

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 Commissioner of the Food and
Drug Administration,

CV 05-366 (ERK)(VVP)

Defendant.

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POHORELSKY, Magistrate Judge:

Before the court are various issues concerning discovery in this action, which challenges several determinations made by the Food and Drug Administration (“FDA”)¹ concerning Plan B, the so-called “morning after” pill. The plaintiffs seek an order requiring the production of various documents withheld on the basis of the deliberative process privilege, and have identified various items of discovery they wish to complete. The defendant seeks a protective order quashing all present and future discovery in this matter, and in the alternative an order prohibiting discovery from the White House. Much of the factual and procedural background for these issues has been addressed in other opinions of the court, familiarity with which is presumed. For the reasons below, the motion for a protective order is denied, and discovery shall proceed as set forth in the following rulings.

I. THE DEFENDANT’S MOTION FOR A PROTECTIVE ORDER

As the protective order sought by the defendant would preclude the need to address the other discovery issues, the court addresses that motion first. The FDA had sought a similar protective order precluding all discovery and limiting this court’s review to the administrative

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

record earlier in the proceedings. That motion relied primarily on the so-called “record rule,” which generally limits judicial review of agency decisions to the administrative record identified by the agency. The court denied the motion in a February 2006 decision on the basis of various exceptions which, if established, would allow “extra-record investigation by the reviewing court” *Tummino v. von Eschenbach*, 427 F. Supp. 2d 212, 230 (E.D.N.Y. 2006) (quoting *Nat’l Audubon Soc’y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997)) (additional citations omitted). Those exceptions included, “[1] a strong showing in support of a claim of bad faith or improper behavior on the part of agency decisionmakers or [2] the absence of formal administrative findings [which] makes such investigation necessary in order to determine the reasons for the agency’s choice.” *Id.* (quoting *Hoffman*, 132 F.3d at 14 (citations omitted)). This court also recognized, as an additional basis for piercing the administrative record, that the plaintiffs’ claims included one which sought to “compel agency action unlawfully withheld or unreasonably delayed.” *Id.* at 231 (citing *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 560 (9th Cir. 2000)) (additional citations omitted). In denying the FDA’s motion for a protective order, the court concluded that the plaintiffs had made a sufficiently strong showing of bad faith on the part of FDA officials to warrant discovery beyond the administrative record. *See id.* at 231-34.

The instant motion rests on recent decisions by the FDA which constitute final agency actions on the two applications that underlie the plaintiffs’ claims. Specifically, the FDA has denied the Citizen’s Petition seeking approval of over-the-counter (“OTC”) sales of Plan B without age restrictions and has granted an amended supplemental new drug application

(“SNDA”) which permits Barr Laboratories to make OTC sales of Plan B to persons 18 and older.

The defendant argues that these agency actions render the plaintiffs’ unreasonable delay claim moot, an argument that the plaintiffs cannot, and do not, contest. Indeed, the plaintiffs have withdrawn the unreasonable delay claim in a recently filed amended complaint, but continue to assert two other claims under the Administrative Procedure Act (“APA”).

Specifically, the fifth amended complaint attacks the decisions imposing age restrictions on OTC access to Plan B as “arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law,” in violation of 5 U.S.C. § 706(2)(a), and as beyond its statutory authority, in violation of 5 U.S.C. § 706(2)(c). Thus, the withdrawal of the unreasonable delay does not end the court’s inquiry into the FDA’s decisionmaking processes. And extra-record review of agency decision-making is just as appropriate when the claims involve final agency action as when the claims involve claims of unreasonable delay. *See, e.g., Sokaogon Chippewa Cmty. v. Babbitt*, 961 F. Supp. 1276 (W.D. Wis. 1997). Thus, the mere change of claims does not render moot the court’s previous finding that a preliminary showing of bad faith justifies discovery beyond the administrative record.

The defendant takes the argument one step further, however, by arguing that because the unreasonable delay claim is moot, the agency’s delays in making its decisions are immaterial and cannot amount to bad faith justifying judicial review beyond the administrative record. The argument is flawed for at least two reasons. First, it rests on the faulty premise that the FDA’s delays were the principal basis for the court’s conclusion that a strong preliminary showing of bad faith had been made. A review of the court’s decision discloses that delay was but one of

the factors considered by the court in reaching that determination. The other factors included questionable conduct surrounding various interim determinations made by the FDA in addressing Plan B issues. The FDA seeks to deflect the significance of that conduct by arguing that the FDA's interlocutory decisions are not reviewable by this court, a premise that, itself, is of dubious merit. *See* 5 U.S.C. § 704 ("A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."). It can only follow then that the court be able to consider the agency's conduct surrounding those interlocutory decisions in reaching a determination that a strong preliminary showing of bad faith remains. And this is true regardless of whether the plaintiffs here have standing to challenge the final decision concerning Barr's SNDA for, as the defendant's counsel acknowledges, the agency's actions on the Citizen's Petition and Barr's SNDA were intertwined. *See* July 26, 2006 Tr. at 40:16-19 ("if Barr wins, they win, and if Barr loses, they lose").²

Second, and perhaps more importantly, the FDA's delays in making its determinations continue to be relevant to a showing of bad faith even though final decisions have been made. Unreasonable delay itself can, of course, constitute arbitrary and capricious conduct. *See Coit Independence Joint Venture v. Federal Sav. and Loan Ins. Corp.*, 489 U.S. 561, 590 (1989) (Scalia, J., concurring in part). Although unreasonable delay by itself furnishes no basis for relief once final agency action is taken, it does not lose its relevance as a factor to be considered in determining whether it is appropriate to extend review of that final agency action beyond the administrative record. In other words, if questionable delay, coupled with other factors, is found

²The term "Tr." preceded by a date refers to the transcript of a conference or hearing held on the date indicated.

to establish a strong preliminary showing of bad faith justifying review beyond the administrative record, that strong preliminary showing does not evaporate simply because the agency finally took action that had been unreasonably delayed.

