological balance on the panel. *See* Pls.' Ex. D-1 at Houn Dep. 33:19-35:20.

While the Advisory Committee does not have the final say regarding the OTC switch applications, the FDA has followed advisory committee recommendations in every OTC switch application in the last decade: Of the 23 OTC switch applications reviewed by advisory committees from 1994 to 2004, the Plan B over-the-counter switch application was the only one that was not approved after the joint committee voted to recommend its approval. *See* Pls.' Ex. B, GAO Report at 1-4, 34-35. A meeting in late December 2003 or early January 2004 sheds light on the reasons for this departure from the FDA's decision-making process.

[*529] During that meeting, Dr. Woodcock, Acting Deputy Commissioner, and Dr. Steven Galson, Acting Director for the Center for Drug Evaluation and Research (CDER), told their subordinates, Drs. Jenkins and Kweder, "that Plan B could not be approved on this round," Pls.' Ex. D-2 at Kweder Dep. 45:6-7, and that the decision was to be made at the level of CDER Director or at the Commissioner's level. Pls.' Ex. D-1 at Jenkins Dep. 17:9-11, 18:16-17. [**24] This was a departure from usual FDA procedures because under its "normal schema" a switch to OTC of a first in class drug, such as Plan B, would be handled at the Office Director level and would not require approval or sign off by the Commissioner's office. *Id.* at 16:9-21. Moreover, they were told that the White House had been involved in the decision on Plan B. Dr. Kweder testified that Dr. Woodcock had told her at that meeting that:

Dr. McClellan had [not] made [the decision] on his own but ... the White House was involved ... we were told, and that it was made very clear that there were a lot of constituents who would be very unhappy with ... an over-the-counter Plan B, and ... [there] was part of the public that needed to have the message that we were taking adolescents and reproductive issues seriously.

Pls.' Ex. D-2 at Kweder Dep. 56:18-57:4; Pls.' Reply Ex. 4 at Kweder Dep. 72:20-73:4. Moreover, the pressure coming from the White House appears to have been transmitted down by the Commissioner's office in such a way as to significantly affect Dr. Galson's position on the over-the-counter switch application. While Dr. Galson would ultimately concur with Commissioner [**25] McClellan's decision and sign the Not-Approvable letter in May 2004, Dr. Jenkins testified

that during the time that we were reviewing the Application before we went

to the Advisory Committee, I never had any indication from either Dr. Woodcock or Dr. Galson that they felt that the product should not be available over the counter without age restriction, so nothing in their communications with me ever led me to think that they were thinking that this should not be approved or should not be available.

Pls.' Reply Ex. 4 at Jenkins Dep. 231:18-232:4. Dr. Jenkins further testified that "[o]ver the course of the time after [this] lunch meeting" and subsequent meetings with review staff and the Commissioner "there were occasions where ... Dr. Galson ... told me that he felt that he didn't have a choice, and ... that he wasn't sure that he would be allowed to remain as Center Director if he didn't agree with the [Not-Approvable] Action." *Id.* at 232:5-17; *see also* Pls.' Ex. D-1 at Jenkins Dep. 51:2-8. Dr. Jenkins' testimony is corroborated by the deposition testimony of Dr. Susan Wood, then-Assistant Commissioner for Women's Health and Director of the FDA Office of Women's Health. Dr. [**26] Wood testified that Dr. Galson conveyed that "he felt that he would not be able to work with the leadership of the Agency in an effective manner if [the Not-Approvable] letter ... did not go through." Pls.' Reply Ex. 4 at Wood Dep. 24:13-16.

Nevertheless, FDA review staff continued their "first review cycle" for the OTC switch application submitted by the Plan B sponsor. On January 9, 2004, Dr. Curtis Rosebraugh, Deputy Director of the Division of OTC Drugs, recommended approval of the application submitted by the Plan B sponsor, concluding that Plan B has a "low misuse and abuse potential" and is "safe and effective." Pls.' Ex. F-1 at T-30454. Moreover, he suggested that Plan B could decrease unwanted teen pregnancy by up to 70 percent and reduce teen abortions. *Id.* at T-30455.

[*530] On January 15, 2004, less than a week after Rosebraugh circulated his memorandum, and before other FDA offices had completed their respective reviews, Dr. Galson met with and informed members of the ODE III, ODE V and OND that the Commissioner's office had decided that the FDA would issue a Not-Approvable letter because of a lack of adequate data to support appropriate use of Plan B by adolescents under 16. [**27] Def.'s Ex. 3 at T-30666-70; Pls.' Ex. D-1 at Houn Dep. 21:7-12. There is evidence that Commissioner McClellan made this decision *before* FDA staff had completed their scientific reviews of that data. *See* Pls.' Ex. B, GAO Report at 21-22. Indeed, Dr. Houn testified that it was "very unusual" that Dr. Galson had informed review staff at the

January 15, 2004 meeting that the data was insufficient because

we had not finished the evaluation process, and we were in the middle of getting data on the question of adolescent use of emergency contraception. So if we were to continue an evidence-based approach, we would hope to have all of the evidence in hand before an evaluation and decision was made.

Pls.' Ex. D-1 at Houn Dep. 22:3-9. This testimony is corroborated by Dr. Jenkins' deposition testimony:

[F]or the Commissioner to convey through Dr. Galson a definitive opinion on the Application and an Action before the reviews were completed and before it had gone up through the subsequent levels of the organization is something I've never encountered before.

Id. at Jenkins Dep. 33:12-17; *see also id.* at 29:7-19. The timing of the Commissioner's decision is particularly striking in light of Dr. Galson's [**28] acknowledgment, at the January 15 meeting, that additional data, which Dr. Galson and the Commissioner were not familiar with, existed on the use of Plan B in adolescent girls in that age group. Def.'s Ex. 3 at T-30666-70. Indeed, as part of its OTC switch application, the Plan B sponsor submitted eight behavioral studies on the use of emergency contraceptives. *See* Pls.' Ex. F-1 at T-30448-50.

Dr. Woodcock called Dr. Houn a day or two after the January 15 meeting at which the decision not to approve the Plan B sponsor's OTC switch application was announced to find out the "reaction [of] the team. [Dr. Woodcock] conveyed to [Dr. Houn] ... that this was the only way to go to issue a non-approval letter to appease the [present] administration's constituents." Pls.' Ex. D-1 at Houn Dep. 59:16-20; *id.* at 59:21-60:6; Pls.' Ex. D-2 at Kweder Dep. 55:14-56:7. Nevertheless, a week after the January meeting, Dr. Jonca Bull, Director of ODE V, circulated a memorandum which concurred with the favorable reviews submitted by a number of other FDA staff reviewers, *supra*. Dr. Bull wrote

*There is no basis on which to assume that young women of child bearing potential would suddenly become promiscuous [**29] because of this product.* Indeed, the data submitted evidenced a decrease in sexual activity short term.... I am unable to identify evidence in the medical literature to support the assertion that the

availability of contraception directly increases high risk sexual behavior.

Pls.' Ex. F-1 at T-30649-50 (emphasis added). Dr. Bull concluded that the Plan B sponsor "adequately demonstrated that women of reproductive potential across relevant age subgroups can use the product appropriately." *Id.* at T-30651.

In mid-February, FDA staff attempted to address Commissioner McClellan's expressed concerns regarding the impact of non-prescription access to Plan B on young adolescents. They presented him with an [*531] analysis of additional data available on the OTC use of Plan B by adolescents. Def.'s Ex. 3 at T-30720-21. Staff concluded that "the benefits of timely access outweighed any risk for all women, including adolescents," and supported OTC availability without any age restriction. *Id.* at T-30720. Commissioner McClellan, however, was "not convinced the studies had enough power to determine if there were behavioral differences between adults and adolescents" and directed CDER to work with the [**30] drug's sponsor on a marketing plan to restrict Plan B access to appropriate age groups. *Id.* at T-30721.

Responding to these concerns, the Plan B sponsor indicated its willingness to modify its original proposal that would have made Plan B available over-the-counter without any age restriction. Instead, the Plan B sponsor submitted an informal proposal to market Plan B OTC to consumers age 16 and over, while maintaining the product's prescription status for consumers under age 16. Def.'s Ex. 4 at SNDA 001-004. Under this proposal, both prescription and OTC Plan B would be marketed in the same package and would be distributed from behind pharmacy counters with proof-of-age required. *Id.* Notwithstanding this revised proposal, FDA scientific review staff uniformly and strongly supported approval of Plan B for OTC sales without age or point-of-sale restrictions. Numerous scientists submitted memoranda to this effect in March and April 2004. Significantly, the memoranda squarely addressed upper management concerns that there was insufficient data on young adolescent use. Reviewers analyzed the actual use data as well as data from five other studies that were submitted with the initial SNDA. [**31] Of the more than 11,000 enrollees in those studies, just over 1,000 were under 16, nearly 2,000 were 17 or younger, and at least 200 of the subjects in one study were aged 13 to 15. Pls.' Ex. A-3 at T-30868; Pls.' Ex. A-2 at T-30809 & n.5.

