UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, et al.,

Plaintiffs,

v.

DECISION AND ORDER

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

CV 05-366 (ERK) (VVP)

Defendant.

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POHORELSKY, Magistrate Judge:

The plaintiffs in this action seek judicial review, under the Administrative Procedure Act ("APA"), *see* 5 U.S.C. § 706, and the United States Constitution, of the actions taken by the Food and Drug Administration (the "FDA") with respect to certain applications requesting the approval of over-the-counter access for Plan B, an emergency contraceptive drug commonly known as the "morning-after pill." The plaintiffs are a group of individuals, all of whom are women, and organizations involved in the areas of reproductive health and reproductive rights. The defendant is the Acting Commissioner of the FDA who is sued here solely in his official capacity.[1]

The FDA has moved for a protective order, *see* Fed. R. Civ. P. 26(c), to quash certain outstanding discovery requests by the plaintiffs and to preclude the plaintiffs from conducting proposed depositions of several present and former FDA officials. The plaintiffs oppose the protective order motion arguing that, despite the general prohibition on a court's consideration of extra-record evidence in cases brought under the APA, various exceptions apply which would allow the consideration of such evidence, including indications of bad faith by the FDA in

[1]Because the individual defendant is sued in name only, the real party in interest as the defendant here is the FDA, and this opinion accordingly refers to the FDA as if it were the defendant.

handling the applications and the existence of an incomplete administrative record. The motion has been fully briefed, and oral argument was held on November 8, 2005 and January 27, 2006. For the reasons below, the motion for a protective order is DENIED.

BACKGROUND

I. Overview and Procedural History

This case is an outgrowth of the continuing disputes over the scope of a woman's reproductive rights, or, if viewed from constitutional dimensions, the scope of one's privacy rights in general.[2] The plaintiffs bring five claims against the FDA, predicated on the Administrative Procedure Act and the United States Constitution, challenging the FDA's handling of various applications, all of which in one form or another, request FDA approval of over-the-counter ("OTC") access to Plan B, an emergency contraceptive drug that, at present, can only be obtained by prescription. The plaintiffs allege that the FDA by either denying or delaying any final decision with respect to these applications, have "violate[d] the rights of women who need [emergency contraception] to privacy and equal protection under the Fifth Amendment, and that the denial violates their rights and the rights of women who need [emergency contraception] because it exceeds the statutory authority of the FDA and is arbitrary and

[2] *See, e.g., Ayotte v. Planned Parenthood of Northern New England*, No. 04-1144, 546 U.S. _____, slip op. at 10 (Jan. 16, 2006) (remanding to lower court to consider a less drastic remedy than the lower court's striking down as unconstitutional and in wholesale fashion New Hampshire's Parental Notification Prior to Abortion Act due to the Act's lack of an explicit health exception and the inadequacy of a judicial bypass procedure); *see also* Jodi Rudoren, *Trial Opens in Challenge to Law Over Teenage Sex: Debate Over Reporting Consensual Acts*, N.Y. Times, Jan. 31, 2006, at A14 ("A federal trial opened here Monday over whether a Kansas law prohibiting virtually all sexual activity by people under age 16 means health care professionals and educators must report such behavior to state authorities, which some say would stop many teenagers from seeking contraception or treatment for sexually transmitted diseases.").

capricious." (Compl. ¶ 1.)[3] As relief, the plaintiffs seek (1) an injunction requiring the FDA to approve OTC access to Plan B, (2) a judgment declaring that the FDA's denial of OTC access to persons of all ages violates the APA and the United States Constitution, and (3) if the court finds the FDA has not taken final action, a judgment declaring that the FDA has unlawfully withheld or unreasonably delayed issuing such a final decision, in violation of the APA and the United States Constitution, and an order requiring the FDA to issue a final decision on OTC access to Plan B.

Simultaneously with the filing of the protective order motion, the FDA filed a motion for judgment on the pleadings, which Judge Korman denied to the extent it challenged the soundness of the plaintiffs' unreasonable delay claim. Decision was reserved as to the remainder of the plaintiffs' claims, primarily because of questions concerning the plaintiffs' standing to assert them. In his ruling, Judge Korman also lifted a stay of discovery previously entered by this court and expressly authorized discovery as to the unreasonable delay claim. (*See* Dec. 22 Oral Argument Tr. 64, 84, 86.) The FDA subsequently filed a motion for partial reconsideration of the decision lifting the stay of discovery, which Judge Korman denied as well. Thus, the scope of the protective order motion has been narrowed, and the question before the court now is not whether discovery beyond the administrative record should be had, but the extent of such discovery.

[3]Unless otherwise noted, citations to "Compl." refer to the Third Amended Complaint, filed on January 31, 2006. (Docket No. 96.)

II. Facts

As the scope of discovery turns in large part on the actions taken by the FDA concerning the applications for OTC access to Plan B, a somewhat detailed explication of facts is necessary. As an emergency contraceptive, Plan B "[is] used to prevent pregnancy following an act of intercourse in which no contraceptive was used or the contraceptive method used failed." (Compl. ¶ 27.)[4] In 1999, the FDA approved Plan B for prescription use by females of all ages. (*Id.* ¶ 43.) In 2001, the FDA received the first of three applications seeking the approval of OTC access for Plan B (*see, e.g.*, Compl. ¶ 44), which is the "first drug in its class to go through the review process by the FDA to determine whether it should be allowed to be sold OTC," GAO Report, *supra* note 4, at 11. The following factual allegations relate to the various Plan B OTC switch applications filed with the FDA, namely, (1) a Citizen's Petition filed on February 14, 2001, (2) a Supplemental New Drug Application filed by Women's Capital Corporation on April

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[4]This opinion periodically cites to and quotes from a November 2005 report issued by the General Accountability Office, entitled *Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual* [hereinafter GAO Report], attached to Compl. as Ex. Q, *available at* http://www.gao.gov/new.items/d06109.pdf. As described in the GAO Report,

> Plan B is a dedicated [emergency contraceptive pill or ECP] containing only levonorgestrel, a type of progestin. The Plan B regimen is a two-pill dose of levonorgestrel (0.75 mg each) that is most effective when the first pill is taken as soon as possible, but no later than 72 hours, after contraceptive failure or unprotected intercourse. The second pill is taken 12 hours after the first pill. Research suggests that a levonorgestrel-only hormone regimen, such as Plan B, can reduce the risk of pregnancy by 89 percent if taken within the 72-hour window. The time constraint for maximum effectiveness associated with Plan B has led many in the medical community and some reproductive health advocates to support switching Plan B to OTC, making it more readily available when needed. In addition, levonorgestrel-only regimens, such as Plan B, have fewer side effects than the combined ECP, reducing the incidence of two common side effects, nausea and vomiting, by 50 percent and 70 percent, respectively.

GAO Report, *supra*, at 12.

16, 2003, and (3) an amended version of the Supplemental New Drug Application filed on July 22, 2004.

A. Citizen Petition

The earliest OTC switch application underlying the plaintiffs' claims is the Citizen Petition. The Petition was filed by a group of family planning and health care organizations, including the Association of Reproductive Health Professionals, one of the plaintiffs in this action.[5] (*See* Compl. ¶¶ 15, 44.) In substance, the Citizen Petition sought FDA approval for over-the-counter marketing of Plan B and other emergency contraceptive drugs. (*See* Letter of Dr. Janet Woodcock, Sept. 6, 2001, attached to Gov't Mot. for Judgment on Pleadings as Ex. B.) On September 6, 2001, the FDA issued an "interim response" stating that it "has not yet resolved issues raised in [the] Citizen Petition because it raises significant issues requiring extensive review and analysis by Agency officials." (*Id.*) The FDA stated further that it would "respond to [the] petition as soon as [the FDA] ha[s] reached a decision on [the request]." (*Id.*)

Since the September 6, 2001 "interim response," however, the FDA has not further responded in any way to the Citizen Petition. (Compl. ¶ 44.) The plaintiffs allege that the FDA has violated its own regulations by failing to "approve, deny, or give a tentative response to the citizen's petition within 180 days of the filing of the petition, thus constructively denying the petition." (*Id.*)[6]

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[5]Under 21 C.F.R. § 310.200(b), "[a] proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption . . . pursuant to Part 10 of this chapter, or in the form of a supplement to an approved new drug application."