The court thus finds no basis for upsetting its prior determination that the plaintiffs have made a sufficiently strong preliminary showing of bad faith that justifies discovery beyond the administrative record. Accordingly, the motion for a protective order staying the completion of discovery is denied.

II. DISCOVERY TO BE COMPLETED

The plaintiffs have identified essentially three areas of discovery that remain to be pursued. First, they wish to depose Dr. Sandra Kweder, an FDA employee, concerning her knowledge of matters relating to decisions made by the FDA. Second, they wish to serve subpoenas for documents from the White House and testimony from a former member of the White House staff, Jay Lefkowitz, concerning contacts between the White House and high-ranking officials of the FDA about Plan B. Finally, they wish to complete outstanding documentary discovery which includes the court's review of documents withheld by the defendant on the basis of the deliberative process privilege.

A. Deposition of Dr. Kweder

As the defendant does not oppose the deposition of Dr. Kweder on any grounds other than that all discovery should be stayed (although he contends her testimony would be cumulative), the plaintiffs should schedule and complete her deposition as soon as reasonably convenient.

B. Subpoenas for White House Information

The defendant's opposition to discovery from the White House rests largely on separation of powers concerns, as enunciated in *Cheney v. United States District Court*, 542 U.S. 367 (2004), which arise when the vice-president and other senior officials in the executive branch are directed to provide discovery. The defendant's standing to raise those concerns is suspect, since the defendant is not asserting his own interests but the interests of absent third parties. Thus, parties typically are deemed to lack standing to quash subpoenas issued to non-parties under Rule 45 absent a claim of privilege or some proprietary or personal interest in the subpoenaed matter. See, e.g., *Estate of Ungar v. Palestinian Authority*, 400 F. Supp. 2d 541, 554 (S.D.N.Y. 2005); *Auto-Owners Ins. Co. v. Southeast Floating Docks, Inc.*, 231 F.R.D. 426, 429 (M.D. Fla. 2005); *Washington v. Thurgood Marshall Academy*, 230 F.R.D. 18, 21 (D.D.C. 2005); *Green v. Sauder Mouldings, Inc.*, 223 F.R.D. 304, 306 (E.D. Va. 2004). A party may of course seek a protective order under Rule 26(c), even as to discovery sought from third parties, but in those circumstances the party generally must be seeking to protect its own interests in precluding the discovery, not the interests of the third party. *American Rock Salt Co., LLC v. Norfolk Southern Corp.*, 228 F.R.D. 426, 466 (W.D.N.Y. 2004); see also 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice And Procedure* § 2035, at 475 (2d ed. 1994) ("A party may not ask for an order to protect the rights of another party or a witness if that party or witness does not claim protection for himself, but a party may seek an order if it believes its own interest is jeopardized by discovery sought from a third person.").

The court is particularly reluctant to consider the separation of powers concerns raised by the defendant now that his counsel has reversed their initial position that the government would

abide by whatever rulings this court made concerning the discovery sought by the plaintiffs from the White House. (*Compare* Oct. 11, 2006 Tr. 44:17-45:17, *with* Aug. 3, 2006 Tr. 23:16-24:4.)

As the White House and the members of its staff from whom the information is sought are not before this court, in the absence of their agreement to abide by this court's decision any ruling made here on those issues would be simply advisory. Rather, because any subpoena for the information sought by the plaintiffs from the White House must emanate from the United States District Court for the District of Columbia, the White House and its staff have the right to have any separation of powers issues, which they will undoubtedly raise, determined by that court. *See* Fed. R. Civ. P. 45(c).

Although this court therefore declines to rule on the separation of powers arguments, as relevancy is part of the *Cheney* calculus in resolving separation of powers concerns, this court offers the following brief observation about the relevancy of the information sought from the White House. The central theory of the plaintiffs' claims here is that the FDA's decisions concerning Plan B were arbitrary and capricious and contrary to law because they were guided by improper political considerations. There is no dispute that high officials of the FDA, including two commissioners, had direct discussions with members of the White House staff concerning the FDA's decisions about Plan B. (*See* Oct. 11, 2006 Tr. 25:2-8.)³ Information concerning the content of those communications is thus directly relevant to the question whether improper political considerations infected the commissioners', and therefore the FDA's, decisionmaking processes. In deposition testimony, the commissioners themselves have

³Jay Lefkowitz, the individual whom the plaintiffs wish to depose, is described by the defendant as "a former high-ranking advisor to the President." (Def.'s Mem. Supp. Prot. Order Mot. 1.)

characterized the discussions as purely informational. But that should not prevent to the plaintiffs from testing those characterizations by obtaining discovery from the other participants in those discussions by means of sufficiently specific document requests and depositions. The court has not closely examined the proposed scope of discovery sought from the White House by the plaintiffs. The question of how broad the discovery ought to be is best left to the court that hears from the persons subpoenaed concerning the burdens the requests impose on them, and the separation of powers concerns that the requested discovery raises. It is enough for this court to say that some measure of inquiry into White House involvement in Plan B decisionmaking ought to be allowed.