In reviewing the available data, Dr. Daniel Davis, Division of Reproductive and Urologic Drug Products (DRUDP) Medical Officer, squarely addressed "concern[s] over the OTC availability of emergency contra-

ception and the effect that this might have on adolescent behavior (e.g., increasing sexual promiscuity)." Pls.' Ex. A-2 at T-30810. Dr. Davis found that the data did not support these concerns, rather it "suggest[ed] that ready access to OTC Plan B . . . would have little impact on sexual behavior and contraceptive practices in younger adolescents." *Id.* at T-30812. Dr. Rosebraugh concluded similarly:

The data . . . is quite compelling to dispel any potential concerns regarding adolescent use or changes in sexual[] 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 Divisions ha[ve] approved for switch in recent memory. *If* [**32] *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.*

Id. at T-30757 (emphasis added).

The positive reviews from staff in favor of the OTC switch without age restriction continued: In April 2004, Dr. Donna Griebel, Deputy Director of Division of Reproductive and Urologic Drug Products (DRUDP), concluded that the risk-benefit ratio of non-prescription access to Plan B supported its approval for OTC status. Pls.' Ex. A-3 at T-30829-79. She concluded that there was no justification for "restrict[ing] access to the benefit of this product on the basis of age." *Id.* at T-30877. Dr. Julie Beitz, Deputy Director of ODE III, also found sufficient data on the [*532] safe and effective use of Plan B to approve use at all age levels. *Id.* at T-30881-90. With respect to the younger adolescent group, Dr. Beitz noted not only that "[o]ver a thousand adolescents aged < 16 years have been evaluated" but that the "[f]indings regarding the use of EC [emergency contraception], frequency of unprotected sex, and frequency of pregnancy and STDs are remarkably consistent across studies, clinical settings, and age strata." *Id.* [**33] at T-30888.

Later in April 2004, Dr. Jenkins, Director of the Office of new Drugs, issued his review concurring with the recommendations of ODE III and ODE V. *Id.* at T-30897-99. He concluded

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.

Id. at T-30898(emphasis added). Responding directly to concerns that the label comprehension and actual use studies enrolled too few young adolescents, Dr. Jenkins noted:

While it is true that the number of adolescents enrolled in the sponsor's studies was relatively small, these studies did not exclude adolescent women from enrollment and were *conducted in settings that would be expected to capture a representative population of women who currently seek emergency contraception. Therefore, it is likely that the percentage of patients enrolled in these studies is an accurate reflection of the potential users of Plan B in an OTC setting.*

Id. at T-30897-98 (emphasis added); *see also* Pls.' Ex. [**34] A-1 at T-10949 (Acting Director of the Division of Pediatric Drug Development concurring that number of adolescents enrolled in study reflected their actual use of Plan B and waiving pediatric study because of the minimal number of individuals of that age using Plan B).

Moreover, Dr. Jenkins concluded that the data "do[es] not suggest that adolescent women are significantly different from older women in their comprehension of the labeling or appropriate use of the product in the OTC setting." Pls.' Ex. A-3 at T-30898. He found no "compelling scientific reason" to "distinguish[] the safety and efficacy of Plan B . . . among different ages of women of childbearing potential." *Id.* To the contrary, Dr. Jenkins wrote, "the Agency has a long history of extrapolating findings from clinical trials in older patients to adolescents in both prescription and non-prescription approvals and this practice was recently incorporated into the Pediatric Research and Equity Act (PREA)." *Id.*; *see 21 U.S.C. § 355c(a)(2)(B)(ii)* ("A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.").

Nevertheless, on May 6, 2004, Dr. Galson, Acting Director [**35] of the Center for Drug Evaluation and Research, sent the Plan B sponsor a Not-Approvable letter on the initial SNDA. Pls.' Ex. A-3 at T-30904. Dr. Galson told the sponsor that before the OTC switch could be approved it needed to provide more information on safe use by women under 16, or more information in support of a dual marketing plan that would sell Plan B

as a prescription-only product to women under 16. *Id.* at T-30904. Central to this decision, was Dr. Galson's refusal to extrapolate the findings from the actual use study in the 17 and older age group (with 518 enrollees) to the 16 and younger age group (with 22 enrollees). *Id.* at T-30913; *see also id.* at [*533] T-30868. Dr. Galson reasoned that it is "very difficult to extrapolate data on behavior from older ages to younger ages" because of the diminished capacity of adolescents to make rational decisions and the "large developmental differences" between early- and mid-adolescence. *Id.* at T-30901. This conclusion was a departure from the FDA's "long history" of extrapolating data for other contraceptives, including prescription oral contraceptives. *See* T-1212-14; Pls.' Ex. B, GAO Report at 5.

Dr. Galson also rejected the view held [**36] by review staff (discussed above) that the behavioral studies the Plan B sponsor had submitted "approximate actual OTC use sufficiently to support approval." Pls.' Ex. A-3 at T-30902. Because some of the studies provided "product education assistance beyond what adolescents would receive in an OTC situation," their results could not properly be analogized to OTC use. *Id.* This conclusion, however, was contradicted by the review staff's detailed analysis of the educational component of two of these studies: the first enrolled 2,090 women, 254 of whom were 16 and younger; the second enrolled 7,756 women, where 613 were 16 and younger, and 202 were 13 to 15 years of age. Pls.' Ex. A-2 at T-30809; Pls.' Ex. A-3 at T-30861-62. Review staff found that "the information provided at study entry" in these two studies was nothing more than "a summary of the label points from the Plan B patient package insert," information which would be available to all OTC users of Plan B. Pls.' Ex. A-3 at T-30862; *see also* Pls.' Ex. F-2 at Rosebraugh Dep. 191:11-192:13. Moreover, contrary to Dr. Galson's concern that the studies had limited relevance because they were "not conducted in the general population," [**37] Pls.' Ex. A-3 at T-30902, review staff found that "several of the studies would have recruited a similar population as that used in the actual use study. Also subjects received advanced provisions to have at home for use as necessary which may simulate how consumers would use the products in an OTC environment." Pls.' Ex. F-1 at T-30449.

3. Review of Second OTC Switch Application: OTC Access for 16 and Older

After it received the May 6, 2004 Not-Approvable letter, the Plan B sponsor submitted an amended SNDA in July 2004, formally proposing a dual marketing plan for Plan B that would allow non-prescription sales to persons age 16 and over who presented a valid identification to a pharmacist, and prescription-only sales to

women 15 years and younger. The amended SNDA proposed that Plan B be kept behind-the-counter ("BTC") at pharmacies so as to enforce the age restriction on non-prescription use. This marketing approach is referred to as the behind-the-counter or "BTC regime." Nevertheless, a number of FDA scientists concluded that an age restriction limiting OTC use of Plan B was not appropriate. Dr. Davis concluded that Plan B was safe for OTC use by all ages and that prescription-only [**38] status for women under 16 was not "warranted or desirable." Pls.' Ex. A-3 at T-31020. Similarly, Dr. Rosebraugh stated that "[a]ny system placing barriers to access would defeat the purpose of the drug and lessen its public health potential." *Id.* at T-31026. Dr. Griebel expressed concern that the BTC regime would set a dangerous precedent that might have negative consequences for other non-prescription drugs, such as condoms and spermicides. Pls.' Ex. A-4 at T-31031. And Dr. Beitz questioned why Plan B had been singled out for BTC status when misuse of some other OTC products carries more safety risks than misuse of Plan B. *Id.* at T-31085-87.

Dr. Jenkins, Director of the Office of New Drugs, reiterated his view that FDA [**534] precedent supported extrapolating data from older to younger adolescent age groups, concluding that there is no unique safety concern for the drug in women under age 16. *Id.* at T-31096. He responded to upper management's concerns regarding the "developmental differences between adolescents and older women," characterizing them as beyond the scope of the FDA's authority because such concerns are "more applicable to the ability of adolescents to make reasoned decisions [**39] 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." *Id.* at T-31097. While recognizing that "OTC access to Plan B for adolescents may be controversial from a societal perspective," Dr. Jenkins could not "think of any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling." *Id.* at T-31098.