[6]Federal regulations require that the Commissioner, upon receipt of a citizen petition, respond to such petition within 180 days by either approving it, 10 C.F.R. § 10.30(e)(2)(i), denying it, 10 C.F.R. §

B. Supplemental New Drug Application – April 16, 2003

On April 16, 2003, Women's Capital Corporation, which was then the owner of the rights to market Plan B, filed a Supplemental New Drug Application ("SNDA") seeking approval by the FDA to market Plan B over-the-counter without any restrictions, such as those relating to the purchaser's age. (*Id.* ¶ 45.) Women's Capital subsequently sold the rights to Plan B to Barr Laboratories ("Barr") which continued to prosecute the application. (*Id.*)

In this "OTC switch application, the proposed OTC dose and administration schedule were identical to that for Plan B's prescription use." GAO Report, *supra* note 4, at 14. In addition, "[t]he application also included an actual use study and a label comprehension study to assess potential users' understanding of how to administer the product." *Id.* Despite virtually unanimous support by senior review staff for the approval of the Plan B OTC switch application, however, senior management at the FDA issued a not-approvable letter in May 2004, denying the application. The events leading to that denial are of significance in deciding the scope of discovery because they suggest that the reasons for the denial are beyond the scope of the FDA's mandate.[7]

10.30(e)(2)(ii), or issuing a "tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information," 10 C.F.R. § 10.30(e)(2)(iii). Furthermore, "[t]he tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished." 10 C.F.R. § 10.30(e)(2)(iii).

[7]The FDA's regulations prescribe the following framework for deciding OTC switch applications:

> 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 effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in the

Several key meetings within the FDA concerning the SNDA between December 2003 and February 2004 give rise to questions concerning the FDA's approach to deciding on OTC status for Plan B. On December 16, 2003, the FDA convened a joint meeting of two committees – the Non-prescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs (hereinafter "joint advisory committee") – to assess the SNDA. (Compl. ¶ 46.)[8] The members of the joint advisory committee voted 23 to 4 in favor of allowing Plan B to be marketed over-the-counter. GAO Report, *supra* note 4, at 14. It also voted as follows in response to the following questions:

(1) Does the Actual Use Study (AUS) demonstrate that consumers used [Plan B] as recommended in the proposed labeling?

Yes - 27 No - 1

(2) Are the AUS data generalizable to the overall population of potential not-Rx users of Plan B?

Yes - 27 No - 1

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proposed labeling.

21 C.F.R. § 310.200(b); *see also* 21 C.F.R. §330.10(a)(4)(i)-(vi) (providing standards for determining when a "category of OTC drugs is safe and effective and not misbranded.").

[8]Advisory committees, as explained in the GAO Report,

> include outside experts, such as medical professionals and researchers, who provide FDA with independent advice and recommendations. Members review data submitted by the sponsor or presented by FDA review staff, address questions, and vote, either supporting or opposing a switch from prescription-to-OTC status. Advisory committees conduct open meetings and offer members of the public the opportunity to express their views. FDA considers the advisory committees' recommendations in its deliberations. However, the agency decides whether to adopt these recommendations on a case-by-case basis and is not required to follow the committees' recommendations.

GAO Report, *supra* note 4, at 10.

(3) Based on the AUS and literature review, is there evidence that not-Rx availability of Plan B leads to substitution of emergency contraception for the regular use of other methods of contraception?

Yes - 0 No - 28

(4) Do the data demonstrate that Plan B is safe for use in the not-prescription setting?

Yes - 28 No - 0

(Compl. ¶¶ 46-47.)

Notwithstanding the nearly unanimous joint advisory committee votes in support of a restriction-free OTC switch, on January 15, 2004 "senior management" at the Center for Drug Evaluation and Research ("CDER")[9] informed the Offices of Drug Evaluation that the Plan B application was not approvable.[10] (Summary Review of New Drug Application, Dr. Donna J. Griebel, Deputy Director of Division of Reproductive and Urologic Drug Products, Office of Drug Evaluation III, Apr. 1, 2004, attached to App. 13-17 (Tummino-30829-30831, 30876-30877) [hereinafter Griebel Review I].)[11] Senior management's stated reason for non-approval "was that there were inadequate data to support adolescent use in the over the counter setting."

[9]CDER, according to FDA operational guidelines, is the entity within the FDA responsible for reviewing OTC switch applications. GAO Report, *supra* note 4, at 1 (footnote omitted).

[10]Plan B is a "first-in-a-class" drug, i.e., first drug in its class, based on a drug's chemical composition, being reviewed for potential OTC status. Its OTC switch application was therefore channeled to "the Office of Drug Evaluation V, which reviews all OTC switch applications, and the office of drug evaluation that has the relevant expertise for the proposed drug." GAO Report, *supra* note 4, at 1. More specifically, the Plan B SNDA "went to the Office of Drug Evaluation V, which includes the Division of Over-the-Counter Drug Products, and the Office of Drug Evaluation III, which includes the Division of Reproductive and Urologic Drug Products, where it was reviewed." *Id.* at 2.

[11]Unless otherwise noted, citations to "App." refer to the Appendix accompanying the plaintiffs' supplemental memorandum of law in opposition to the FDA's motion for a protective order. Since some of the documents contained within the appendix have been produced by the FDA in the course of its compilation and production of the administrative record, where applicable, the court will also cite to the Bates number appended to these produced documents, which is in the form of "Tummino-XXXXX."

(App. 13 (Tummino-30829).) Specifically, "[t]he Divisions and Offices were told that the Commissioner and senior CDER management believed that the number of adolescents in the actual use study was inadequate, that management believed that there were inadequate data to show that adolescents could dose the product correctly, and that adolescents needed a learned intermediary involved in their access to emergency contraception." (*Id.*)[12]

At a February 18 meeting, the review staff within the Offices of Drug Evaluation responded to the concerns raised at the January 15 meeting, and provided additional adolescent data concerning usage. (App. 13 (Tummino-30829).) Despite the review staff's beliefs that this additional data "provided sufficient evidence that there was neither an increase in risky behaviors nor any difference in appropriate use between younger adolescents and older populations," GAO Report, *supra* note 4, at 18, the Commissioner still considered the data inadequate (App. 13

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[12]According to the GAO Report's description of the same January 15 meeting, Dr. Galson, the Acting Director of CDER, stated that a not-approvable letter was "recommended" by the Office of the Commissioner, because of the "need for more data to clearly establish appropriate use in younger adolescents." GAO Report, *supra* note 4, at 16 (footnote omitted). In addition, the Acting Director had told the review staff (those charged with the responsibility of reviewing the Plan B OTC switch application) that "the decision on the Plan B OTC switch application would be made at a 'level higher than them [the Offices of Drug Evaluation].' " *Id.* at 17 (footnote omitted). The GAO Report also concluded that evidence was conflicted as to when the FDA arrived at its not-approvable decision. *See id.* at 21-22, 31-32. Specifically,

> The Director and Deputy Director of the Office of New Drugs and other officials told [the GAO] that they were informed during December 2003 and January 2004 that the application would not be approved. The Acting Director of CDER denied this [stating that] his rationale for the not-approvable decision was not fully developed until early May 2004.

Id. at 32.

Elsewhere in the GAO Report, CDER's Acting Director is quoted as saying that "he was '90 percent sure' as early as January 2004, that the decision would be not-approvable." GAO Report, *supra* note 4, at 22.

(Tummino-30829)). In concluding the meeting, the Commissioner suggested that "CDER staff continue working with the sponsor on a 'marketing plan to limit availability of the product over the counter and to consider the most appropriate age groups to be restricted from access to the product.' " GAO Report, *supra* note 4, at 18-19. The Commissioner also referred to the Plan B OTC switch application as having "rapid action" priority. *Id.* at 19.