C. Documents Withheld Under Deliberative Process Privilege

Some background is necessary before proceeding to the merits of the parties' arguments concerning the documents withheld by the defendant on the basis of the deliberative process privilege. At a discovery hearing on May 31, 2006, this court overruled the defendant's assertion of the deliberative process privilege as a basis for withholding documents sought by the plaintiffs in their second set of document requests.⁴ The defendant appealed that ruling⁵ to Judge

⁴That request seeks the production of "all correspondence, including email correspondence, concerning Plan B that was received by, sent by, or copied to any of the following individuals: Jane Axelrad, Jin Chen, Lester Crawford, Steven Galson, John Jenkins, Mark McClellan, and Janet Woodcock." (Pls.' Letter to Mag. J. Pohorelsky, May 5, 2006, *available at* docket. entry 133.)

⁵The following colloquy took place at the hearing, which forms the basis of the defendant's objection:

MR. AMANAT: [Y]our Honor, just to clarify for the record your Honor's ruling with regard to deliberative process privilege. Am I correct in understanding that your Honor has precluded the government from asserting the deliberative process privilege in regards to any document that may be responsive to these discovery requests?

THE COURT: No, you can assert any privilege you want but the deliberative process privilege

Korman, who deferred decision on the objection, opting instead to deal with the issue “on a practical basis.” (July 26, 2006 Tr. 4:3-4.) To that end, Judge Korman provided the defendant an opportunity (without prejudice to any arguments advanced by the plaintiffs) to withhold, and subsequently submit to this court for *in camera* review, a subset of the assertedly privileged documents. In conducting the *in camera* review, this court was instructed to “consider whether the documents evidence bad faith such that they would be directly relevant to the plaintiff’s claims and assure that the privilege [sic] documents are not merely duplicative of previously-disclosed documents.” (Minute Entry and Order for July 26, 2006 Status Conference, *available at* docket entry 179.) Judge Korman instructed further that those documents which this court finds evidence bad faith should be disclosed by the defendant. (*See* July 26, 2006 Tr. 13 (“[T]he instruction to the magistrate should be is that if in his judgment it is deliberative, these documents evidence bad faith, that they should be disclosed.”).) In accordance with Judge Korman’s directions, the defendant submitted 1,179 pages of documents along with a privilege log and supporting affidavit by an FDA official to this court for *in camera* review. (*See* Def.’s Letter to Mag. J. Pohorelsky, Aug. 11, 2006, *available at* docket entry 183.) In the defendant’s estimate, this submission constitutes approximately fifteen to twenty percent of the assertedly privileged documents responsive to the document request at issue. (July 26, 2006 Tr. 4:19-24.) More significantly, as counsel for the defendant pointed out at the latest hearing, this 1,179-page

is not a basis to withhold production. I am overruling that as a basis on which to withhold production. It’s a qualified privilege and the privilege in my view with respect to deliberations concerning Plan B has been effectively taken out of this case by the Court’s prior [February 2006] ruling.

(May 31, 2006 Tr. 62:12-63:5.)

submission represents only “one-sixth” of the documents the defendant intends to withhold on the basis of the deliberative process privilege. (Oct. 11, 2006 Tr. 42:11-22.)

The plaintiffs have challenged the defendant’s *in camera* submission, arguing that the log itself is insufficient in some respects and questioning the assertions of the privilege as to some of the documents identified in the log. (*See* Pls.’ Letter to Mag. J. Pohorelsky 1-4, Aug. 29, 2006, *available at* docket entry 191.) The plaintiffs also point to various documents identified in the log which, in their view, are likely to evidence bad faith. (*See* Pls.’ Response to Def.’s Aug. 11, 2006 Privilege Log, *available at* docket entry 191.)

Given the parties’ positions and Judge Korman’s instruction, the court’s task here is threefold. First, the court must make a threshold determination as to whether the privilege applies at all to the documents withheld by the defendant. Certainly, those documents found to be non-privileged must be disclosed. Indeed, the defendant construes the plaintiffs’ opposition to its *in camera* submission as a “motion to compel production of documents withheld on the basis of the deliberative process privilege.” (*See, e.g.*, Def.’s Mem. of Law Opp’n Pls.’ Mot. to Compel, *available at* docket entry 202.) These non-privileged document are listed in Appendix A. Second, the court must undertake the task assigned by Judge Korman, namely, reviewing the remaining documents, i.e., those not listed in Appendix A, for evidence of bad faith, and ordering the disclosure of those that contain such evidence. Those documents that evidence bad faith are identified in Appendix B. As to the remainder of the submission, i.e., documents not listed in Appendices A and B, including the accompanying privilege log, the court addresses various defects it finds with the defendant’s assertion of the privilege. Those documents which exhibit such defects are listed in Appendix C.

One aspect of Judge Korman's assignment is beyond this court's capability at present, however. In addition to reviewing the withheld documents for evidence of bad faith, Judge Korman requested that this court "assure that the privilege[d] documents are not merely duplicative of previously-disclosed non-privileged documents." (Minute Entry and Order for July 26, 2006 Status Conference, *available at* docket entry 179). Because the court has not been provided with all previously disclosed documents, no such comparison could be undertaken. To the extent the defendant objects to the disclosure of the privileged documents identified in Appendix B to this opinion on the basis of redundancy, it may submit copies of already produced documents which support its objection for this court's review. Such submissions must be made within five days.