In January 2005, notwithstanding review staff's continued view that OTC access should be approved without age restriction, Dr. Galson, Acting Director of the Center for Drug Evaluation and Research, asked Dr. Jenkins to draft an approvable letter for the Plan B OTC switch application approving OTC status for women age 17 and over. Pls.' Ex. D-2 at Jenkins Dep. 145:18-147:15. Dr. Galson had concluded and informed Acting Commissioner Crawford that he was "comfortable with the science" and that OTC use of Plan B "should be approved over the counter for 17 and up." Pls.' Ex. D-1 at Crawford Dep. 140:14-15, 140:22. Acting Commissioner Crawford testified at his deposition that he concurred

with Dr. Galson's [**40] recommendation. *Id.* at Crawford Dep. 46:13-14, 49:12-20. Nevertheless, in January or February 2005, before Dr. Galson could issue the letter he had instructed Dr. Jenkins to draft, Acting Commissioner Crawford removed Dr. Galson's authority to make a decision on the OTC switch application. This was the only time Dr. Galson had had his authority to make such a decision removed and the only time he is aware of it happening to any Center of Drug Evaluation and Research Director. *Id.* at Galson Dep. 186:20-187:13.

Acting Commissioner Crawford's decision to remove Dr. Galson's authority effectively froze the review process for more than seven months - no further scientific reviews were conducted between January 2005 (the date of Dr. Jenkins' memorandum) and Acting Commissioner Crawford's first communication with the Plan B sponsor in August of 2005. As a result, the FDA failed, as required by law, to respond to the SNDA filed by the Plan B sponsor within 180 days of its filing. See 21 U.S.C. §355(c); 21 C.F.R. § 314.100(a). Moreover, during this seven month period - during which time no FDA staff appear to have worked on the Plan B matter - neither Acting Deputy Commissioner Woodcock nor [**41] Acting CDER Director Galson knew what Acting Commissioner Crawford was doing on the Plan B SNDA. Pls.' Ex. D-2 at Woodcock Dep. 68:16-22; Pls.' Ex. D-1 at Galson Dep. 202:4-9. Despite repeated inquiries from members of the Senate, Acting Commissioner Crawford failed to provide an answer as to when a decision on the Plan B switch application could be expected. This continued inaction moved Senators Patty Murray and Hillary Clinton to place a hold on his confirmation as Commissioner. To remove the hold, Michael Leavitt, the Secretary of Health and Human Services, sent a letter on July 13, 2005 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. See Def's Ltr., dated July 25, 2005. On July [**535] 18, 2005, Crawford was confirmed by the Senate as FDA Commissioner.

Notwithstanding assurances that the FDA would act by September 1, 2005, Commissioner Crawford announced in late August 2005 that he would put off the decision yet again. In a letter dated August 26, 2005, Commissioner Crawford stated that, although the "scientific data [is] sufficient to support the [**42] safe use of Plan B as an OTC product ... for women who are 17 years of age and older," the FDA is unable to reach a decision on the approvability of the application - even as to women 17 and older - because of "unresolved issues" related to the FDA's authority to approve the BTC regime of Plan B and the logistics of enforcing the age

based and point-of-sale restrictions. Def.'s Ex. 2 at T-10813-14. That same day, the FDA announced its intention to issue an advance notice of a 60-day public comment period on whether rulemaking procedures were necessary to resolve and clarify these unresolved issues. This decision presented a new obstacle to the Senate deadline of September 1, 2005 for a decision on Plan B, which had been a condition of the Senate's confirmation of Commissioner Crawford.

In August 2005, days after Commissioner Crawford's decision to further delay the decision-making on Plan B, Dr. Wood, Assistant Commissioner and Director of the FDA Office of Women's Health, resigned over the FDA's handling of the Plan B OTC switch application. Pls.' Ex. E at E006; Pls.' Ex. D-2 at Wood Dep. 13:17-14:17. In her resignation letter to Commissioner Crawford, Dr. Wood wrote:

Sadly, your [**43] recent decision to not approve Plan B emergency contraception, overturning the clear scientific and clinical evidence, contradicts both the FDA mission and my commitment to women's health. The rationale offered is not convincing, and is in fact a denial of access to a product clearly established as safe and effective for all women who need it.

Pls.' Ex. E at E006. When Dr. Wood met with Dr. Woodcock to discuss her resignation, Dr. Woodcock expressed concern that the FDA's handling of Plan B could damage her own credibility. Pls.' Ex. D-2 at Wood Dep. 40:2-19. On October 7, 2005, Dr. Frank Davidoff, a member of the FDA's Nonprescription Drug Advisory Committee, also resigned because of the FDA's delayed action on the Plan B switch application. Pls.' Ex. A-1 at T-7509-10; Pls.' Ex. D-2 at Jenkins Dep. 258:20-260:11.

The 60-day period for public comment on whether rulemaking procedures were necessary closed on November 1, 2005. The FDA received approximately 47,000 public comments and hired an outside company to review and summarize those comments. Def.'s Ex. 2 at T-11094. That review was completed six months later on May 19, 2006. *Id.* After reviewing these materials, the FDA finally concluded [**44] - more than eleven months after halting its review of the OTC switch application to seek public comment - that it was not necessary after all to engage in agency rulemaking before deciding the Plan B sponsor's OTC switch application. *Id.* Instead, on July 31, 2006, the FDA announced that "[n]on-prescription sales of [Plan B] could be approved for women 18 and older within weeks," Stephanie Saul, *F.D.A. Shifts View on Next-Day Pill*, N.Y. Times, Aug.

1, 2006, at A1, although it requested more information regarding the Plan B sponsor's plan to enforce the age and point-of-sale restrictions, which required that Plan B be kept behind the pharmacy counter. Def.'s Ex. 2 at T-11095. By this point in time, Commissioner Crawford had resigned and Dr. von Eschenbach had been made Acting Commissioner and nominated to replace him. This change in policy was announced a day before Dr. von Eschenbach's confirmation hearing.

[*536] In response to the FDA's request, the Plan B sponsor submitted yet another switch application in August 2006, this time asking the FDA to approve OTC use by women 18 and over instead of 16 and over. At the FDA's insistence, the sponsor agreed to take primary responsibility for enforcing [**45] compliance with the age restriction, to distribute the product only to licensed pharmacists, and to direct pharmacies to keep Plan B behind-the-counter. *Id.* at T-10921. Moreover, the Plan B sponsor agreed to collect data and conduct post-market research to determine the effectiveness of the Plan B dual marketing regime. *Id.* at T-10871-74, T-10915-25.

The Plan B sponsor's revised switch application conformed to the FDA's expressed willingness to entertain an application to make Plan B available without a prescription to women over the age of 18. Notwithstanding the conclusion of his immediate predecessor, Dr. Crawford, that the "scientific data [is] sufficient to support the safe use of Plan B as an OTC product ... for women who are 17 years of age and older," *id.* at T-10813-14, Commissioner von Eschenbach had decided that 18, rather than age 17, is the "more appropriate cut-off point" for OTC use of Plan B because of "well-established state and private-sector infrastructures [which] restrict certain products to consumers 18 and older." *Id.* at T-10866-67. He concluded "that to best protect and promote the public health," perceived regulatory efficiencies should outweigh the substantial [**46] health benefit 17 year old women would gain through OTC access to a drug product that - experts agreed - they could use safely and effectively. *Id.* at T-10867. The following day, Dr. Galson issued a memorandum stating that "although [he had] previously concluded that OTC use would be restricted to women 17 or older, I have now determined that for the reasons Dr. von Eschenbach outlines," OTC use of Plan B should be restricted to women age 18 and over. *Id.* at T-10870. Finally, on August 24, 2006, the FDA approved non-prescription use of Plan B for consumers 18 and older. *Id.* at T-at 10880-10925.

4. Denial of Citizen Petition

In June 2006, less than two months before the FDA announced that it would approve non-prescription use of Plan B only for women over the age of 18, the FDA is-

sued a final agency decision denying the Citizen Petition - which had requested non-prescription access to Plan B for women of all ages - finding that petitioners had failed to provide sufficient data or information to meet the statutory and regulatory requirements for an OTC switch for any age group, much less the under 16 age group. Def.'s Ex. 1 at CP001-19. The parties dispute what led the FDA to issue [**47] the denial of the Citizen Petition when it did. Plaintiffs claim the FDA's action was a litigation tactic: that the FDA used the denial as a means of bringing discovery to a halt, particularly plaintiffs' discovery requests seeking documents describing the White House's role in the FDA's handling of the Plan B switch applications. The FDA asserted that it responded when it did, in part, because of the public interest in the petition and plaintiffs' amendment of their complaint to allege that the FDA had unreasonably delayed responding to the petition. *Id.* at CP003 & n.2.

