UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION, Plaintiff, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	CASE NO. CV 11-07925 MMM (JEMx) ORDER RE: DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

On September 23, 2011, plaintiff AIDS Healthcare Foundation ("AHF") filed this action against the United States Food and Drug Administration ("FDA") and certain fictitious defendants under the Freedom of Information Act, 5 U.S.C. § 552 et seq. ("FOIA").[1] On February 1, 2013, the FDA filed a motion for summary judgment.[2] AHF opposes the motion.[3]

[1]Complaint for Injunctive Relief, Docket No 1 (Sept. 23, 2011).

[2]Motion for Summary Judgment as to Rule 56 of the Federal Rules of Civil Procedure ("Motion"), Docket No. 41 (Feb. 1, 2013).

[3]Opposition to Motion for Summary Judgment as to Rule 56 of the Federal Rules of Civil Procedure ("Opp."), Docket No. 45 (Jun. 10, 2013).

I. BACKGROUND

AHF is a California nonprofit corporation whose mission is to provide medical care to and advocacy for people living with HIV/AIDS regardless of their ability to pay.[4] The FDA is an executive branch agency of the United States government, located within the Department of Health and Human Services.[5]

In a February 25, 2011 letter, AHF requested that the FDA's Freedom of Information Division produce certain documents showing "whether, from January 1, 2010 to the present, Gilead Sciences, Inc., ha[d] submitted an Investigational New Drug [IND] application and/or a New Drug Application [NDA] and/or request for a new use or indication for the use of the drug Truvada (Tenofovir/Emtricitabine) as a means of 'pre-exposure prophylaxis' [PrEP] to prevent transmission of [HIV]."[6]

On March 31, 2011, AHF sent a second FOIA request to the FDA, seeking information "pertaining to or showing any communications or discussions, either within the FDA or between the FDA and Gilead Sciences Inc. concerning the possible indication for the use of the drug Truvada . . . as a means of 'pre-exposure prophylaxis to prevent transmission of [HIV]."[7]

On July 18, 2011, the FDA answered both of AHF's FOIA requests in a single letter. The FDA stated that it could not "acknowledge receipt of [the drug] applications until they [were] otherwise publicly disclosed, e.g., by the applicant or when an approvable or approval letter [was] issued to the firm."[8] The FDA asserted that disclosure of the requested information would "cause competitive harm," such that the information was exempt from disclosure as "confidential

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[4]Complaint, ¶ 4; Response of Plaintiff AIDS Healthcare Foundation to Separate Statement of Undisputed Material Facts ("Response"), Docket No. 45-2 (June 10, 2013), ¶ 1.

[5]Complaint, ¶ 5; Response, ¶ 2.

[6]Complaint, ¶ 7 and Exh. 1 ("February 25 Request").

[7]*Id.*, ¶ 8 and Exh. 2 ("March 31 Request"); Response, ¶ 3.

[8]*Id.*, ¶ 9 and Exh. 3.

commercial information" under FOIA's trade secrets exemption, 5 U.S.C. § 552(b)(4).[9]

The FDA subsequently received a written waiver from Gilead permitting the agency to reveal to AHF that Gilead had filed an application for the use of Truvada for pre-exposure prophylaxis to prevent the transmission of HIV.[10] FDA counsel then verbally informed AHF that the application existed, and gave AHF a letter from Gilead's counsel publicly disclosing that the company had submitted the Truvada application.[11] Following the disclosure of this information, the FDA filed a motion to dismiss all of AHF's claims based on the February 25, 2011 request as moot.[12] The court granted the government's motion, conditioned on the FDA's filing of a document already in its possession that confirmed its receipt of Gilead's application.[13]

On March 19, 2012, the court conducted a scheduling conference; at the conference, the parties represented that the FDA had given AHF a document confirming the existence of Gilead's application.[14] The court directed the parties to meet and confer and file a joint report indicating: (1) whether the government should file a *Vaughn* index prior to, or in conjunction with, a motion for summary judgment, and (2) whether the motion for summary judgment proposed by the parties was even necessary, given that the government had already disclosed the existence of Gilead's pending application, which made the basis for its refusal to disclose the information arguably no longer operative.[15] On March 20, 2012, the parties filed a report stating that (1) a *Vaughn* index was not necessary to resolve the dispute, and (2) a motion for summary judgment could resolve

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[9]*Id.*

[10]Motion for Partial Dismissal ("MPD"), Docket No. 7 (Nov. 14, 2011), Exh. F.

[11]MPD, Exh. H.

[12]See generally MPD.

[13]Order Conditionally Granting Defendant's Motion to Dismiss, Docket No. 14 (Feb. 16, 2012).