1. Review of Documents for Proper Application of the Deliberative Process Privilege

a. Scope of the Privilege

The common-law deliberative process privilege is a "sub-species" of the work-product privilege, available to the government for purposes of civil discovery. *See Nat'l Council of La Raza v. U.S. Dep't of Justice*, 411 F.3d 350, 356 (2d Cir. 2005) (citation omitted); *Litton Industries, Inc. v. Lehman Bros. Kuhn Loeb Inc.*, 125 F.R.D. 51, 53 (S.D.N.Y. 1989) (citation omitted). When asserted, the privilege shields from disclosure "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *U.S. Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (citation and internal quotation marks omitted);

accord Nat'l Council of La Raza, 411 F.3d at 356 (citation omitted).⁶ The policy underlying the deliberative process privilege,

[R]ests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance 'the quality of agency decisions' by open and frank discussion among those who make them within the Government.

Klamath, 532 U.S. at 8-9 (citations omitted). As one court put it, "when [determining] whether an agency properly withheld documents under the deliberative process privilege, the critical question that must be answered is whether 'disclosure of [the] materials would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions.'" *Wilderness Soc'y v. U.S. Dep't of Interior*, 344 F. Supp. 2d 1, 10 (D.D.C. 2004) (quoting *Formaldehyde Inst. v. U.S. Dep't of Health and Human Servs.*, 889 F.2d 1118, 1122 (D.C. Cir. 1989)).

To properly assert the privilege as to inter- or intra-agency documents, the government must satisfy a two-part test, showing that the documents it seeks to shield from disclosure are both "predecisional" and "deliberative." *Nat'l Council of La Raza*, 411 F.3d at 356 (citations omitted). In doing so, however, the government must avoid "conclusory assertion[s]" of the privilege, "where no factual support is provided for an *essential* element of the claimed privilege or shield." *Senate of the Commonwealth of Puerto Rico on Behalf of Judiciary Comm. v. U.S. Dep't of Justice*, 823 F.2d 574, 585 (D.C. Cir. 1987) (citations and internal quotation marks omitted).

⁶See also 5 U.S.C. § 552(b)(5) (otherwise known as "Exemption 5" of the Freedom of Information Act, which incorporates various civil discovery privileges, including the deliberative process privilege, thus allowing the government to withhold "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency.").

“A document is predecisional when it is prepared in order to assist an agency decisionmaker in arriving at his decision.” *Tigue v. U.S. Dep’t of Justice*, 312 F.3d 70, 80 (2d Cir. 2002) (citation and internal quotation marks omitted). This must be distinguished from a document that is “postdecisional” or one which “set[s] forth the reasons for an agency decision already made.” *Dipace v. Goord*, 218 F.R.D. 399, 403 (S.D.N.Y. 2003) (quoting *Renegotiation Bd. v. Grumman Aircraft Eng’g Dev.*, 421 U.S. 168, 184 (1975)) (additional citation and internal quotation marks omitted). Nor is a document predecisional, if it is “ ‘merely peripheral to actual policy formation.’ ” *Tigue*, 312 F.3d at 80 (citations omitted). Courts have found a document “predecisional” if the agency can “(i) pinpoint the specific agency decision to which the document correlates, (ii) establish that its author prepared the document for the purpose of assisting the agency official charged with making the agency decision, and (iii) verify that the document precedes, in temporal sequence, the decision to which it relates.” *Nat’l Cong. for Puerto Rican Rights ex rel. Perez v. City of New York*, 194 F.R.D. 88, 92 (S.D.N.Y. 2000) (quoting *Providence Journal Co. v. U.S. Dep’t of Army*, 981 F.2d 552, 557 (1st Cir. 1992)) (internal quotation marks omitted); *accord Grand Cent. P’ship, Inc. v. Cuomo*, 166 F.3d 473, 482 (2d Cir. 1999) (citations omitted); *Mitchell v. Fishbein*, 227 F.R.D. 239, 250 (S.D.N.Y. 2005) (citations omitted). Examples of documents considered predecisional for purposes of the privilege are “recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency.” *Tigue*, 312 F.3d at 80 (citation and internal quotation marks omitted).

Even these documents, however, may lose their predecisional character “ ‘if . . . adopted, formally or informally, as the agency position on an issue or . . . used by the agency in its

dealings with the public.’ ” *Nat’l Council of La Raza*, 411 F.3d at 356-57 (quoting *Coastal States Gas Corp v. U.S. Dep’t of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980)). Disclosure is warranted in such circumstances because, as the Supreme Court explained,

The probability that an agency employee will be inhibited from freely advising a decisionmaker for fear that his advice if adopted, will become public is slight. First, when adopted, the reasoning becomes that of the agency and becomes its responsibility to defend. Second, agency employees will generally be encouraged rather than discouraged by public knowledge that their policy suggestions have been adopted by the agency. Moreover, the public interest in knowing the reasons for a policy actually adopted by an agency supports [disclosure].

Id. (quoting *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 161 (1975)).