Senior management and the Commissioner continued in their vocal disapprovals of the Plan B OTC application at a February 19 meeting. (*See* Memorandum of Dr. Curtis Rosebraugh, Mar. 23, 2004, attached to App. 8-9 (Tummino-30745-30746) [hereinafter Rosebraugh Mem. I].) During this meeting, Dr. Janet Woodcock, worried that approval of the OTC switch application could potentially lead to "extreme promiscuous behaviors such as the medication taking on an 'urban legend' status that would lead adolescents to form sex based cults centered around the use of Plan B." (*Id.* at 8-9 (Tummino-30745-30746).)[13] Dr. Galson, Acting Director of CDER and ultimate author of the not-approvable letter in May 2004 agreed with Dr. Woodcock's concern. (App. 9 (Tummino-30746).)

Immediately after the Commissioner first expressed his concerns about the adequacy of the data in predicting adolescent sexual behavior, and throughout the ensuing months until the issuance of the not-approvable letter in May, FDA senior review staff within CDER sought to allay those concerns by gathering further information and presenting it to senior management in

[13]Dr. Woodcock was the Deputy Commissioner for Operations at the FDA and one of the few FDA officials who generally agreed with the Commissioner's concerns regarding adolescent behavior. *See also* GAO Report, *supra* note 4, at 21 n.43 ("[Dr. Woodcock] became the Acting Deputy Commissioner for Operations in March 2004, and . . . her role in the review of the initial Plan B OTC switch application was as a consultant to the Acting Director of CDER.").

various memoranda. Those communications, some of which are detailed below, uniformly and emphatically recommended that the application be approved without restrictions, arguing that the mandate of the FDA did not allow it to consider adolescent sexual behavior in making its decision, and that, in any event, the data submitted by the applicant was sufficient to allay the concerns of the Commissioner.

Just days following the January 15 meeting where the Commissioner first raised his adolescent behavior concerns, Jonca Bull, MD, the Deputy Director of the Office of Drug Evaluation V – CDER, issued a memorandum expressing her "regulatory review concerns" regarding the Plan B OTC switch application. (*See* Memorandum of Dr. Jonca Bull, Jan. 21, 2004, attached to App. 73-76.) Dr. Bull strenuously objected to the Commissioner's adolescent behavior concerns, describing them as "speculative and unbalanced." (*Id.* at 75.) Dr. Bull also argued that their inclusion in the review process "spuriously raise the review standard for approval of this product and indeed any contraceptive product," noting further that "the agency's regulatory mandate is not to regulate behavior or morality but to serve the public by ensuring that safe and effective products are made available for prescriber and patient choice." (*Id.*) In conclusion, Dr. Bull reiterated her agreement with the "overwhelmingly favorable assessment and majority votes to agency questions by the Joint Advisory Committee," which found sufficient data had been provided for approval of the OTC switch application. (*Id.*)

On March 23, 2005, Deputy Director Curtis Rosebraugh, MD, of the Division of OTC Drug Products – CDER, issued an addendum to an earlier memorandum which summarized his views on the Plan B OTC switch application, including the concerns regarding adolescent behavior raised by "upper management." (*See* Rosebraugh Mem. I, *supra*, attached to App. 8-12

(Tummino-30745-30746, 30757-30759).) Specifically, Dr. Rosebraugh disagreed with upper management on the adolescent behavior issues and found "[t]he data reviewed . . . quite compelling to dispel any potential concerns regarding adolescent use or changes in sexually [sic] behaviors associated with [P]lan B use . . . ." (*Id.* at 10 (Tummino-30757).) Dr. Rosebraugh went even further, however, and expressed his dismay over upper management's continued reference to the lack of sufficient data regarding adolescent behavior, noting that " [i]n terms of OTC switch applications, this drug has more information available to allow us [the FDA] to predict consumer behaviors than any drug the Division has approved for switch in recent memory." (*Id.*) He hypothesized that "[i]f this is not enough data upon which to base a decision, it is unclear what could constitute enough data or even if that is a obtainable goal." (*Id.*) In closing, Dr. Rosebraugh reiterated his view that there was "compelling data" to allow over-the-counter access to Plan B without restrictions. (*Id.* at 12 (Tummino-30759).)

On April 1, 2004, Deputy Director Donna Griebel, MD, of the FDA's Division of Reproductive and Urologic Products, Office of Drug Evaluation III – CDER, issued a summary review emphatically recommending that the Plan B OTC switch application be approved. (*See* Griebel Review I, *supra*, attached to App. 13-17 (Tummino-30829-30831, 30876-30877).) Dr. Griebel found that "the risk benefit ratio of the non-prescription access to Plan B supports its approval for switch to non-prescription status." (*Id.* at 17 (Tummino-30877).) She also described as "unjustified" any attempt to "restrict access to the benefit of [Plan B] on the basis of age." (*Id.*)

Dr. Julie Beitz, Deputy Director of the FDA's Office of Drug Evaluation III – CDER, was yet another senior official in CDER to issue a memorandum calling for the approval of the OTC

switch application. (*See* Memorandum of Dr. Julie Beitz, Apr. 2, 2004, attached to App. 18-19 (Tummino-30881-30882).) She emphasized that there were no "efficacy concerns raised in [the Plan B] application since the proposed OTC dose is the same as that for the prescription product." (App. 18 (Tummino-30881).) In addition, Dr. Beitz, like the other deputy directors who had addressed the matter, pointed to the overwhelming approval of the Plan B OTC switch application by the joint advisory committee as a firm basis for allowing over-the-counter marketing of Plan B without any age restrictions. (*Id.*)

Finally, on April 22, 2004, Dr. John Jenkins, Director of the FDA's Office of New Drugs, issued a memorandum which represents the culmination of the reviews and findings presented by the four deputy directors at CDER, as well as a forceful and authoritative statement on the approvability of the Plan B OTC switch application. (*See* Memorandum of Dr. John Jenkins, Apr. 22, 2004, attached to App. 20-23 (Tummino-30897-30900).) Dr. Jenkins agreed with the conclusions reached by CDER review staff and recommended that Plan B be approved for sale over-the-counter without age restrictions. (*See id.* at 20-21 (Tummino-30897-30898).) He addressed the concerns regarding the effect that over-the-counter access to Plan B may have on adolescent sexual behavior. Acknowledging his "sensitiv[ity] to and respect for" such concerns, Dr. Jenkins refuted their underlying legitimacy as a matter of FDA concern, pointing out that issues on adolescent behavior "are derived from individual views and attitudes about the morality of adolescent sexual behavior and also overlap with concerns about the role for parents and health care professional in decisions about contraceptive use in adolescents." (*Id.* at 21-22 (Tummino-30898-30899).) Most critically, in Dr. Jenkins' view,"the available data clearly support a conclusion that Plan B meets the statutory and regulatory requirements for availability

without a prescription for all age groups." (*Id.* at 22 (Tummino-30899).) Therefore, as Dr. Jenkins noted in closing, "[w]hile OTC access to Plan B for adolescents may be controversial from a societal perspective, [there cannot be] any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling." (*Id.*)

These formal communications by senior review staff did not alter senior management's view. They did, however, prompt some confidential e-mail communications between Dr. Steven Galson, Acting Director of CDER, and Dr. Dianne Murphy, Director of the FDA's Office of Pediatric Therapeutics, which provide a window to senior management's approach to making their decision not to approve OTC access to Plan B. Just days before Dr. Galson issued the May 6 not-approvable letter, he sent a May 2 email, under the subject header "confidential," to Dr. Murphy, asking her to provide support for his proposition that studies of adult behavior could not be extrapolated to adolescent behavior. (*See* Email of Dr. Steven Galson to Dr. Dianne Murphy, May 2, 2004, attached to App. 26 (Tummino-30910).) Dr. Murphy promptly responded by assuring Dr. Galson that she and her colleagues would "provide 2 or 3 sentences that focus on the differences in behavior and judgement between the early and late adolescent period," or, put another way, "behavioral science information as to why one *cannot* extrapolate decision making on safety issues from the older adolescent to the younger one." (*Id.* (emphasis added).) A May 9 e-mail message from Dr. Galson to Dr. Florence Houn, Director of the Office of Drug Evaluation III, suggests that the entire extrapolation issue was merely window dressing, however, because he