Nevertheless, the record is clear that the FDA took more than five years to respond to the petition after it provided its tentative response in September 2001. Moreover, even though the May 6, 2004 Not-Approvable Action letter on the Plan B sponsor's SNDA effectively rejected the full relief sought by the Citizen Petition - unrestricted OTC access to Plan B - the FDA waited more than two years from [**537] that date to formally deny the petition. Perhaps more significantly, the FDA acknowledged that the issues presented by the SNDAs and the Citizen Petition were one and the same. Indeed, in the denial letter the FDA informed [**48] petitioner that "we had intended to defer our response to your petition until we could issue a response contemporaneously with our issuance of a final decision on [the Plan B sponsor]'s SNDA," *id.* at CPO17, because "we expected that some or all of the issues you raised in your petition would be resolved in the ... anticipated SNDA proceeding." *Id.* at CPO13.

C. GAO Investigation

At the request of members of Congress, including 19 Senators and 29 Representatives, the Government Accountability Office ("GAO") initiated an investigation into the process which led to the issuance of the May 6, 2004, Not-Approvable letter, denying the initial supplemental new drug application filed by the Plan B sponsor. *See* Pls.' Ex. B, GAO Report. The Congressional request emanated from concern that "the not-approvable decision for the initial Plan B OTC switch application was contrary to the recommendations of the joint advisory

committee and the FDA review staff." *Id.* at 3. For this reason, the GAO Report examined,

- (1) how the decision was made to not approve the switch of Plan B from prescription to OTC, (2) how the Plan B de-

cision compares to the [67] decisions for other proposed prescription-to-OTC [**49] switches from 1994 through 2004, and (3) whether there are age-related marketing restrictions for prescription Plan B and other prescription and OTC contraceptives.

Id. at 3-4. The investigation was limited in scope to the FDA's actions leading up to the May 6, 2004 Not-Approvable letter for the initial SNDA, *id.* at 4, and did not take into consideration the Citizen Petition or later SNDAs. Nevertheless, the findings of a congressional agency provide relevant background to this litigation and confirm conclusions that are compelled by the record here.

In reviewing the FDA's decision regarding the OTC switch application, the GAO concluded that four aspects of the FDA's review process were "unusual" and departed from the typical FDA review procedures. *Id.* at 5. First, it noted that "the Directors of the Offices of Drug Evaluation III and V, who would normally have been responsible for signing the Plan B action letter, disagreed with the decision and did not sign the not-approvable letter for Plan B." *Id.* For the same reasons, the Director of the Office of New Drugs, Dr. Jenkins, also did not sign the letter. *Id.* Second, the GAO found that the FDA's senior leadership was more heavily involved [**50] in Plan B than it was in other OTC switch applications. Specifically, GAO investigators wrote that "FDA review staff told us that they were told early in the review process that the decision would be made by high-level management." *Id.* Third, the GAO noted that "there are conflicting accounts of whether the decision to not approve the application was made before the reviews were completed." *Id.* The Director and Deputy Director of OND and Directors of ODE III and V told GAO "that they were told by high-level management that the Plan B OTC switch application would be denied months before staff had completed their reviews of the application." *Id.* at 21. Dr. Galson, however, told GAO that while he was '90 percent sure' as early as January 2004, that the decision would be not-approvable," he did not make his final decision until shortly before the action letter was sent out in May 2004. *Id.* at 22. Finally, the GAO concluded that "the rationale for [Dr. Galson's] decision was novel and did not follow FDA's traditional practices." *Id.* at 5. [**538] Specifically, it noted that he was "concerned about the potential impact that the OTC marketing of Plan B would have on the propensity for younger adolescents [**51] to engage in unsafe sexual behaviors because of their lack of cognitive maturity compared to older adolescents" even though "the agency has not con-

sidered behavioral implications due to differences in cognitive development in prior OTC switch decisions." *Id.* In addition, Dr. Galson "stated that it was invalid to extrapolate data from older to younger adolescents in this case" even though "the agency has considered it scientifically appropriate" to do so. *Id.*

With respect to how the Plan B decision compared to that for other proposed OTC switches, the GAO found that "the Plan B OTC switch application was the only I of th[e] 23 [switch applications reviewed by the joint advisory committee from 1994 to 2004] that was not approved after the joint committee voted to recommend approval of the application." *Id.* The GAO also pointed out that "the Plan B action letter was the only one signed by the Director of CDER ... instead of the directors of the offices or divisions that reviewed the application, who would normally sign an action letter." *Id.*

In its final area of examination, the GAO concluded that "there are no age-related marketing restrictions for safety reasons for any of the prescription [**52] or OTC contraceptives that FDA has approved, and FDA has not required pediatric studies for them." *Id.* at 6. In particular, it noted, "[a]ll FDA-approved OTC contraceptives are available to anyone, and all FDA-approved prescription contraceptives are available to anyone with a prescription." *Id.* at 6. Finally, the GAO noted that the "FDA did not identify any issues that would require age-related restrictions in its review of the original application for prescription Plan B, and prescription Plan B is available to women of any age." *Id.*

D. Litigation History

1. The Complaints

Plaintiffs brought this action in January 2005 against Lester M. Crawford, then Commissioner of the FDA, pursuant to the Administrative Procedure Act ("APA"), and the Constitution. Plaintiffs challenge the FDA's denial of the Citizen Petition seeking to make Plan B available on an over-the-counter basis without age or point-of-sale restriction.

In their most recent amended complaint, plaintiffs allege that the denial of the over-the-counter switch for women of all ages and the imposition of the BTC regime (1) is arbitrary, capricious, and otherwise contrary to law, Compl. P 163; (2) exceeds the FDA's statutory authority, [**53] *id.* P 165; (3) violates women's rights to privacy, *id.* P 167; (4) discriminates against women and those persons wishing to exercise their right to privacy in violation of the *Fifth Amendment's Equal Protection Clause*, *id.* PP 169-70; and (5) violates women's rights to informational privacy. *Id.* P 172. Plaintiffs seek an injunction requiring the FDA to approve the OTC switch without

age or point-of-sale restrictions and a declaratory judgment that the FDA's actions violate the APA and the Constitution. *Id.* P 1.

Underlying all of these claims is plaintiffs' allegation that the FDA's decisions were made in bad faith because they were improperly influenced by political considerations wholly outside the scope of the FDA's statutory authority. Specifically, plaintiffs allege that, in refusing to approve over-the-counter access without age or point-of-sale restriction, the FDA bowed to political pressure from the White House and anti-abortion constituents despite the, uniform recommendation of the FDA's scientific review staff to approve over-the-counter access to Plan B without limitation.

[*539] 2. Dispositive Motions

Plaintiffs have moved for summary judgment on all of their claims pursuant to *Rule 56 of the Federal Rules of Civil Procedure*. [**54] The FDA has cross-moved to dismiss for lack of subject matter jurisdiction pursuant to *Rule 12(b)(1)* or, in the alternative, for summary judgment pursuant to *Rule 56*. The FDA had argued earlier in this litigation (though not in the present motions) that jurisdiction lies exclusively in the Court of Appeals. Before discussing the issues raised by the present dispositive motions I briefly address this issue here.

The FDCA contains no overarching section on judicial review, but makes specific allocations of jurisdiction over specific types of cases to the Court of Appeals. Thus, while the FDCA grants jurisdiction to the Court of Appeals over a sponsor's challenge to the denial of a new drug application, see *21 U.S.C. § 355(h)*, it contains no provision applicable to a petitioner's challenge of the denial of its citizen petition. The D.C. Circuit has held that "[a]gency 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." *Cutler v. Hayes*, 260 U.S. App. D.C. 230, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987). Moreover, FDA regulations [**55] make clear that petitions for judicial review of a citizen petition may be filed in district court. See *21 C.F.R. § 10.45(g)*.

II. Discussion

A. Standing

Article III of the Constitution limits the role of the judiciary to the resolution of "cases" and "controversies." *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471, 102 S. Ct. 752, 70 L. Ed. 2d 700 (1982). The question of standing is "whether the plaintiff is the proper party to

bring [the] suit." *Raines v. Byrd*, 521 U.S. 811, 818, 117 S. Ct. 2312, 138 L. Ed. 2d 849 (1997). Moreover, the conclusion that an individual has standing to bring an action occurs before addressing the merits of that individual's claim. *Id.* at 820. Standing means that the individual bringing the claim has "establish[ed] that [his or her] claimed injury is personal, particularized, concrete, and otherwise judicially cognizable." *Id.* In order for a case to be properly before a court, plaintiffs must establish constitutional and prudential standing. Here, plaintiffs are responding to a motion to dismiss, so their allegations in the complaint must be accepted as true for purposes of standing. *See Warth v. Seldin*, 422 U.S. 490, 501, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975) (when plaintiffs respond to a motion [**56] to dismiss for lack of standing, "both the trial and reviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party").