A document is “deliberative” if it “actually . . . relate[s] to the process by which policies are formulated.” *Grand Cent. P’ship*, 166 F.3d at 482 (quoting *Hopkins v. HUD*, 929 F.2d 81, 84 (2d Cir. 1991) (quoting *Jordan v. U.S. Dep’t of Justice*, 591 F.2d 753, 774 (D.C. Cir. 1978) (en banc))) (internal quotation marks omitted). To make this determination, courts have found it helpful to look at whether the document “(i) formed an essential link in a specified consultative process, (ii) reflected the personal opinions of the writer rather than the policy of the agency, and (iii) if released, would inaccurately reflect or prematurely disclose the views of the agency.” *Id.* (quoting *Providence Journal Co.*, 981 F.2d at 559 (quoting *Nat’l Wildlife Fed’n v. Forest Serv.*, 861 F.2d 1114, 1118-19 (9th Cir. 1988))) (internal quotation marks omitted). To that end, documents “reflecting advisory opinions, recommendations, and deliberations comprising part of a process by which governmental decisions and policies are formulated,” fall within the class of deliberative documents contemplated by the privilege. *Id.* (quoting *Hopkins*, 929 F.2d at 84-85 (quoting *Sears*, 421 U.S. at 150)) (internal quotation marks omitted).

To be sure, the concern here is whether the documents at issue “reflect the ‘give-and-take of the consultative process.’ ” *Alloco Recycling, Ltd. v. Doherty*, 220 F.R.D. 407, 414 (S.D.N.Y. 2004) (quoting *Judicial Watch, Inc. v. U.S. Postal Serv.*, 297 F. Supp. 2d 252, 263 (D.D.C. 2004)) (additional citations omitted). To qualify for the privilege, however, such “give-and-take must regard opinions on legal or policy matters.” *Id.* at 414 (quoting *Judicial Watch*, 297 F. Supp. 2d at 263) (additional citations and internal quotation marks omitted) (emphasis added). Therefore, even where “give-and-take” involves “comments from an agency employee . . . with respect to the content of documents,” “[i]f the [documents] themselves merely restate facts, and do not involve ‘legal or policy matters,’ any comments or opinions about these same [documents] are not privileged.” *Id.* (quoting *Judicial Watch*, 297 F. Supp. 2d at 263 (quoting *Vaughn v. Rosen*, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975))). By extension then, “purely factual” materials which do not reflect an agency’s deliberations are also not covered by the privilege. *Id.* (citations omitted). Therefore, “[i]f factual portions of a document are ‘severable without compromising the private remainder of the document[,]’ then the factual portions must be disclosed, even though the deliberative material remains protected.” *Alloco Recycling, Ltd. v. Doherty*, 220 F.R.D. 407, 412 (S.D.N.Y. 2004) (quoting *EPA v. Mink*, 410 U.S. 73, 91 (1973), *superseded on other grounds by* Pub. L. No. 93-502, 88 Stat. 1561 (1974)).

Lastly, the court emphasizes that the deliberative process privilege, even if properly asserted, does not guarantee nondisclosure. That is to say the privilege is qualified, and must yield to certain competing interests. *See In re Franklin Nat’l Bank Sec. Litig.*, 478 F. Supp. 577, 582 (E.D.N.Y. 1979) (Weinstein, J.). “Foremost is the interest of the litigants, and ultimately of society, in accurate judicial fact finding.” *Id.* (citations omitted). Other competing interests

which the court may take into account are: “(i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the ‘seriousness’ of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.” *Id.* at 583 (citations omitted). *Accord In re Subpoena Served Upon Comptroller of Currency, and Secretary of Bd. of Governors of Fed. Reserve Sys.*, 967 F.2d 630, 634 (D.C. Cir. 1992); *Martin v. Valley Nat. Bank of Arizona*, 140 F.R.D. 291, 303-04 (S.D.N.Y. 1991).

Especially applicable to the present matter, and as the *Franklin National Bank* case makes clear, the deliberative process privilege must, at times, yield to the “public interest in opening for scrutiny the government’s decision making process.” *In re Franklin Nat’l Bank Sec. Litig.*, 478 F. Supp. at 582. As Judge Weinstein, quoting the late-Justice Brennan, cogently observed, this limitation is a reflection of a certain “paradox” inherent in the exercise of the deliberative process privilege – that is, “‘to enable the government more effectively to implement the will of the people, the people are kept in ignorance of the workings of their government.’” *Id.* (quoting *Herbert v. Lando*, 441 U.S. 153, 195 (1979) (Brennan, J., dissenting)). “[J]ustification for the privilege [is therefore] attenuated” “when the public’s interest in effective government would be *furthered* by disclosure,” and disclosure is proper. *Id.* (emphasis added). Of particular relevance, “where the documents sought may shed light on alleged government malfeasance, the privilege is denied.” *Id.* (additional citations omitted).

b. Documents Not Falling Within the Scope of the Privilege

Applying the principles set forth above, the court finds that the documents listed in Appendix A to this opinion are not covered by the privilege. Foremost among these unprivileged

documents are “agendas” or “executive summaries” (draft and final versions) of meetings. These documents typically contain a brief background on the Plan B OTC-switch application process, and a listing of topics for discussion. (*See, e.g.*, Tummino-895-96, 1063-65, 2737-39, 3879-81, 3884-86, 3888-90, 4049-51, 4079-80, 4081-83, 4693-94, 4702-03.)⁷ These documents may of course form the basis for internal deliberations on agency policy. However, as the documents do not disclose what was eventually discussed or indeed whether they were even relied upon by agency officials, these types of documents are neither “predecisional,” *Grand Cent. P’ship*, 166 F.3d at 482 (documents which are “merely peripheral to actual policy formation” are not predecisional) (citation omitted), nor “deliberative,” *id.* (documents which do not reflect personal opinions of the writer are not deliberative) (citations omitted).⁸

As to the other documents listed in Appendix A, the court overrules the assertion of privilege because they are either “purely factual” in nature, in which case their disclosure would raise none of the concerns the privilege was meant to address, i.e., exposure of internal agency deliberations chilling future inter-governmental debate, or have, in one form or other, been “adopted, formally or informally, as the agency position on an issue or . . . used by the agency in its dealings with the public.” *Nat’l Council of La Raza*, 411 F.3d at 356-57 (citation and internal quotation marks omitted).