[14]See also Joint Report Regarding Defendant's Compliance with Court's Order Conditionally Granting Defendant's Motion to Dismiss, Docket No. 20 (Mar. 22, 2012).

[15]Minutes of Scheduling Conference, Docket No. 27 (Mar. 19, 2012).

the "appropriateness" of the government's blanket non-response to AHF's second FOIA request.[16]

After reviewing the joint report, the court concluded that the parties had not clearly articulated what legal issues they wished to have the court resolve, raising serious questions about the utility of a summary judgment motion. The court determined, however, that the parties' dispute appeared to be based on the FDA's continued withholding of certain documents under FOIA's trade secrets exemption, a position AHF disputed. The court concluded that the most practical manner in which to approach this dispute was to order the production of a *Vaughn* index that the court could analyze in the context of a proper motion for summary judgment. It reasoned that it could not determine which documents were properly withheld and which had to be disclosed without knowing the documents the FDA had in its possession. The court therefore ordered the parties to show cause why the action should not be dismissed, or alternatively, why defendant should not be required to produce a *Vaughn* index.[17]

On July 3, 2012, after considering the parties' replies to the order to show cause, the court ordered the FDA to produce a *Vaughn* index of all documents responsive to plaintiff's second FOIA request.[18] The court ordered that the *Vaughn* index be produced within sixty days of the date of entry of the order.[19]

Thirteen days after entry of the court's order, the FDA approved Gilead's supplemental New Drug Application ("sNDA") for Truvada for pre-exposure prophylaxis.[20] After the FDA approved Gilead's application, it posted on its website approximately 1,175 pages of FDA internal

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[16]Joint Stipulation re: Briefing Schedule, Docket No. 19 (Mar. 20, 2012).

[17]Order to Show Cause Why Action Should Not Be Dismissed, or Alternatively, Why Defendant Should Not Be Required to Produce Vaughn Index in Response to Plaintiff's FOIA Request, Docket No. 22 (Apr. 2, 2012).

[18]Order Directing FDA to Produce *Vaughn* Index, Docket No. 29 (July 3, 2012).

[19]*Id.*

[20]Declaration of Nancy B. Sager in Support of Defendant's Request for Additional Time ("Sager Time Decl."), Docket No. 30-2 (August 17, 2012), ¶ 10; Response, ¶ 15.

reviews, administrative documents, and correspondence concerning the approval of Truvada.[21]

On August 17, 2012, two weeks before the deadline to produce a *Vaughn* index, the FDA filed an *ex parte* application to continue the deadline.[22] It requested an extension to allow the parties to meet and confer concerning the release of non-exempt data.[23] The FDA suggested that if, after the parties met and confer, AHF was not satisfied with the records that had been released, the agency would release, on a rolling basis, the non-exempt data that could be released frollow FDA approval of the NDA.[24] The FDA proposed that within 60 days after producing the last document to AHF that the agency deemed properly released and responsive to the March 2011 Request, it would produce a *Vaughn* index itemizing all redactions and withheld documents.[25]

The court denied the application.[26] It directed the FDA to file a complete *Vaughn* index no later than November 1, 2012,[27] and directed the parties to meet and confer no later than November 13, 2012 to determine if the documents available on the FDA's website and the documents that had been and would be produced by the agency in response to AHF's request provided the information AHF sought in the March 2011 FOIA request, and whether it was necessary to expend further resources litigating this action.[28] The court directed the parties to file

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[21]Sager Time Decl., ¶ 13.

[22]*Ex Parte* Application to Continue the Deadline to File a Vaughn Index ("Application"), Docket No. 30 (August 17, 2012), at 3.

[23]*Id.*

[24]*Id.*

[25]*Id.*

[26]Order Denying Defendant's Ex Parte Application to Continue Deadline to File a Vaughn Index, Docket No. 32 (Oct. 15, 2012).

[27]*Id.*

[28]*Id.*

a joint report no later than November 19, 2012.[29]

On September 14, 2012, the FDA produced approximately 2,300 pages of IND correspondence responsive to AHF's FOIA request.[30] It filed a *Vaughn* index on November 1, 2012.[31] The FDA also produced approximately 160 additional pages of documents discussing the Truvada for PrEP IND.[32] On November 19, 2012, the parties filed a joint report.[33] The parties reported that AHF believed the *Vaughn* index was incomplete; the FDA did not disagree, and stated that it would file a revised *Vaughn* index by December 31, 2012. The FDA in fact filed the revised index on January 2, 2013.[34]

On February 1, 2013, the FDA filed a motion for summary judgment, asserting that it had conducted an adequate search for records responsive to AHF's March 2011 request and produced all responsive records to which AHF was entitled. AHF opposed the motion. AHF does not assert that the FDA failed to conduct an adequate search for records responsive to its March 2011 request. Nor does it challenge the bulk of the justifications the FDA offers for withholding and/or redacting records responsive to its request.