1. Constitutional Standing

Constitutional standing requires a plaintiff to show (1) an "injury in fact" which is (2) "fairly traceable" to the defendant's conduct and (3) likely to be redressed by the requested relief. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992). An "injury in fact" is defined as "an invasion of a legally protected interest which is (a) concrete and particularized ... and (b) 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 560 (citations omitted). The plaintiff bears the burden of establishing each element of standing. *Id.* at 561.

Plan B is most effective when taken within 24 hours of sexual intercourse and loses its effectiveness if taken later than 72 hours after intercourse. Thus, the [**540] delay occasioned by having to obtain a prescription from a licensed physician prior to purchasing Plan B may increase the chance of unwanted pregnancy. As approved, Plan B is a behind-the-counter (BTC) drug for which the adolescent plaintiffs, who are all [**57] under the age of 16, must obtain a prescription. The prescription requirement presents substantial obstacles to the adolescent plaintiffs' quick access to Plan B. For Plan B to be effective, an adolescent plaintiff must locate and visit a doctor before locating and obtaining Plan B at a pharmacy, all within 72 hours of sexual intercourse. *See, e.g.,* Pls.' Reply Ex. 1 at Angelica Jaffe Dec. PP 6, 10. Any delay encountered during this process may render access to Plan B useless. Moreover, the fear and anxiety that delayed access to Plan B may cause the adolescent plaintiffs is sufficient to meet the injury in fact requirement. Indeed, the Second Circuit has held that "[i]njury in fact is a low threshold, which . . . 'need not be capable of sustaining a valid cause of action,' but 'may simply be the

fear or anxiety of future harm.'" *Ross v. Bank of Am., N.A. (U.S.A.)*, 524 F.3d 217, 222 (2d Cir. 2008). Because of the burden imposed by the prescription requirement and the fear and anxiety it causes, the adolescent plaintiffs have alleged sufficient injury from the FDA's denial of the Citizen Petition.

The FDA argues that the adolescent plaintiffs have suffered no injury because their parents [**58] may obtain Plan B on behalf of their daughters without having to obtain a prescription. Passing over the validity of the assumption that parents would in fact obtain Plan B for their adolescent daughters in advance, this argument ignores statutory provisions which prohibit the dispensing of a prescription drug other than upon the "written prescription of a practitioner licensed by law to administer the drug." 21 U.S.C. § 353(b). Parents who obtain Plan B to provide it to their daughters, absent a prescription for their daughters' use, would be engaged in a prohibited act under the FDCA, *id.* §331(k), for which they may be "imprisoned for not more than one year or fined not more than \$ 1,000, or both." *Id.* § 333(a)(1). The FDA argues that there is no evidence a parent who provided Plan B to his or her own child would be prosecuted. The suggestion that it would be appropriate for parents to violate the FDCA misses the point. That the threat of prosecution is unlikely does not sufficiently address the injury to the adolescent plaintiffs. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 154, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967).

The MAP Conspiracy plaintiffs, individual members of - the Morning-After Pill Conspiracy who bring [**59] suit as individuals and in their organizational capacity, adequately allege injury with respect to their own use of Plan B. Compl. PP 4-14; *see* Pls.' Ex. C-1 at Jenny Brown Dec. The burden imposed by the point-of-sale restriction may so delay a woman's ability to obtain Plan B quickly that it would reduce the efficacy of the drug and increase the chance of unwanted pregnancy. Brown Dec. PP 4, 5, 9. For some women, it may be nearly impossible to find an open pharmacy or health clinic quickly enough after engaging in unprotected sex for Plan B to be effective. *Id.* at P 3.

While the FDA challenges only the injury component of the standing inquiry, it is necessary to evaluate the remaining two elements: causation and redressability. Here, the claimed injuries are clearly traceable to the FDA's actions. Each plaintiff claims a specific injury resulting from the FDA's denial of OTC access without restriction and implementation of the BTC regime for Plan B. The FDA's action prevents the adolescent plaintiffs from obtaining Plan B without a prescription. It also limits its availability to the MAP Conspiracy [**541] plaintiffs because they must produce government identification to obtain the drug, and [**60] may only do so at a pharmacy or health clinic. There is no question that

the FDA has directly affected these plaintiffs' access to Plan B. Moreover, these plaintiffs have also shown that their injuries would be redressed if the FDA was ordered to approve OTC use of Plan B without age or point-of-sale restrictions or if on remand the FDA reconsidered and removed these restrictions.

2. Prudential Standing and the Zone of Interests

The FDA argues that even if plaintiffs have constitutional standing, they lack prudential standing because they do not fall within the zone of interests of the FDCA. Prudential standing requires that "the constitutional or statutory provision on which the claim rests properly can be understood as granting persons in the plaintiff's position a right to judicial relief." *Warth*, 422 U. S. at 500. In other words, to establish prudential standing, "a plaintiff's grievance must arguably fall within the zone of interests protected or regulated by the statutory provision or constitutional guarantee invoked in the suit." *Bennett v. Spear*, 520 U.S. 154, 162, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997). The prudential standing test denies review if the plaintiffs interests are only "marginally related" to [**61] the statute's purpose, but prudential standing is not intended to be a harsh barrier to the courts. *Clarke v. Secs. Indus. Ass'n*, 479 U.S. 388, 399, 107 S. Ct. 750, 93 L. Ed. 2d 757 (1987). Indeed, the zone of interests encompasses "parties whose interests, while not in any specific or obvious sense among those Congress intended to protect, coincide with the protected interests." *Hazardous Waste Treatment Council v. Thomas*, 280 U.S. App. D.C. 296, 885 F.2d 918, 922 (D.C. Cir. 1989).

Both the adolescent plaintiffs and the MAP Conspiracy plaintiffs meet prudential standing requirements. The FDA argues that the FDCA was not intended to provide anonymous access to emergency contraception. Plaintiffs, however, do not argue this to be the FDCA's purpose. Instead, they argue that the FDCA's purpose goes beyond simply protecting consumers from dangerous or harmful drugs. Plaintiffs rely on *DeFreese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959), in which the Fifth Circuit held that section 353(b)(1) of the FDCA was intended, in part, to relieve pharmacists and the public from burdensome restrictions regulating the dispensing of drugs that are sold without a physician's supervision. *Id.* (citing H.R. Rep. No. 82-700 at 2454 (1951)); *see also* S. [**62] Rep. No. 82-946 (1951), *as reprinted in* 1951 U.S.C.C.A.N. 2454, 2454. The adolescent plaintiffs fall within the zone of interests of the FDCA because they are among the class of individuals whom the statute was intended to protect by providing non-prescription access to a drug when a prescription would be "burdensome and unnecessary." *Id.* Plaintiffs have alleged that the prescription requirement is unne-

cessary because young adolescents can use Plan B safely without a prescription. Whether it is, in fact, unnecessary goes to the merits of plaintiffs' claims, not to standing. *See Ross*, 524 F.3d at 222 ("the fact that the injury may be outweighed by other benefits . . . does not negate standing."). The MAP Conspiracy plaintiffs also fall within the zone of interests of the FDCA because they can claim they should not be subjected to the burdensome restriction of having to locate a pharmacy that sells Plan B and produce valid identification in order to obtain it.

B. Review of Agency Action under the Arbitrary and Capricious Standard

The APA provides that a district court may set aside an agency's findings, conclusions [**542] of law or action only if they are "arbitrary, capricious, an abuse of discretion, [**63] or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency decision may be deemed arbitrary and capricious:

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.

Motor Vehicle Mfrs. Assn of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983); *accord Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 79 (2d Cir. 2006). Moreover, "proof of subjective bad faith by [agency decision-makers], depriving a [petitioner] of fair and honest consideration of its proposal, generally constitutes arbitrary and capricious action." *Latecoere Int'l, Inc. v. U.S. Dept. of Navy*, 19 F.3d 1342, 1356 (11th Cir. 1994); *James Madison Ltd. v. Ludwig*, 317 U.S. App. D.C. 281, 82 F.3d 1085, 1096 (D.C. Cir. 1996) (bad faith is "material to determining whether the Government acted arbitrarily").

While this standard of review is deferential, courts "do not hear cases merely to rubber stamp agency actions. To play that role [**64] would be tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act." *Nat'l Res. Def. Council v. Daley*, 341 U.S. App. D.C. 119, 209 F.3d 747, 755 (D.C. Cir. 2000) (quoting *A.L. Pharma, Inc. v. Shalala*, 314 U.S. App. D.C. 152, 62 F.3d 1484, 1491 (D.C. Cir. 1995)). On the contrary, to be upheld upon judicial review, the agency must have articulated "a rational con-

nection between the facts found and the choice made." *Henley v. Food and Drug Admin.*, 77 F.3d 616, 620 (2d Cir. 1996) (quotations marks omitted).