⁷Citations to the Bates numbers assigned to documents involved in this litigation are in the form of “Tummino-XXXXX.”

⁸The defendant had, at certain junctures of the discovery process, apparently operated under a similar rationale where some of the documents it turned over to the plaintiffs without any claim of privilege also contain agenda-like language. (*See, e.g.*, Tummino-1818-1822, attached to Ex.C of Pls.’ Letter to Mag. J. Pohorelsky, Aug. 29, 2006.)

2. Review of Documents for Evidence of Bad Faith

Having set aside those documents which do not qualify for the privilege, the court turns to a review of the defendant's submission for evidence of bad faith.⁹ That task is of course preceded by defining what "bad faith" means in relation to the present matter. Because of the case's complexity, "bad faith" should not, and indeed, cannot be distilled into a one-line definition. Rather, consistent with the claims pressed by the plaintiffs, and in reliance on past submissions and its February 24, 2006 decision, the court has considered the following five categories of information to be reflective of improper FDA behavior – or in other words, agency bad faith – in considering OTC access to Plan B:

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

As stated earlier, the bates numbers of the documents which contain information that falls within one or more of the above categories are listed in Appendix B to this opinion.

⁹Some of the nonprivileged documents listed in Appendix A exhibit evidence of bad faith and are therefore also noted in Appendix B.

To the list in Appendix B the court has also added documents which reflect viewpoints within the FDA opposed to an age-restricted Plan B OTC-distribution plan. While these documents undoubtedly demonstrate a healthy intra-agency debate, thus militating against disclosure, many of the authors have already had their dissenting views aired in public. *See Tummino*, 427 F. Supp. 2d at 220-25, 228-29 (reciting communications from FDA senior review staff which “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.”). As the material at issue has already been disclosed presumably with the consent of the author, or at the very least the agency, there is less risk that agency deliberations would suffer any chilling effect. More importantly, these documents offer clues as to why the FDA reached the result it did despite vocal opposition among many agency employees, and thus shed light on the agency decisionmaking process, the proof of which lies at the heart of the plaintiffs’ case.

3. The Sufficiency of the Defendant’s Privilege Log

Finally, the court turns to a remaining body of documents for which a determination cannot be made concerning the proper application of the privilege. For these documents, listed in Appendix C below (and indeed for the submission as a whole), the court is troubled that the defendant has made no effort to tailor its assertion of the privilege to ensure that only those portions of documents which qualify as *both* deliberative and predecisional are withheld, or to offer any explanation as to why the privilege applies in such a way that entire documents should

be shielded from disclosure. In essence, the defendant has taken an all-or-nothing approach in asserting the privilege, which has complicated the court's task.

For example, many of the documents in the 1,179-page *in camera* submission seem to contain factual portions which may be segregated from the deliberative portions of the document. In particular, the submission is densely populated with lengthy FDA studies, ranging from 20 to 50 pages, which the defendant contends are entirely privileged. Surely that cannot be the case when large portions of these studies simply recite results from other publicly available scientific studies.¹⁰ Of course, it may turn out that such information, even if disclosed, would be of limited value to the plaintiffs. That, however, does not relieve the defendant of the obligation to avoid blanket assertions of the privilege, which unnecessarily compromise the public's interest in "accurate judicial fact finding." *In re Franklin Nat'l Bank Sec. Litig.*, 478 F. Supp. at 582. Moreover, as the District of Columbia Circuit emphasized in its landmark decision in *Vaughn v. Rosen*, in withholding production of a large document "it is vital that the agency specify in detail which portions of the document are disclosable and which are allegedly exempt." 484 F.2d 820, 827 (D.C. Cir. 1973).

To its credit, the defendant has included, with its extensive *in camera* submission, a privilege log to support its assertions of privilege. *See* Local Civ. R. 26.2(a)(2)(A) (setting forth types of information a litigant must provide when objecting to disclosure of documentary evidence on basis of privilege); *Bowne of New York City, Inc. v. AmBase Corp.*, 150 F.R.D. 465,

¹⁰Many such documents are also described as "drafts" in the privilege log, but bear scant indications that one anticipates seeing in a draft document. In any event, the law is clear that "simply designating a document as a 'draft' does not automatically make it privileged under the deliberative process privilege." *Wilderness Soc'y*, 344 F. Supp. 2d at 14 (citation omitted); *see also* *Judicial Watch, Inc. v. U.S. Postal Serv.*, 297 F. Supp. 2d at 260-61 (finding ambiguities in agency descriptions of draft documents foreclosing summary judgment in FOIA case) (citations omitted).