"had made up [his] mind concerning the essential contents of the [not-approvable] letter & memo *before* [having spoken] to Dianne . . . ." (*Id.* (emphasis added).)[14]

On May 6, 2004, Dr. Galson issued the FDA's letter informing Barr that the Plan B application could not be approved. (Letter of Dr. Steven Galson to Joseph Carrado, May 6, 2004, attached to App. 1-3 (Tummino-10796-10798).) The FDA's guidelines contemplate that the directors of the offices of drug evalulation within CDER, and not Dr. Galson, are the appropriate officials to issue such letters.[15] The task fell to Dr. Galson, however, after both of the directors within the CDER, as well as the Director of the Office of New Drugs, declined to issue the letter.[16] Dr. Galson gave the following reason for the not-approvable decision:

> Although the Joint Committee recommended that your proposal to switch Plan B be approved, some members of the Joint Committee, including the Chair, raised questions concerning whether the actual use data were generalizable to the overall population of nonprescription users, chiefly because of inadequate sampling of younger age groups.
>
> Based on a review of the data, we have concluded that you have not provided adequate data to support a conclusion that Plan B can be used safely by young

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[14]The "memo" reference is to an official memorandum written by Dr. Galson and submitted to the record, explaining in greater detail his reasons for denying Barr's Plan B application. (*See* Memorandam of Dr. Steven Galson, May 6, 2004, attached to GAO Report, *supra* note 4, at 48-49, as Appendix IV.)

[15]As the GAO Report points out, "[f]rom 1994 through 2004, 94 action letters were issued during the review processes for the 68 prescription-to-OTC switch applications, and only 1 action letter – the not-approvable letter for Plan B – was signed by the Director, in this case the Acting Director, of CDER." GAO Report, *supra* note 4, at 30.

[16]This intra-agency dispute concerning the drafting and signing of the not-approvable letter is documented in the GAO Report. *See* GAO Report, *supra* note 4, at 19-20. The report notes that according to Dr. Jenkins, the director of the Office of New Drugs, it was " 'very, very rare' that his office would become involved in the signing of an action letter." *Id.* at 19-20. Upon review of various FDA manuals the GAO found that "the Office of New Drugs would review decisions from the offices of drug evaluation only if there was disagreement between these two reviewing offices." *Id.* at 20. However, as documented above, and as noted by the GAO, "there was no disagreement between the two reviewing offices of drug evaluation on the approvability of the application." *Id.*

> adolescent women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug.

(App. 1 (Tummino-10796).)

In the rest of the letter, Dr. Galson discussed Barr's "preliminary proposal," which was submitted on March 11, 2004, "to allow for marketing of Plan B as a prescription-only product for women under 16 years of age and a nonprescription product for women 16 years and older." (*Id.* at 2 (Tumminio-10797).) A review of this proposal could not be completed, however, because of its "preliminary and incomplete nature." (*Id.*) Dr. Galson then informed Barr of the application deficiencies and suggested ways of curing them in an amended application. (*Id.*)

C. Amended Supplemental New Drug Application – July 22, 2004

On July 22, 2004, Barr filed an amended application (hereinafter "ASNDA"), formally requesting approval of the dual-marketing proposal found to be incomplete by the FDA in the May 6 not-approvable letter. The general framework of the proposal remained unchanged, seeking OTC status for women ages sixteen and older and prescription-only status for women under sixteen years of age. (Compl. ¶ 55.) In response to this application, senior FDA review staff issued another string of reviews and memoranda. Throughout these documents, some of which are reviewed below, senior FDA staff forcefully objected to restricting access to Plan B on the basis of age, believing such an approach would have wide-ranging detrimental effects on how the FDA approaches future OTC switch applications and would also have a negative impact on public health generally. Members of the review staff went so far as to recommend that the amended application be denied, insisting that the FDA approve a restriction-free OTC access plan for Plan B. Ultimately, however, the FDA decided not to permit OTC access to Plan B

even to non-adolescent females. Events during that decisionmaking process are helpful in determining the appropriate scope of discovery.

On January 12, 2005, Dr. Davis of the FDA's Division of Reproductive and Urological Products, Office of Drug Evaluation III – CDER, completed his review of the ASNDA and found the lack of any new evidence which would justify a denial of restriction-free OTC access to Plan B. (Memorandum of Dr. Daniel Davis, Jan. 12, 2005, attached to App. 28 (Tummino-31020).) He maintained the position that data provided during the initial application process demonstrated that Plan B could be safely distributed and used over-the-counter without age restrictions and disagreed with the applicant's proposed dual-marketing approach, finding it not warranted or desirable. (*Id.*)

On the same day Dr. Davis completed his review, Deputy Director Rosebraugh emphasized his continued belief that "an age restriction is not appropriate for [Plan B]." (Memorandum of Dr. Rosebraugh, Jan. 12, 2005, attached to App. 29-31 (Tummino-31026-31028).) After briefly summarizing his recommendations made in connection with the initial OTC switch application, (*see id.* at 29 (Tummino-31026)), Dr. Rosebraugh stated that, "I have not been presented with data that would dissuade me from my original conclusion. I also continue to believe that adequate data was submitted to allow Plan B to be marketed without regard to age," (*id.* at 30 (Tummino-31027)). Dr. Rosebraugh also rejected Barr's dual-marketing proposal, citing to "the regulatory precedent that approval of this plan would set and possible unintended consequences." (*Id.*) In particular, Dr. Rosebraugh expressed his concern about "the regulatory precedent that would be set by requiring adolescents to obtain a prescription to access an otherwise OTC contraceptive product [which] may have implications for other OTC

contraceptive products that are currently marketed which do not bear age restrictions and have not submitted adolescent data for OTC marketing." (*Id.*) Furthermore, Dr. Rosebraugh found that implementing an age-based access system would "place an unacceptable legal burden on pharmacies" resulting in limited access and problematic enforcement. (*Id.*)

Like her senior review staff colleagues, Deputy Director Griebel continued to press her original recommendation that Plan B be approved for OTC access without age restrictions, and declined to support the dual-marketing approach proposed in the ASNDA. (Memorandum of Dr. Griebel, Jan. 12, 2005, attached to App. 34-36 (Tummino-31031-31033).) She cited two reasons why Barr's amended application should not be approved. First was the concern that "[l]abeling the product to only be sold with a prescription to consumers under the age of 16 sets a precedent that could have negative consequences on current products sold as non-prescription products, including contraceptive products like condoms and spermicidal products." (*Id.*) Dr. Griebel's second concern involved "the unintended public health consequence" which would result from restricting access to Plan B on the basis of age. In particular, Dr. Griebel predicted that such an approach would have the effect of limiting access to Plan B by women of all ages where pharmacies may cease to carry Plan B altogether because of (1) the "undesirable legal burden" of enforcing an age-based sale approach and (2) the personal beliefs of certain pharmacists who believe that Plan B causes "medical abortion." (*Id.* at 35 (Tummino-31032).) This reduction in access to Plan B would be even more pronounced if, as Dr. Griebel explained, "those pharmacists who object to the product on the basis of their personal beliefs remain in a position of controlling access to the product . . . ." (*Id.*)

Director Jenkins (Office of New Drugs), too, reiterated his opinion that OTC access to Plan B should be unrestricted as to age. (Memorandum of Dr. Jenkins, Jan. 14, 2005, attached to App. 37-39 (Tummino-31096-31098).) Dr. Jenkins expressly disagreed with Dr. Galson's not-approvable decision and voiced his opposition to the proposed dual-marketing approach, finding "no scientific basis for the differentiation in prescription and non-prescription status based on age. . . ." (*Id.* at 37 (Tummino-31096).) In addition, Dr. Jenkins found "such an approach . . . inconsistent with well established FDA precedent with regard to labeling OTC products for use in adult and pediatric populations." (*Id.* at 37-38 (Tummino-31096-31097).)