C. The Proper Record on Review

Before applying the foregoing standard, it is necessary to consider the threshold issue of the proper record on review. Throughout this litigation, the FDA has attempted to sever the relationship between its review of the supplemental new drug applications (SNDAs) submitted by the Plan B sponsor and the Citizen Petition, arguing that judicial review of its denial of the Citizen Petition must be limited to the administrative record compiled for the Citizen Petition alone. Consistent with this position, the FDA moved to strike from plaintiffs' motion all references to, and attachments of, materials not contained in the administrative record for the Citizen Petition, [**65] including all materials contained in the administrative record for the SNDA and all declarations, deposition transcripts, and documents obtained in discovery.

The FDA relies on the rule that a reviewing court must judge the propriety of administrative agency action "by the grounds invoked by the agency." *Secs. Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196, 67 S. Ct. 1575, 91 L. Ed. 1995 (1947). "[T]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44, 105 S. Ct. 1598, 84 L. Ed. 2d 643 (1985). "Generally, a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision." *Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (citing *Fla. Power*, 470 U.S. at 743-44). The rationale behind the "record rule" is that a reviewing court, "in dealing with a determination or judgment which an administrative agency alone is authorized to make," [*543] *Chenery*, 332 U.S. at 196, should not conduct a *de novo* trial, review materials not before the agency when the decision was made, or substitute its opinion for that [**66] of the agency.

None of the dangers the record rule is designed to prevent are implicated by consideration of the materials in the administrative record for the SNDAs submitted by the Plan B sponsor because these materials were "before the agency when the decision was made" and because the FDA itself relied on those materials when it denied the Citizen Petition. Indeed, from the very beginning, FDA staff acknowledged that the Plan B sponsor would work with the FDA to address any concerns raised by the Citizen Petition. Def.'s Ex. 3 at T-30023. Moreover, no meaningful review of the denial of the Citizen Petition would be possible without a review of the administrative

record for the SNDAs because the FDA understood the issues presented by the SNDAs and Citizen Petition to be one and the same. The FDA conceded as much when, in its denial of the Citizen Petition, it wrote that it "expected that some or all of the issues ... raised in [the] petition would be resolved in the then-anticipated SNDA proceeding; in fact, they might still be resolved in that proceeding," Def.'s Ex. 1 at C013.

The FDA's actions and decisions with respect to the initial SNDA were inextricably tied to its decision-making [**67] on the Citizen Petition. And the later decisions, which occurred after the denial of the Citizen Petition, are relevant to a review of the decision on the Citizen Petition because, by the FDA's own admission, those later decisions "resolved" some of the issues raised in the Citizen Petition. In short, the complete "record" for the FDA's decision regarding the Citizen Petition includes its own administrative record for both the Citizen Petition and the SNDAs.

Moreover, the law is clear that, despite the "record rule," a reviewing court may consider extra-record materials in certain circumstances. *See Nat'l Audubon*, 132 F.3d at 14. Indeed, "a strong showing of bad faith or improper behavior" may justify supplementing the record. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420, 91 S. Ct. 814, 28 L. Ed. 2d 136 (1971). Thus, when the agency action cannot be adequately explained in the record it compiled, the court's consideration of evidence outside the agency's "administrative record" is not only warranted, *Esch v. Yeutter*, 278 U.S. App. D.C. 98, 876 F.2d 976, 991 (D.C. Cir. 1989), but necessary to a meaningful judicial review of the agency's action. *See Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980) (agency record may [**68] be supplemented when additional information "fully explicate[s] . . . [the agency's] course of conduct" in reaching its decision.).

U.S. Magistrate Judge Pohorelsky, who presided over various discovery disputes, and I both have found that plaintiffs have made a strong showing that the FDA acted in bad faith with respect to the Plan B switch applications. *See, e.g., Tummino v. von Eschenbach*, 427 F. Supp. 2d 212, 231-34 (E.D.N.Y. 2006); Oct. 11, 2006 Hr'g Tr. 20; July 26, 2006 Hr'g Tr. 9:1; Dec. 22, 2005 Hr'g. Tr. 95. The FDA argues that U.S. Magistrate Judge Pohorelsky's finding of bad faith was limited to its failure at the time to make a final decision with regard to either the Citizen Petition or the initial SNDA. Thus, it argues that finding is now irrelevant because it has made a final decision and plaintiffs have abandoned their unreasonable delay claim as moot. This argument might have some plausibility if this was the only evidence of bad faith. Instead, it was merely the tip of the iceberg.

Thus, U.S. Magistrate Judge Pohorelsky observed that there was a "real" concern [*544] about the general "integrity of the FDA's decisionmaking in connection with OTC access to Plan B." *Tummino*, 427 F. Supp. 2d at 234. He noted the unusual involvement [*69] of FDA upper management in the review process; evidence that FDA officials were motivated by "improper concerns about the morality of adolescent sexual activity;" evidence that the decision not to approve the OTC switch was made before review staff had completed their reviews; the refusal to adopt the recommendations of professional review staff and the Advisory Committee; the resignations of Drs. Wood and Davidoff; and the GAO's findings of procedural irregularities in the FDA's consideration of the Plan B OTC switch. *Id.* at 231-34. Indeed, the FDA's conduct and the chain of events leading up to the decision on the Citizen Petition cannot be fully understood without reviewing the administrative record the FDA compiled with respect to the Plan B sponsor's OTC switch applications, the deposition testimony of key FDA decision-makers and other materials illuminating these decision-making processes and the extent to which impermissible political and ideological considerations influenced the FDA's decisions on the Plan B switch applications.

D. The FDA's Decision Was Not the Result of Good Faith and Reasoned Agency Decision-Making

Plaintiffs have presented un rebutted evidence of the FDA's [*70] lack of good faith regarding its decisions on the Plan B switch applications. This lack of good faith is evidenced by, among other things, (1) repeated and unreasonable delays, pressure emanating from the White House, and the obvious connection between the confirmation process of two FDA Commissioners and the timing of the FDA's decisions; and (2) significant departures from the FDA's normal procedures and policies in the review of the Plan B switch applications as compared to the review of other switch applications in the past 10 years. I address each in turn.

1. Improper Political Influence

"To support a claim of improper political influence on a federal administrative agency, there must be some showing that the political pressure was intended to and did cause the agency's action to be influenced by factors not relevant under the controlling statute." *Town of Orangetown v. Ruckelshaus*, 740 F.2d 185, 188 (2d Cir. 1984). An agency's consideration of some relevant factors does not "immunize" the decision; it would still "be invalid if based in whole or in part on the pressures emanating from [political actors]." *D.C. Fed'n of Civic Assocs. v. Volpe*, 148 U.S. App. D.C. 207, 459 F.2d 1231, 1246, 1248 (D.C. Cir. 1971).

The [*71] D.C. Circuit's decision in *D.C. Fed'n* is instructive. *D.C. Fed'n* involved the approval of a bridge construction project over the Potomac River by the Secretary of Transportation. While the agency decision was pending, an influential Congressman made public statements that he would do everything in his power to block appropriations for the D.C. subway system until the bridge project was approved. *Id.* at 1236. The D.C. Circuit found the Congressman's statements had improperly influenced the Secretary's decision to approve the bridge project. Although the lack of a sufficient administrative record for the decision troubled the court, it held that "[e]ven if the Secretary had taken every formal step required by every applicable statutory provision, reversal would be required . . . because extraneous pressure intruded into the calculus of considerations on which the Secretary's decision was based." *Id.* at 1245-46. Thus, while the FDA may have considered certain relevant factors in deciding to restrict OTC access to Plan B, *D.C. Fed'n* suggests that [*545] the mere existence of "extraneous pressure" from the White House or other political quarters would render its decision invalid.