473-74 (2d Cir. 1993) (suggesting, in cases involving “large quantities of disputed documents,” a court utilize “an adequately detailed privilege log in conjunction with evidentiary submissions to fill in any factual gaps.”) (citations omitted). The log fails, however, to provide sufficient aid to the court in determining whether the documents listed in Appendix C are properly withheld as material, which, if released, would compromise the sanctity of the agency’s deliberative process. At a bare minimum, the log must comply with Rule 26(b)(5)’s requirement that a party seeking to shield documents by a claim of privilege describe the nature of the documents withheld in sufficient detail “to enable other parties to assess the applicability of the privilege or protection.” Fed. R. Civ. P. 26(b)(5). Determining whether this objective is accomplished requires that “[t]he focus [be] on the specific descriptive portion of the log, and not on the conclusory invocations of the privilege.” *Bowne*, 150 F.R.D. at 474 (citations omitted). This is so because “the burden of the party withholding documents cannot be ‘discharged by mere conclusory or *ipse dixit* assertions.’ ” *Id.* (citations omitted). The defendant’s log suffers that failing.

A typical entry in the log provides information as to the document’s bates number, length in pages, author, and recipient. The entries also contain a one-line description of the withheld document and the type of privilege or privileges claimed to support nondisclosure. Describing a document as, for example, a “Draft Request for Clinical Inspection – Auditing Plan B Actual Use Study,” and labeling it “confidential commercial information” and “deliberative process” privileged material, is of little use to the plaintiffs, and especially the court, which has sparse knowledge of the complex details associated with this matter, in determining whether the defendant is correct in its application of the privilege. (*See* Entry for Tummino-2752-54, Def.’s Privilege Log, Aug. 10, 2006, attached to Def.’s Letter to Mag. J. Pohorelsky, Aug. 11, 2006.)

No information is provided as to whether this document was relied upon by FDA staff in formulating Plan B policy or what distinguishing features warrant the “draft” label.

Of course, the privilege log is only part of the submission, since the documents identified in the log were also produced to the court for *in camera* review. Indeed, it may have been recognition of this fact that caused the defendant to submit a privilege log with truncated information. The law is clear, however, that, even when submitting the documents for *in camera* review, the burden remains on the defendant to sustain its invocation of the deliberative process privilege by, among other things, “showing ‘what deliberative process is involved, and the role played by the documents in issue in the course of that process.’ ” *Arthur Anderson & Co. v. I.R.S.*, 679 F.2d 254, 258 (D.C. Cir. 1982) (quoting 5 U.S.C. § 552(a)(4)(B) (provision setting forth framework for obtaining governmental records under FOIA), *and Coastal States*, 617 F.2d at 868).

In this respect, the court receives considerable guidance from the well-developed body of law, primarily in the District of Columbia Circuit, concerning agency assertions of privilege in the Freedom of Information Act or FOIA context.¹¹ In these situations, an agency seeking to shield documents from disclosure on the basis of privilege, including the oft-employed deliberative process privilege, must provide “ ‘the reviewing court a reasonable basis to evaluate the claim of privilege.’ ” *Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 146 (D.C. Cir. 2006) (quoting *Gallant v. N.L.R.B.*, 26 F.3d 168, 172-73 (D.C. Cir. 1994)). This often involves

¹¹The court notes that both parties have relied on FOIA cases in their submissions to the court. (See, e.g., Def.’s Mem. of Law in Opp’n Pls.’ Mot. to Compel 9 (citing *Mobil Oil Corp. v. EPA*, 879 F.2d 698 (9th Cir. 1989)); Pls.’ Letter to Mag. J. Pohorelsky 2, Aug. 29, 2006 (citing *Hopkins*, 929 F.2d at 81).)

submission of a so-called *Vaughn* index, similar in form and function to a privilege log,¹² in addition to other measures such as submitting the documents themselves for *in camera* review. *See, e.g., Grand Cent. P'ship*, 166 F.3d at 477 (pursuant to FOIA claim, *Vaughn* index and documents withheld on basis of deliberative process privilege submitted for *in camera* review). Although the defendant's privilege log complies in form with these requirements, it does not give the court sufficient guidance about what to look for in testing the defendant's assertions of privilege. Not even a single page out of the 1,179 pages of documents submitted for review contained any limitation concerning assertion of the privilege by, for example, redactions or indications of portions not subject to the privilege. Nor has the defendant offered any document-specific explanation, individually or by type of document, which would aid the court in assessing the applicability of the privilege. The significance of the problem is exacerbated when the *in*

¹²To pass muster, a *Vaughn* index must, at a minimum,

- (1) [B]e contained in one document, complete in itself;
- (2) [A]dequately describe each withheld document or deletion from a released document; [and]
- (3) [S]tate the exemption claimed for each deletion or withheld document, and explain why the exemption is applicable to that deletion.

Founding Church of Scientology of Washington, D. C., Inc. v. Bell, 603 F.2d 945, 949 (D.C. Cir. 1979); *accord Lawyers Comm. for Human Rights v. I.N.S.*, 721 F. Supp. 552, 560 (S.D.N.Y. 1989) (citations omitted).

As the District of Columbia Circuit recently explained,

The *Vaughn* index . . . serves three important functions: [I]t forces the government to analyze carefully any material withheld, it enables the trial court to fulfill its duty of ruling on the applicability of the exemption, and it enables the adversary system to operate by giving the requester as much information as possible, on the basis of which he can present his case to the trial court.