Responding to Dr. Galson's stated concern about the extrapolation of data from adult to adolescent populations, Dr. Jenkins found such concerns "are more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse." (*Id.* at 38 (Tummino-31097).) In Dr. Jenkins' view, approval of the amended application could not "be justified based on scientific data" and could potentially "raise other serious scientific and policy issues." (*Id.*) As an example, Dr. Jenkins noted the possibility that, with the approval of Plan B as a dual-status product, the public would petition the FDA seeking similar restrictions on other over-the-counter contraceptives, thus limiting their availability to "sexually active adolescents, a group where pregnancy leads to serious short and long-term risks to the mother and the child." (*Id.*)

On January 21, 2005, the FDA announced that a decision on Barr's amended application would be delayed beyond the 180-day period in which it is ordinarily required to act on such an application. (*See* Compl. ¶ 55 (citing 21 U.S.C. § 355(c)(1)).) Nevertheless, in the ensuing

months up through August of 2005, the FDA apparently did nothing to advance the decisionmaking process, adding but two documents to the administrative record during that entire period. (*See id*l. ¶¶ 59-60.)

On July 13, 2005, however, Michael O. Leavitt, Secretary of Health and Human Services, wrote a letter to Senator Michael Enzi, Chairman of the Committee on Health, Education, Labor and Pensions, in response to the Senator's concern that the FDA had not "acted on" the amended application. (Letter of Secretary Leavitt to Senator Enzi, July 13, 2005, attached to Compl. as Ex. L [hereinafter Leavitt letter].)[17] Secretary Leavitt stated that while he was not part of the decision-making process in reviewing Barr's application, he had communicated with the FDA and had been assured by them (the FDA) that action would be taken on the application by September 1, 2005. (*Id.*)[18] This letter was subsequently submitted by the FDA in

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[17]According to press reports, Senators Hillary Rodham Clinton and Patty Murray, members of the Committee on Health, Education, Labor and Pensions, sent a letter on May 12 to Secretary Leavitt requesting an investigation into the issuance of a memorandum written by Dr. W. David Hager, a former member of the Reproductive Health Drugs Advisory Committee (one of the two committees voting in December 2004 to approve Plan B for OTC access) which argued against allowing Plan B to be sold without a prescription. *See Clinton, Murray Ask Leavitt to Investigate Hager's Memo on Plan B*, FDA Week, May 13, 2005, *available at* 2005 WLNR 7566025. Dr. Hager was "one of four panel members [out of twenty-eight] who voted to recommend against approving non-prescription sales of . . . Plan B." Marc Kaufman, *Abortion Foe to Be Reappointed to FDA Panel, Four Lawmakers Tell Bush That Doctor Has 'Allowed His Personal Beliefs to Overshadow His Duty'*, Wash. Post, June 29, 2004, at A6 ("Hager has been a lighting rod for groups active in national debates over abortion and emergency contraception because of this opposition to abortion and his strong Christian beliefs. While he has written numerous articles for mainstream medical journals and some textbook chapters on reproductive issues, he has also authored several books that mix his medical and religious views. This background has made abortion rights groups sharply critical, but others see him as a hero."). It is unclear, however, whether the two Senators received any response from Secretary Leavitt to their joint request.

[18]After issuance of the Leavitt letter, Senators Clinton and Murray, both of whom initially blocked a confirmation vote on FDA Acting Commissioner Lester Crawford to become Commissioner of the agency because of the " 'FDA's failure to provide an answer on Plan B,' " agreed to allow the confirmation process to go forward citing to Secretary Leavitt's September 1 deadline and stating that " '[i]t is long past time that the American people had a decision on Plan B, and the FDA has finally agreed to give women

the present action as a basis for seeking an abeyance of the case "[g]iven the agency's commitment to take action on the pending Plan B application within the next 45 days . . . ." (Letter of FDA to Chief Judge Korman, July 25, 2005, attached to Compl. as Ex. M.)[19]

On August 26, 2005, the FDA finally issued a response to Barr's amended OTC switch application of July 21, 2004. (Letter of Former Commissioner Crawford to Joseph Carrado, Aug. 26, 2005, attached to App. 5-7 (Tummino-10813-10815) [hereinafter Crawford letter].)[20] Former Commissioner Crawford, while recognizing that CDER had "concluded that the available scientific data are sufficient to support the safe use of Plan B as an OTC product, but only for women who are 17 years of age and older," nonetheless declined to issue a definitive decision on

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across the country what we have fought for from the beginning - a yes or no answer.' " Marc Kaufman, *Three Senators Agree to Allow Floor Vote on FDA Nominee*, Wash. Post, July 16, 2005, *available at* 2005 WLNR 11144050; *see also* Kevin Freking, *Action on Morning-after Pill Ends FDA Limbo, A deadline for an agency decision on approval also sets the stage for a vote on confirming a nominee*, Phila. Inquirer, July 16, 2005, *available at* 2005 WLNR 11152854.

[19]The plaintiffs strenuously opposed this request and requested that Judge Korman maintain the current briefing schedule. (Letter of Pls.' Counsel to Chief Judge Korman, July 28, 2005, *available at* Docket No. 22.) At one point in their letter to Judge Korman, the plaintiffs argued that the FDA's delays in reaching a decision on OTC status for Plan B "are of such magnitude that it is difficult to give credence to any promise of future action by the FDA regarding Plan B . . . . Thus, a Citizen's Petition seeking OTC status for Plan B has been pending before the FDA for *over four years*, and the government's letter gives no indication that the FDA is considering any action now on that Petition . . . ." (*Id.* (citation omitted).) After a telephone conference with the parties, Judge Korman issued an order requiring the FDA to file its answer by August 5, 2005 as well as an itemization of the administrative record by September 6, 2005. (Docket No. 26.)

[20] On the same day, Dr. Galson issued a lengthy internal memorandum defending his view "that as a matter of science, Barr's July 21, 2004 proposal to switch Plan B to OTC status meets statutory standards for approval of an NDA supplement set for in 21 U.S.C. [§] 355(d) for women age 17 and older, but does not meet the statutory standards for women under age 17." (Memorandum of Dr. Galson, Aug. 26, 2004, attached to App. 42-53 (Tummino-31214-31226).) Dr. Galson also expressed his willingness to "reevaluate [his] conclusions"in the event "additional data on actual use and labeling comprehension in women under 17 are provided, or Barr is able to demonstrate that women age 16 can be differentiated from younger women in the actual and label comprehension studies . . . ." (*Id.* at 53 (Tummino-31225).)

the amended application "because of unresolved issues that relate to [the amended application]." (*Id.* at 5 (Tummino-10813).) Crawford's stated inability to issue a decision on the application stemmed from what he described as "three difficult and novel issues." (*Id.*) First, Crawford pointed out that "the Agency has never determined whether a drug may be both Rx and OTC based on the age of the individual using the drug," the approach proposed by Barr in its amended application. (*Id.*) Second, he questioned "how, as a practical matter, an age-based distinction could be enforced." (*Id.*) The third concern raised by Crawford was that the FDA has "never been confronted with whether the Rx and OTC versions of the same active ingredient may be marketed in a single package." (*Id.*)

Because of these outstanding issues, Crawford stated that the "appropriate course" would be for the FDA "to ask for public comments on whether [the Agency] should initiate a rulemaking to codify our interpretation of section 503(b) [of the Food, Drug, and Cosmetic Act] regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product." (*Id.* at 6 (Tummino-10814).)[21] Crawford concluded the letter by reminding Barr that Plan B could not be marketed over-the-counter "[a]t this time." (App. 6 (Tummino-10814).)

[21]As the GAO observed in its report, "[the] FDA delayed taking action on the amended application to seek public comment on marketing issues related to this decision." GAO Report, *supra* note 4, at 3 n.11 (citing Drug Approvals: Circumstances Under Which an Active Ingredient May be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product, 70 Fed. Reg. 52050 (2005)).