Another case, [*72] *Latecoere Int'l, Inc. v. U.S. Dep't of Navy*, 19 F.3d 1342 (11th Cir. 1994), whose facts are analogous to those here, also supplies compelling support for plaintiffs' position that the FDA's bad faith renders its decision arbitrary and capricious. There, a disappointed bidder on a Navy contract, Latecoere, challenged the Navy's decision to award a pilot training system contract to a competitor, ETC. Specifically, Latecoere argued that no rational basis existed for awarding the contract to ETC and that the award was motivated by bias for ETC, an American company, and against Latecoere, a French company. *Id.* at 1344. Under a Memorandum of Understanding between the United States and France, the Navy was required to treat all French firms as it would an American firm. *Id.* at 1346-47. In the initial review of proposals for the contract, the experts charged with assisting in the decision "all agreed that Latecoere's proposal was acceptable and ETC's was not." *Id.* at 1347. Despite this recommendation, however, the officials within the Office of the Secretary of the Navy decided to award the contract to ETC. *Id.* at 1351. Notwithstanding evidence that the decision was based on the "potential [*73] political consequences of . . . awarding the contract to a foreign company," *id.* at 1350-51, the Navy justified the decision on the basis of cost. *Id.* at 1352. The Eleventh Circuit held that "by the simple expedient of denying bias, a government official can [not] wipe away all evidence of it." *Id.* at 1365. Referring to the actions of the official charged with overseeing the contract award decision, the court wrote:

Assistant Director Ford[s] . . . actions evidencing bias speak louder than his

words denying it. When the matter came to him, the forty or so experts of the Evaluation Board, after carefully studying all of the proposals, had found that ... Latecoere . . . [was] capable of satisfying the requirements for constructing the system; ETC was not. The Advisory Council, composed of the senior officials of the Training Center, had agreed with that finding and recommended that the contract be awarded to Latecoere. The original Selection Authority . . . had chosen Latecoere, warning in a selection decision document that the proposals of ETC and two other domestic corporations were "unacceptable" and that awarding the project to an unacceptable offeror, such as ETC, would risk the [**74] loss of human lives. In the face of all of those uniform recommendations - and in spite of the warnings about human lives being at stake -- Ford refused to sign off on the decision to award the contract to Latecoere. Instead, after his senior procurement analyst raised "Buy American" considerations and political ramifications, Ford demanded that negotiations be conducted with all the companies no matter how "unacceptable" their offers were. Furthermore, Ford did so only after expressing his own concern about the political problems of awarding the contract to a French company when American companies had been found to be outside the competitive range. Whatever Ford may have said later when pinned down and speaking "on the record," the evidence strongly supports the inference that his actions manifested bias. Those actions sent a message that was heard -- and responded to -- during the remainder of the ... procurement process.

Id. at 1365.

Just as in *Latecoerethe* Advisory Committee and FDA scientific review staff strongly recommended approving Plan B OTC without age restriction, finding that [**546] restricting access to young adolescents would present greater health risks than making Plan B freely available. [**75] And just as in *Latecoere*, despite this recommendation, the FDA refused to approve the Citizen Petition and first SNDA submitted by the Plan B sponsor. Instead, before the scientific reviews were complete,

the Commissioner decided that unrestricted OTC access could not be approved, because of his concern about the inadequacy of data available for young adolescents. Plaintiffs have proffered evidence that the Commissioner did not make the decision on his own, but was pressured by the White House and "constituents who would be very unhappy with . . . an over-the-counter Plan B." Pls.' Ex. D-2 at Kweder Dep. 56:21-22. There is also evidence that the Commissioner transmitted this pressure down the chain of command at the FDA: pressuring Dr. Galson not to approve over-the-counter use of Plan B without age restriction, *see* Pls.' Reply Ex. 4 at Jenkins Dep. 232:5-17; *id.* at Wood Dep. 24:9-22; and removing Dr. Galson's authority to make any decision on Plan B after he told the Commissioner that he believed Plan B could be used safely OTC by adolescents 17 and older. Pls.' Ex. D-1 at Galson Dep. 186:20-187:18. Moreover, despite the overwhelming evidence that Plan B could be used safely and effectively [**76] by 17 year olds without a prescription, the FDA, citing fanciful and wholly unsubstantiated "enforcement" concerns, arbitrarily and capriciously limited that age groups access to Plan B.

Indeed, the evidence strongly suggests that even the decision to permit the OTC sale of Plan B to women over the age of 18 was made solely to facilitate the confirmation of Dr. von Eschenbach as Commissioner of the FDA. This change of policy came one day before Dr. von Eschenbach's confirmation hearing before a Senate committee. *See* Stephanie Saul, *F.D.A. Shifts View on Next-Day Pill*, N.Y. Times, Aug. 1, 2006 at A1. Dr. von Eschenbach had become Acting Commissioner after the resignation of his predecessor, Dr. Crawford, and he was subsequently nominated to be Commissioner. Significantly, Senators Hillary Clinton and Patty Murray had previously vowed to block any vote on Dr. von Eschenbach's nomination until the FDA decided whether to allow over-the-counter sales of Plan B. *Id.*; Gardiner Harris, *Bush Picks F.D.A. Chief; but Vote is Unlikely Soon*, N.Y. Times, Mar. 16, 2006 at A1 8. Since the FDA had already reneged on its earlier promise to promptly reach a final decision on Plan B in order to obtain former-Commissioner [**77] Crawford's confirmation, it must have been apparent to the FDA that a mere promise to decide would no longer suffice to secure Dr. von Eschenbach's confirmation.

This inference, that the timing of the FDA's decision was linked to Dr. von Eschenbach's confirmation hearings, is buttressed by representations made by the attorneys representing the FDA during this litigation. At a hearing in this proceeding only one week before the FDA decided to act on Plan B, I inquired why, if the FDA had determined that women 17 and older could use Plan B safely, it had not yet approved over-the-counter use for that age group. July 26, 2006 Hr'g Tr. 17:9-14. The at-

torneys representing the FDA - an Assistant United States Attorney with an FDA attorney at his side - responded that "the [FDCA] does not provide the agency - at least it does not clearly provide the agency with the statutory authority to make that kind of age based distinction." *Id.* at 19:11-14. Under the FDCA, he continued, "a product is either Rx only or non-prescription," *id.* at 20:19-20, "[t]here is no behind the counter option available under federal law." *Id.* at 20:14-15. "Congress, [he said,] has not given [the FDA] an enforcement [**78] mechanism that would provide it with an ability to enforce that kind of age restriction." *Id.* at 22:7-9. [*547] Nevertheless, within a month of this representation, the gap in the FDA's authority had somehow been filled and Dr. von Eschenbach confirmed.

2. Departures from Its Own Policies

The evidence of lack of good faith is also confirmed by the manner in which the FDA departed from its normal procedures for evaluating OTC switch applications when it considered the Plan B applications. The most glaring procedural departure was the decision to act against the Advisory Committee's recommendation to approve the Plan B OTC switch application without age restriction. Pls.' Ex. B, GAO Report at 29. While advisory committees do not have the final say on OTC switch applications, the fact remains that in every such application in the last decade, the FDA has followed committee recommendations.

The FDA's decision regarding Plan B departed from its general policies and practices in at least four other respects. The first is the placement of additional members on the Reproductive Health Drugs Advisory Committee for the purpose of achieving ideological balance. *See, e.g.,* Pls.' Ex. D-2 at Kweder Dep. 36:12-21; [**79] 37:8-10. This goal of ideological diversity does not aid the FDA in its obligation to examine the safety and effectiveness of a drug's use in self-medication. 21 U.S.C. §§ 353(b)(1), 355(d).

The second departure was the unusual involvement of the White House in the Plan B decision-making process. *See* Pls.' Ex. D-2 at McClellan Dep. 127-132, 140:19-141:13; *id.* at Kweder Dep. 56:8-58:19. Whether or not it was permissible for the FDA to discuss such questions with the White House, these discussions were not the norm for the FDA with respect to this type of decision.

The third departure concerns the timing of the decision to deny OTC use without age restriction. Plaintiffs presented evidence and the GAO made findings which indicate that the decision regarding the OTC status of Plan B may have been made before the scientific reviews of the OTC switch application were complete, and with-

out consultation with FDA scientists. Pls.' Ex. B, GAO Report at 21-22. If the decision was made prior to the completion of the scientific reviews, this would certainly be evidence of a departure from the typical FDA decision-making process. Moreover, such a premature decision would lend further support to plaintiffs' [**80] theory that FDA upper management were pressured by the White House to deny young adolescents OTC access to Plan B regardless of whether the scientific evidence supported a finding that they could use Plan B safely and effectively. *See D.C. Fed'n, 459 F.2d at 1245* (finding evidence that "the Secretary [of Transportations] determinations - in particular, his effort to make the determinations before, plans for the bridge were complete - lend color to plaintiffs' contention that [political pressure] did have an impact on the Secretary's decisions.").

The fourth departure was the FDA's refusal to extrapolate actual use study data from the older age group to the 16 and younger age group. There is evidence in the record that the FDA routinely extrapolated such data when reviewing the safety and effectiveness of various other contraceptives. Indeed, the draft minutes from an internal FDA meeting held in May 2004, contain the following comment regarding the decision not to extrapolate for Plan B:

The inability to extrapolate adolescent safety and effectiveness for <14 year old females is not consistent with how CDER handles approval and distribution of prescription oral contraceptives, OTC male contraceptives such as condoms and spermicides or OTC female contraceptives such as gels and sponges. [*548] In addition, CDER routinely denies sponsors requests to issues Written Requests for Pediatric Studies for oral contraceptives as the responses to these drugs are considered the same for all menstruating females and additional studies are not necessary.