Judicial Watch, Inc. v. FDA, 449 F.3d at 146 (quoting *Keys v. U.S. Dep't of Justice*, 830 F.2d 337, 349 (D.C. Cir. 1987)). These principles are equally applicable to the present matter, especially since it is also the government here which seeks to shield information from public view.

camera review is voluminous, as it is here, which creates the “ ‘unreasonable . . . expect[ation] [that] a trial judge . . . do as thorough a job of illumination and characterization as would a party interested in the case.’ ” *Arthur Anderson*, 679 F.2d at 258 (quoting *Vaughn*, 484 F.2d at 825).¹³ At the end, it is the defendant’s, not the court’s, burden to offer a justification as to why a document should be withheld as privileged, and to delineate the proper reach of the privilege within the document. *Judicial Watch, Inc. v. FDA*, 449 F.3d at 147 (“Broad, sweeping claims of privilege without reference to the withheld documents would impede judicial review and undermine the functions served by the *Vaughn* index requirement. The agency must therefore explain *why* the exemption applies and *may not ignore the contents of the withheld documents.*”) (citing *Campbell v. U.S. Dep’t of Justice*, 164 F.3d 20, 30-31 (D.C. Cir. 1998)) (emphasis added). The defendant has, thus far, failed to provide the court with information that even remotely satisfies these requirements.

These failings do not warrant complete disclosure of these documents at this point in the proceedings, however. Instead, as the FOIA-line of authority suggests, the defendant, having failed to carry its burden, can amend the privilege log to address the court’s concerns as expressed above. *See, e.g., Judicial Watch, Inc. v. FDA*, 449 F.3d at 153-54 (remanding matter to allow defendant an opportunity to remedy various defects in *Vaughn* index); *Wilderness Soc’y*, 344 F. Supp. 2d at 14 (same). To that end, the defendant shall identify those portions of

¹³As the *Arthur Anderson* court explained in further detail,

Because the party seeking disclosure is ignorant of the contents of withheld documents and a court may be unable to undertake an exhaustive in camera review, *Vaughn* required that an agency justify withholding of documents through itemized and indexed explanations. Otherwise, the burden of justification would be imposed on the court.

Id.

the documents listed in Appendix C which it still wishes to withhold as privileged. In doing so, the defendant shall supplement the log with information that would aid the court in determining why the privilege applies, including details of the document's " 'function and significance . . . in the agency's decisionmaking process.' " *Arthur Anderson*, 679 F.2d at 258 (quoting *Taxation With Representation Fund v. IRS*, 646 F.2d 666, 678 (D.C. Cir. 1981)). The defendant shall also make a concerted, good faith effort to segregate from and disclose those portions of the Attachment C documents which are "purely factual," or otherwise do not qualify for the privilege according to the principles set forth above.

CONCLUSION

For the foregoing reasons, the defendant's motion for a protective order to stay all discovery or in the alternative to preclude discovery relating to the White House is denied. The deposition of Dr. Kweder may proceed. The defendant shall produce for inspection and copying the documents listed in Appendices A and B within ten days. As to the documents listed in Appendix C the defendant shall produce such portions as are purely factual or otherwise not covered by the privilege in accordance with this opinion within ten days, and as to those portions to which the defendant continues to assert the privilege the defendant shall supplement the privilege log to provide the necessary information to enable review of the assertions within twenty days. Finally, as to the remaining documents withheld by the defendant but which have not yet been submitted for *in camera* review, the defendant shall review all such documents in light of this opinion and produce such documents and portions of documents that are not privileged within 30 days. The remaining documents and an appropriate privilege log are to be submitted for *in camera* review within 45 days.

SO ORDERED:

Viktor V. Pohorelsky

VIKTOR V. POHORELSKY
United States Magistrate Judge

Dated: Brooklyn, New York
November 6, 2006

APPENDIX A – NON-PRIVILEGED DOCUMENTS

Bates Numbers:

TUMMINO – 895-896
1063-1065
2737-2739
2966-2968
3197
3782
3879-3881
3884-3886
3888-3890
3914-3915
4049-4051
4079-4080
4081-4083
4251-4254
4693-4694
4702-4703
5933

APPENDIX B – DOCUMENTS EVIDENCING BAD FAITH

Bates Numbers:

TUMMINO – 1038	5415-5417
1156	5435-5436
1162-1166	5540-5541
1212-1214	5575
1235	5774
1236	5818
1237	
1243-1245	
1741-1743	
1746-1747	
1780-1781	
1782-1784	
1787	
1789	
1853	
1866	
1871	
1872	
1875	
1876	
1902	
2928-2934	
3139	
3197	
3205-3206	
3512-3522	
3851-3852	
3928-3929	
4079-4080	
5168-5177	
5192-5195	
5197-5200	
5202-5204	
5263-5266	
5273-5276	
5279	
5364-5365	
5366	
5409-5413	

APPENDIX C – DOCUMENTS REQUIRING REASSESSMENT FOR PROPER APPLICATION OF THE PRIVILEGE

Bates Numbers:

TUMMINO – 1059-1061	5576-5590
1215-1216	5592-5600
1223-1234	5736-5739
1756-1757	5745-5756
2752-2754	5761-5772
2787-2790	5841-5847
2823-2826	
2860-2863	
2866-2867	
2936-2937	
2939-2942	
2962-2965	
3028-3077	
3086-3136	
3141-3188	
3207-3225	
3235-3255	
3257-3307	
3317-3365	
3367-3415	
3800-3850	
3854-3873	
3892-3911	
3955-4003	
4005-4024	
4031-4041	
4057-4076	
4087-4106	
4246-4249	
4256-4285	
4294-4324	
4338-4358	
4427-4452	
4626-4629	
4717-4721	
5268-5271	
5367-5375	
5552-5558	