D. Subsequent Events

Since the issuance of the August 26 letter delaying a decision on Barr's amended application, several other significant events have occurred. First, two FDA officials have publicly resigned in protest to the agency's handling of the Plan B OTC applications. Second, as noted above, at the request of numerous Congressmen and Congresswomen, the Government Accountability Office has conducted an investigation into the FDA's processing of the initial April 2003 application seeking Plan B OTC access for women of all ages and has issued a report entitled, *Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual. See, e.g.*, GAO Report, *supra* note 4, at 1.

1. Resignations of Dr. Susan Wood, Former Director of the FDA's Office of Women's Health and Dr. Frank Davidoff, Former Member of the FDA's Nonprescription Drugs Advisory Committee

Five days after the issuance of the Crawford letter, Dr. Wood, then-Director of the Office of Women's Health at the FDA, resigned in protest over the FDA's handling of the Plan B application, expressing her view that "science was being overruled at [the] FDA and women's health was being damaged." (Interview with Dr. Susan Wood, former Director of Office of Women's Health, FDA, in Washington by Ted Koppel, Nightline (Sept. 27, 2005), attached to App. 80-87.) In a departing email sent by Dr. Wood to her colleagues at the FDA, she stated that "I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled." (Marc Kaufman,

FDA Official Quits Over Delay on Plan B, Women's Health Chief Says Commissioner's Decision on Contraceptive Was Political, Wash. Post, Sept. 1, 2005, at A8, attached to App. 78.)[22]

Some time in early October 2005, another FDA official, Dr. Frank Davidoff, resigned as a member of the Nonprescription Drugs Advisory Committee for essentially the same reasons as that of Dr. Wood. (Rinker Buck, *Plan B Casualties*, Hartford Courant, Oct. 2, 2005, attached to App. 98-102 ("Davidoff had considered resigning in May 2004, when the FDA first disapproved the drug for over-the-counter distribution, but he felt strongly that he might be more effective continuing to work with the agency. He abandoned that thinking, however, when Crawford once more delayed action in August.").) In his resignation letter, Dr. Davidoff stated that "I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than the scientific and clinical evidence." (*Id.* at 98.)

2. November 2005 Government Accountability Office Report: *Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual*

Pursuant to the request of members of Congress, including twenty-one Senators and twenty-seven Representatives, the Government Accountability Office initiated an investigation into the FDA process which led to the issuance of the May 6, 2004 not-approvable letter denying Barr's April 2003 application seeking Plan B OTC access for women of all ages. *See* GAO Report, *supra* note 4, at 1-4, 34-35.[23] The Congressional request emanated from the concern

[22]On September 24, 2005, former Commissioner Crawford also resigned after serving in the position for about two months.

[23]The scope of the GAO investigation focused "only [on] FDA's actions prior to the May 6, 2004, not-approvable letter for the initial application, and . . . did not examine aspects of FDA's subsequent

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. The GAO Report thus examined,

> (1) how the decision was made to not approve the switch of Plan B from prescription to OTC, (2) how the Plan B decision compares to the decisions for other proposed prescription-to-OTC 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.

With respect to the first area of focus outlined above, the GAO concluded that "four aspects of FDA's review process were unusual":

- First, the Directors of the Offices of Drug Evaluation III and V, who would normally have been responsible for signing the Plan B action letter, disagreed with the decision and did not sign the not-approvable letter for Plan B. The Director of the Office of New Drugs also disagreed and did not sign the letter.

- Second, FDA's high-level management was more involved in the review of Plan B than in those of other OTC switch applications. For example, FDA review staff told [the GAO] that they were told early in the review process that the decision would be made by high-level management.

- Third, as documented in the reviews of FDA staff and in [the GAO's] interviews with FDA officials, there are conflicting accounts of whether the decision to not approve the application was made before the reviews were completed.

- Fourth, the rationale for the Acting Director of CDER's decision was novel and did not follow FDA's traditional practices. Specifically, the Acting Director was concerned about the potential impact that the OTC marketing of Plan B would have on the propensity for younger adolescents to engage in unsafe sexual behaviors because of their lack of cognitive maturity compared to older adolescents. He also stated that it was invalid

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deliberations about Plan B." *Id.* at 4.

> to extrapolate data from older to younger adolescents in this case. FDA review officials noted that the agency has not considered behavioral implications due to differences in cognitive development in prior OTC switch decisions and that the agency has considered it scientifically appropriate to extrapolate data from older to younger adolescents.

Id. at 5.[24]

As to the second area of focus, the GAO found that "[t]he decision to not approve the Plan B OTC switch application was not typical of the other 67 prescription-to-OTC switch decisions made from 1994 through 2004." *Id.* Out of 23 OTC switch applications reviewed by the joint advisory committee during this period, the GAO noted that "the Plan B OTC switch application was the only 1 of those 23 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, in this case the Acting 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 or OTC contraceptives that FDA has approved, and FDA has not required pediatric studies for them." *Id.* at 6. In particular,

> All FDA-approved OTC contraceptives are available to anyone, and all FDA-approved prescription contraceptives are available to anyone with a prescription. For hormonal contraceptives [like Plan B], FDA assumes that suppression of ovulation would be the same for any female after menarche, regardless of age. [Menarhche, as defined in the GAO report, "is the initial menstrual period, normally occurring between a female's 9th and 17th year."] FDA did not identify any issues that would require age-related restrictions in its review of the original

[24]The bullet-style list is not a quotation from the GAO Report, but rather was adopted by the court for the ease of the reader.

> application for prescription Plan B, and prescription Plan B is available to women of any age.

Id. at 6, n.13.[25]

DISCUSSION

I. The Appropriate Scope of Discovery

A. Legal Considerations – Judicial Review of Agency Proceedings

As the court has denied the government's motion for judgment on the pleadings and has lifted the stay of discovery, the government's principal remaining argument in support of its motion for a protective order is that the limited scope of judicial review of the FDA's actions renders most, if not all, of the discovery sought by the plaintiffs simply irrelevant. Specifically, the government argues that in the circumstances in this case the court is limited to a review of the administrative record, all of which has already been provided to the plaintiffs (as compiled through August 2005). The argument requires a brief discussion of the scope of judicial review of agency proceedings.

"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

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[25]Prior to the issuance of the final version of the GAO Report, the FDA was provided an opportunity to respond to a draft version, which it did. *See id.* at 6-7, 31-33. The day after the GAO released its report, Congressman Henry Waxman, a member of the Committee on Government Reform, wrote a letter to Tom Davis, the Chairman of the Committee, requesting that the Committee "hold a hearing on FDA's Plan B decisions and the influence of political and ideological considerations on the FDA actions." (Letter from Congressman Waxman to Congressman Davis, Nov. 15, 2005, attached to Compl. as Ex. R.) Congressman Waxman also requested the Committee request certain documents from the FDA, Health and Human Services, and White House "relating to the Plan B decisions." (*Id.*) The Committee, however, has yet to act on this request.

7, 14 (2d Cir. 1997) (citing *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985)).

As explained by the Supreme Court in *Lorion*,

> "[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). The 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. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971).

470 U.S. at 743-44.

This so-called "record rule," however, is not unbending and certain exceptions exist which, if established by a litigant, may allow for the consideration of extra-record evidence. As this circuit has expressly recognized,

> Despite the general 'record rule,' an extra-record investigation by the reviewing court may be appropriate when there has been a strong showing in support of a claim of bad faith or improper behavior on the part of agency decisionmakers or where the absence of formal administrative findings makes such investigation necessary in order to determine the reasons for the agency's choice.

Hoffman, 132 F.3d at 14 (citations omitted).