T-1213. This was contained in an initial draft of the minutes, although it was subsequently deleted for reasons which [**81] are unclear. Nevertheless, it accurately reflected the FDA's policy of extrapolating data from older to younger populations. *See* Pls.' Ex. A-3 at T-30898 (referring to the FDA's "long history" of extrapolating data). Indeed, not only did review staff find it appropriate to extrapolate findings in this case, but, in one of its first communications with the Plan B sponsor concerning the anticipated OTC switch application, the FDA indicated that the "proposed trials [i.e., the actual use study] could be conducted in the adult population

and the results extrapolated to the postmenarcheal pediatric population." Pls.' Ex. F-1 at T-30100.

Plaintiffs point to other FDA actions that they claim were departures from standard FDA practices. For example, this was the only OTC switch application decided at the level of CDER Director or higher in the past 10 years - the decision is typically made by the Office Director. Pls.' Ex. B, GAO Report at 30. Indeed, at the guidance meeting held with the Plan B sponsor on January 23, 2004, FDA staff informed the sponsor that the "Divisions were ready to negotiate labeling with you today, but on January 15, 2004 we were informed by ... Dr. Steven Galson, [**82] that the regulatory decision for the action on your application would be made by CDER [Center for Drug Evaluation and Research] upper management (above the ODE level). *This is not the usual or typical CDER process for determining approvability of an NDA.*" Pls.' Ex. A-2 at T-30686 (emphasis added); see also Pls.' Ex. D-1 at Jenkins Dep. 33:8-12 ("I think it's important to explain that for most applications the Commissioner's not directly involved in the decision-making of the Application").

Plaintiffs also argue that Plan B is the first drug for which the FDA sought additional data for adolescents, and that it is the only drug for which the FDA based its decision on adolescent cognitive development. Pls.' Ex. B, GAO Report at 5-6; Pls.' Ex. A-4 at T-31098. The FDA argues that Plan B is different from other drugs because it is preventive rather than reactive. While it may have been rational for the FDA to consider adolescent cognitive development in its evaluation of Plan B as an OTC drug, plaintiffs have presented un rebutted evidence that the FDA's focus on these behavioral concerns stemmed from political pressure rather than permissible health and safety concerns.

Notwithstanding all [**83] of these departures, the FDA argues that there is no customary agency practice and "[e]very drug presents a unique collection of issues, and no two reviews will be identical." See Mem. in Opp'n to Pls.' Mot. for Summ. J. at 32. Plaintiffs do not argue, however, that the scientific review or risk benefit assessment of all proposed OTC drugs must be evaluated in the same manner. They question why the review of Plan B differed in so many significant ways from the review of other switch applications in the last 10 years. The FDA simply has not come forward with an adequate explanation, nor has it presented any evidence to rebut plaintiffs' showing that it acted in bad faith and in response to political pressure.

Instead, the FDA has pursued a litigation strategy dependent on the assertion of the deliberative process privilege to prevent plaintiffs from obtaining conclusive evidence as to the merits of its claim. The [*549] FDA

claims that it acted in good faith but has consistently sought to prevent plaintiffs from obtaining discovery to show otherwise. This claim of good faith fails in the face of the showing plaintiffs have made here. See *Latecoere Int'l*, 19 F.3d at 1365 (the simple denial of [**84] bias, or bad faith cannot "wipe away all evidence of it.").

E. The Appropriate Remedy

When a court reviewing an agency decision rules in favor of the plaintiff, it generally remands to the agency rather than granting affirmative relief. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744, 105 S. Ct. 1598, 84 L. Ed. 2d 643 (1985). Certain circumstances, however, warrant exception to this general remand rule. *Fla. Power*, 470 U.S. at 744. Where a court has found that an agency decision is not supported by the record, but "the record has been fully developed," remand would fail to "serve a useful purpose." *Sierra Club v. EPA*, 346 F.3d 955, 963 (9th Cir. 2003) (quoting *Smolen v. Chater*, 80 F.3d 1273, 1292 (9th Cir.1996)). *Sierra Club* is instructive. There, the Ninth Circuit found erroneous the EPA's conclusion that, but for transborder emissions coming from Mexico, Imperial Valley, CA, would have satisfied the standards for air quality emissions required by the Clean Air Act. *Id.* at 958. Instead of remanding for the EPA to reconsider its decision, the Ninth Circuit remanded with instructions that the EPA classify Imperial Valley as a "serious' nonattainment area" - i.e., noncompliant with applicable air quality standards [**85] - because it "fail[ed] to see how further administrative proceedings would serve a useful purpose; the record here has been fully developed, and *the conclusions that must follow from it are clear.*" *Id.* at 963 (emphasis added).

Plaintiffs argue that remand here is unnecessary because no further agency investigation or explanation would be of any value. Remand would be fruitless, they argue, because "the agency is set on a course to treat Plan B as a *sui generis* drug that demands unprecedented restrictions." Pls.' Reply Mem. in Supp. of Mot. for Summ. J. at 8-9. Additionally, plaintiffs argue that "the agency has acted so improperly and in such bad faith that it cannot be trusted to conduct a fair assessment of the scientific evidence." *Id.* at 9. Nevertheless, remand to the FDA for it to reconsider its denial of the Citizen Petition is the appropriate remedy for two reasons. First, the circumstances have changed since these words were written. Commissioner von Eschenbach has resigned and his replacement, as well as a new Deputy Commissioner, has been nominated by the President. This change in the leadership suggests that, in plaintiffs' words, it can be "trusted to conduct a fair assessment [**86] of the scientific evidence." Second, a decision whether Plan B, a systemic hormonal contraceptive drug, may be used

safely without a prescription by children as young as 11 or 12, is best left to the expertise of the FDA, to which Congress has entrusted this responsibility; it should not be made by a federal district court judge.

A remand would serve no purpose with respect to one aspect of the FDA's decision - requiring that 17 year olds obtain a prescription for Plan B. The record is clear: the FDA's justification for the denial of OTC access to Plan B for women over the age of 17 - rather than 18 - "runs counter to the evidence" and "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983). Indeed, the sole justification for limiting access based on age was that the Commissioner had decided that there was a lack of adequate data to support a finding that women age 16 and [*550] younger could use Plan B safely without a prescription. Def.'s Ex. 3 at T-30666-70. But as to 17 year olds, the "scientific data [is] sufficient to support the safe [**87] use of Plan B as an OTC product ... for women who are 17 years of age and older." Def.'s Ex. 2 at T-10813. The scientific data notwithstanding, Commissioner von Eschenbach decided that because of "the difficulty of enforcing an age-based restriction on the availability of this oral hormonal contraceptive, . . . 18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health." Def.'s Ex. 2 at T-10866. The notion that those selling Plan B would not be able to determine whether an individual was 17, as opposed to 18, based on government issued identification is simply untenable.

Plan B is a time sensitive drug and is most effective if taken within 24 hours of sexual intercourse and loses effectiveness if not taken within 72 hours. Thus, barriers like a prescription requirement, which delay access to Plan B, may needlessly increase the chances that 17 year olds will suffer unwanted pregnancies. The hypothetical enforcement issue is an implausible explanation for the decision to deprive 17 year olds, whom the FDA has

concluded can use Plan B OTC safely, of the much enhanced ease of obtaining Plan B without a prescription. The FDA simply has offered [**88] no evidence that the age restriction would be unenforceable at 17 rather than 18. With respect to this issue, it is difficult "to see how further administrative proceedings would serve a useful purpose; the record [on this issue] has been fully developed, and the conclusions that follow from it are clear." *Sierra Club*, 346 F.3d at 963.

Conclusion

The denial of the Citizen Petition is vacated and the matter is remanded to the FDA to reconsider its decisions regarding the Plan B switch to OTC use. The FDA is also ordered to permit Barr Pharmaceuticals, Inc., the Plan B drug sponsor, to make Plan B available to 17 year olds without a prescription, under the same conditions as Plan B is now available to women over the age of 18. The latter order should be complied with within thirty days. Because of the foregoing, it is unnecessary to rule on plaintiffs various substantive challenges to the FDA's decisions regarding Plan B. Similarly, it would be premature to reach the merits of plaintiffs' various constitutional challenges to the FDA's decisions regarding Plan B. "A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in [**89] advance of the necessity of deciding them." *Lyng v. Northwest Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445, 108 S. Ct. 1319, 99 L. Ed. 2d 534 (1988).

SO ORDERED.

Brooklyn, New York

March 23, 2009

/s/ Edward Korman

Edward R. Korman

United States District Judge