The recognition that bad faith or improper behavior by agency decisionmakers serves as a basis for expanding the scope of review, and thereby the scope of discovery, was first specifically enunciated by the Supreme Court in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. at 420, *overruled on other grounds, Califano v. Sanders*, 430 U.S. 99, 105 (1977). Thus, where a "strong preliminary showing" of bad faith or improper behavior is made, agency officials can be required to give testimony to explain the reasons for their actions. *See Nat'l Nutritional Foods Ass'n v. FDA*, 491 F.2d 1141, 1145 (2d Cir. 1974). What constitutes a strong preliminary showing of bad faith or improper behavior, however, is a matter that the courts have been

reluctant to define, preferring in the main simply to declare that on the facts of a given case, the showing has not, or occasionally has, been made. *See, e.g., Latecoere Intern., Inc. v. U.S. Dep't of Navy*, 19 F.3d 1342, 1357 (11th Cir. 1994) (bad faith shown); *TOMAC v. Norton*, 193 F. Supp. 2d 182, 195 (D.D.C. 2002) (bad faith not shown), *aff'd*, 433 F.3d 852 (D.C. Cir. 2006); *Amfac Resorts, L.L.C. v. U.S. Dep't of Interior*, 143 F. Supp. 2d 7, 13-14 (D.D.C. 2001) (bad faith not shown), *aff'd in part, rev'd in part on other grounds*, 282 F.3d 818 (D.C. Cir. 2002), *vacated on other grounds sub nom.*, *Nat'l Park Hospitality Ass'n v. U.S. Dep't of Interior*, 538 U.S. 803 (2003); *Sokaogon Chippewa Cmty. v. Babbitt*, 961 F. Supp. 1276, 1282-84 (W.D. Wis. 1997) (distinct possibility of improper political influence shown).

A showing of bad faith or improper behavior is by no means the only basis for inquiry beyond the administrative record. Thus, the court's review of agency conduct is not limited to the record in an action to "compel agency action unlawfully withheld or unreasonably delayed." *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 560 (9th Cir. 2000); *see also San Francisco Baykeeper v. Whitman*, 297 F.3d 877, 886 (9th Cir. 2002); *Independence Mining Co. v. Babbit*, 105 F.3d 502, 511 (9th Cir. 1997). In such cases, to determine the reasonableness of a delay the court is guided by the following considerations, known as the *TRAC* factors:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"

In re Barr Laboratories, Inc., 930 F.2d 72, 74-75 (D.C. Cir. 1991) (quoting *Telecommunications Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984)). Of particular significance, given the issues in this case, is the observation made by the District of Columbia Circuit when examining an earlier claim of unreasonable delay by the FDA in a matter concerning over-the-counter drugs:

> The agency must justify its delay to the court's satisfaction. If the court determines that the agency delays in bad faith, it should conclude that the delay is unreasonable.

Cutler v. Hayes, 818 F.2d 879, 898 (D.C. Cir. 1987).

B. Analysis

Given these considerations, discovery beyond the administrative record is appropriate in this case. First, discovery concerning matters relating to the *TRAC* factors above must be allowed. Specifically, given that a "rule of reason" ultimately governs the issue of unreasonable delay, some inquiry into the legitimacy of the reasons offered for the delay must be permitted. Moreover, because a delay that is the result of bad faith – that is, a delay for improper reasons – is a delay that is *per se* unreasonable, inquiry into whether the reasons offered by the agency are the actual reasons for the delay must also be permitted. *See Cutler*, 818 F.2d at 898.

Inquiry which includes testimony by agency personnel, including the senior level personnel who overruled the professional staff, is particularly appropriate in this case because the court finds that a strong preliminary showing of "bad faith or improper behavior" has been made. *See, e.g., Overton Park*, 401 U.S. at 420. The finding rests on a number of facts. First, the length of the delay in deciding the Citizen Petition, now five years, alone raises questions about the good faith of the FDA. Moreover, the actions of the FDA in dealing with the SNDA and the

amended SNDA, strongly suggest that the delay is a calculated "filibuster" designed to avoid making a decision subject to judicial review. Thus, instead of making a decision within the 180-day statutory period after the filing of the SNDA in April 2003, *see* 21 U.S.C. § 355(c)(1), the agency did not issue its not-approvable letter until over a year later in May 2004. When Barr, apparently prompted by the FDA, modified its SNDA to meet the FDA's concerns, the FDA again failed to act on it within the 180-day statutory period, on the basis that it needed more time to review matters. In the ensuing seven months after the expiration of the 180-day statutory period, however, the administrative record reveals that the FDA did little if anything to advance toward decision. Rather, without any warning, and after apparently assuring the Secretary of Health and Human Resources and its own counsel in this case that a decision would be made soon, the FDA announced that it wished to consider whether a rulemaking proceeding was necessary to explore the feasibility of permitting partial OTC access to Plan B based on age, a course that will inevitably forestall decision for months if not years. *See, e.g., Pub. Citizen Health Research Group v. Commissioner of FDA*, 740 F.2d 21, 34 (D.C. Cir. 1984) ("[T]he agency, by reversing course and issuing an advance notice of proposed rulemaking, has embarked on the least responsive course short of inaction") (citation omitted). This record of inaction led Judge Korman to observe that there is "more than ample basis for concluding for present purposes that the delay in ruling on the Citizen Petition is unreasonable." *Tummino v. von Eschenbach*, No. 05-CV-366 (E.D.N.Y. Jan. 17, 2006) (order denying motion for partial reconsideration).[26]

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[26]Judge Korman noted further at oral argument on the defendant's motion for judgment on the pleadings that because of the FDA's delay,

> There is a serious issue here as to whether they [the FDA] are acting in good faith. I

By its inaction in making a final determination on the Citizen Petition, one way or the other, the agency has evaded judicial review of its decisionmaking concerning OTC access for Plan B. *See Cutler*, 818 F.2d at 897 n.154 (citing *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093, 1099 (1970) ("when administrative inaction has precisely the same impact on the rights of the parties as denial of relief, an agency cannot preclude judicial review by casting its decision in the form of inaction rather than in the form of an order denying relief.")) (additional citation omitted). Although the court is not in a position now to decide whether OTC access to Plan B is appropriate, the overwhelming support of the professional staff of the FDA for OTC access, as detailed above, provides substantial evidence to question the agency's failure to authorize OTC access. More importantly, the unanimous conclusion of the joint advisory committee that the data submitted to the FDA demonstrated it to be safe for OTC use and the 27-1 vote of the committee that the data was "generalizable" to the entire range of potential OTC users raises substantial question about the legitimacy of the FDA's stated concerns about whether adolescents could safely use the product. Rather, the statements of some senior decisionmakers, including Dr. Woodcock and Dr. Galson, *see supra* at 9-10, suggest that the real reason for concern about granting OTC access to adolescents was the prospect that this might increase sexual activity in that age group. The professional staff of the FDA voiced strenuous objection to the consideration of such matters as being beyond the mandate of the agency, and

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> mean, there's a very serious issue that certainly can be dealt with in discovery in terms of the cause of action relating to the unreasonable delay in ruling on their application.

(Dec. 22 Oral Argument Tr. 23.)

even the Acting Director of CDER, who signed the first not-approvable letter in May 2004 conceded that the "non-medical implications of teen sexual behavior, or judgments about the propriety of this activity . . . are beyond the scope of our drug approval process." GAO Report, *supra* note 4, at 49. Nevertheless the Acting Director also confessed later that he signed the not-approvable letter because of his concerns about an increase in "unsafe sexual activity" among younger adolescents. *Id*. at 23.

The prospect that the agency's senior decisionmakers were resting on improper concerns about the morality of adolescent sexual activity is buttressed by the statements of many involved in the process that the decision not to approve the first SNDA had already been made and communicated to the professional staff as early as December 2003 and January 2004. (*See* App. 8 (Tummino-30745) (memorandum of Deputy Director Rosebraugh) ("[Dr. Galson] stated [at the January 15 meeting] that Plan B would receive a non-approvable action."), 13 (Tummino-30829) (memorandum of Deputy Director Griebel) ("However, in a January 15, 2004 meeting, senior CDER management informed the Division and Offices that this application is not approvable.").) *See also* GAO Report, *supra* note 4, at 32 ("The Director and Deputy Director of the Office of New Drugs and other officials told [the GAO] that they were informed during December 2003 and January 2004 that the application would not be approved.").

Certainly, a plausible interpretation of the e-mail correspondence by the author of the not-approvable letter just before and after he issued the letter in May 2004 is that senior management of the FDA had long since decided not to approve the application but needed to find acceptable rationales for the decision. Thus, only days before issuance of the letter he sought some last-minute "scientific" support for the contention that the data submitted in

support of the application could not be "extrapolated" across age groups and was thus insufficient. Several days later, however, he confessed that he had already made up his mind about the issue before he had sought that scientific support, leading to obvious questions about whether that *stated* reason for his decision was an actual reason, and if not, what the actual reasons were. (*See* App. 25-26 (Tummino-30909-30910).) The fact that the Director of the Office of Women's Health, a senior career employee of the FDA, as well as a longstanding member of one of the FDA's advisory committees, both chose to resign from the agency in protest over the decisionmaking process lends further support for the plaintiffs' position that improper considerations, unrelated to science or the mandate of the FDA, has prompted the FDA's decisions concerning Plan B.

Finally, the conclusions of the GAO Report that the FDA's decisionmaking processes were unusual in four significant respects satisfies the court that the necessary showing of bad faith or improper behavior has been made by the plaintiffs here. As detailed above, the GAO concluded, among other things, that the agency deviated from its traditional practices in reaching the decision not to grant the SNDA. *See* GAO Report, *supra* note 4, at 5-7. The Report further casts doubt on the supposed age-related concerns by pointing out that "there are no-age-related marketing restrictions for safety reasons for any of the prescription or OTC contraceptives that FDA has approved, and FDA has not required pediatric studies for them." *Id.* at 6. Indeed, out of 67 switch application decisions made by the FDA in the ten-year period preceding the May 2004 not-approvable letter, this one was the only one not to be approved after the advisory committees had recommended approval. *Id.* at 5. Thus, the plaintiffs' concerns about the integrity of the FDA's decisionmaking in connection with OTC access to

Plan B have substance, and the prospect that the FDA's continued delay in reaching a final decision is calculated to avoid review is real.[27]

II. Rulings On The Plaintiffs' Discovery Requests and Proposed Further Discovery

Having determined that the plaintiffs are entitled to discovery beyond the administrative record, the court considers the defendant's objections to the various requests for information already served by the plaintiffs, as well as the additional discovery the plaintiffs have proposed to conduct. Specifically, the plaintiffs have served document requests and interrogatories, and have advised the defendant and the court that they wish to depose various present and former high-ranking officials of the FDA. The defendant has objected to virtually all of the document requests and interrogatories on the grounds of lack of relevance and burdensomeness. In addition, the defendant has asserted that confidentiality concerns and various privileges, including the deliberative process privilege, prevent the production of some of the information sought by the plaintiffs as well as the depositions of the FDA officials.

As to the deliberative process privilege, the decision in *Overton Park* implicitly rejects the application of the privilege to agency proceedings where a showing of bad faith has been made. 401 U.S. at 420 (emphasizing that while "inquiry into the mental processes of administrative decisionmakers is usually to be avoided [citing *United States v. Morgan*, 313 U.S. 409, 422 (1941)]," such an inquiry is justified where there is "a strong showing of bad faith or improper behavior"). Inquiry into matters that would otherwise be covered by a deliberative process

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[27]Referring to the GAO Report at oral argument, Judge Korman noted that "[i]t does have a bearing on the issue of the good faith of the agency and the reasonableness of the delay." (Dec. 22 Oral Argument Tr. 60.)

privilege must of course be carefully limited to matters relevant to the issues before the court. The court's rulings below concerning the discovery requests that have been served by the plaintiffs reflect determinations of the appropriate scope of relevant inquiry taking into account the deliberative process privilege. As to deposition testimony, the parties may seek rulings from the court during the depositions to resolve disputes about appropriate areas of inquiry. To the extent the information ordered below is protected by privileges other than the deliberative process privilege, the defendant may assert such privileges but must comply with the requirements of Local Civil Rule 26.2(a).

Turning first to the plaintiffs' document requests, the requests primarily seek information concerning communications and correspondence between individuals within the FDA and those outside the FDA for the purpose of determining the concerns that influenced the decisions made by senior management and the sources of those concerns. As the court has indicated earlier, inquiry about those matters is appropriate. In seeking to justify the reasonableness of the delay in deciding the Citizen Petition, the defendant will undoubtedly point to the need for rulemaking to decide whether it is feasible to market Plan B on an OTC basis but with age restrictions. To assess the reasonableness of that asserted need for rulemaking, the court will inevitably be required to determine the preliminary question of whether there is a reasonable basis for believing that there is a need to adopt age restrictions in the first place. That inquiry will in turn raise the question of whether the asserted need for age restrictions, *viz.*, inadequate data to assess whether adolescents can use Plan B safely, is the real reason for seeking age restrictions, or whether some other improper reasons have infected that assessment. Thus, inquiry about

contacts between those outside the agency and those within the agency is appropriate to expose whether improper influences led to the FDA's actions.

The defendant's objection based on burdensomeness, however, appears to have merit with respect to requests seven through nine. Compliance with those requests would require substantial efforts by a number of agency employees, including many whose decisions concerning Plan B are not being questioned. (*See* Supplemental Decl. of J. Axelrad ¶ 11, attached to Def. Supp. Mem. of Law, as Ex. A.) Since the central inquiry here concerns the decisionmaking of the senior officials ultimately responsible for the decisions not to authorize OTC access for Plan B and to instead refer the issue to proposed rulemaking, and not to the many other employees of the agency who in some way participated in reviewing Plan B, the broad categories of discovery sought by requests seven through nine are only relevant as they pertain to contacts between or among those senior decisionmakers and the outside parties identified in the requests. Thus, compliance with those requests is limited to the senior decisionmakers rather than all agency employees.[28]

As to the remaining document requests, the defendant shall comply fully except for requests three and six which have been withdrawn. All documents responsive to all requests, including requests seven through nine, are to be produced within 30 days of this decision. If the documents have not all been gathered within 30 days, the defendant shall nevertheless produce all documents that have been gathered to that point, and shall advise the plaintiffs in writing

[28]Although there may be others, the senior decisionmakers would include the two former Commissioners, as well as Drs. Galson and Woodcock. If the parties are unable to agree on any others that may fall in that category, they should bring the dispute to the court's attention promptly.

when the remaining documents will be produced. In addition, within 40 days after this decision, the defendant shall provide a log of privileged documents that have been withheld thus far, whether or not production has yet been completed, and shall update the log if necessary when production has been completed.

As to the interrogatories, with the exception of interrogatories 3 (which has been withdrawn) and 26, the information sought in all of the interrogatories is relevant and the defendant has not demonstrated that producing the information (now limited to a five-year period instead of ten) is burdensome. Accordingly, to the extent that the information sought by interrogatories 1, 2, and 4 through 25 is available in the records of the FDA it is to be provided. No response to interrogatory 26 is required as the documents responsive to requests seven through nine are sufficient to provide the type of information sought to the extent it is relevant. The court notes that some of the information requested by the interrogatories has been provided in the form of a chart, which appears to be an acceptable format for responding to the interrogatories. The information required to complete the responses shall be provided within 30 days.

Finally, the plaintiffs may conduct depositions of the individuals identified in their supplemental memorandum. The individuals are to be deposed in the judicial district where they work or reside, and reasonable efforts are to be made to accommodate their schedules. Each deposition shall not exceed seven hours of testimony. In addition, if it appears after one or more of the depositions have been conducted that depositions of one or more of the remaining proposed deponents are either unnecessary or should be further limited in time, the defendant may seek rulings from the court.

CONCLUSION

For the foregoing reasons the defendant's motion for a protective order is denied and discovery shall proceed in accordance with this order. A status conference will be held on **April 28, 2006 at 11:00 a.m.**

SO ORDERED:

Viktor V. Pohorelsky

VIKTOR V. POHORELSKY
United States Magistrate Judge

Dated: Brooklyn, New York
February 24, 2006