AHF's opposition to FDA's motion for summary judgment is limited to the FDA's redactions and withholding of certain records under FOIA Exemptions 4 and 5. It asserts that the FDA improperly withheld safety and efficacy data and data summaries; correspondence with non-

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[29]*Id.*

[30]Response, ¶ 17.

[31]Notice of Filing of *Vaughn* Index, Docket Nos. 33-34 (Nov. 1, 2012).

[32]Response, ¶ 19.

[33]Joint Report re Meeting of Parties in Accordance with the Court's 10/15/12 Order, Docket No. 35 (Nov. 19, 2012).

[34]Notice of Filing of Revised *Vaughn* Index, Docket No. 36 (Jan. 2, 2013). Along with the *Vaughn* index, the FDA filed the declaration of the Assistant United States Attorney representing the FDA in this case, which explained that the holiday vacation and technical difficulties had delayed the filing of the index. (See also Declaration of Nancy B. Sager ("Sager Decl."), Docket No. 41-8 (Feb. 1, 2013), Exh. A ("*Vaughn* Index").)

governmental entities; opinions of third parties; and internal agency documents not subject to the deliberative process exception. It contends that the FDA's *Vaughn* index does not sufficiently describe or justify the withholding of these documents. The FDA argues that it has met its burden of demonstrating that it properly invoked Exemptions 4 and 5 in withholding confidential commercial information and documents protected by the deliberative process privilege.[35]

II. DISCUSSION

A. Legal Standard Governing Motions for Summary Judgment

A motion for summary judgment must be granted when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED.R.CIV.PROC. 56. A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Where the moving party will have the burden of proof on an issue at trial, the movant must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. On an issue as to which the nonmoving party will have the burden of proof, however, the movant can prevail merely by pointing out that there is an absence of evidence to support the nonmoving party's case. See *id.* If the moving party meets its initial burden, the nonmoving party must set forth, by affidavit or as otherwise provided in Rule 56, "specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); FED.R.CIV.PROC. 56(e)(2). Evidence presented by the parties at the summary judgment stage must be admissible. FED.R.CIV.PROC. 56(e)(1). In reviewing the record, the court does not make credibility determinations or weigh conflicting evidence. Rather, it draws all inferences in the light most favorable to the nonmoving party. See *T.W. Electric Service, Inc. v.*

[35]Reply to Plaintiff's Opposition to Defendant's Motion for Summary Judgment ("Reply"), Docket No. 46 (June 20, 2013), at 4.

Pacific Electric Contractors Ass'n, 809 F.2d 626, 630-31 (9th Cir. 1987).

B. Legal Standard under the Freedom of Information Act

The Freedom of Information Act "sets forth a policy of broad disclosure of Government documents in order 'to ensure an informed citizenry, vital to the functioning of a democratic society.'" *FBI v. Abramson*, 456 U.S. 615, 621 (1982) (quoting *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978)). The statute "places a general obligation on the [government] to make information available to the public. . . ." *Pacific Architects & Eng. v. United States Dep't of State*, 906 F.2d 1345, 1346 (9th Cir. 1990). FOIA's "general philosophy of full agency disclosure" controls "unless information is exempted under clearly delineated statutory language." *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 152 (1989).

FOIA contains nine exemptions to the presumption that information must be disclosed, each of which is "narrowly construed by the courts." *GC Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1112 (9th Cir. 1994). In assessing exemption claims, the burden of justifying nondisclosure is on the governmental agency, and the district court must review the agency's determination *de novo*. See 5 U.S.C. § 552(a)(4)(B); see also *Department of Justice v. Reports Comm. for Freedom of the Press*, 489 U.S. 749, 755 (1989) ("Unlike the review of other agency action that must be upheld if supported by substantial evidence and not arbitrary or capricious, the FOIA expressly places the burden on the agency to sustain its action and directs the district courts to determine the matter *de novo*" (quotations omitted)).

Typically, to justify withholding information, the agency must submit declarations or other evidence demonstrating "that the documents are properly classified and thus clearly exempt from disclosure." *Hayden v. National Security Ass'n.*, 608 F.2d 1381, 1386 (D.C. Cir. 1979). When a FOIA dispute proceeds to litigation, the agency bears the burden of justifying its refusal to produce documents by providing a sufficiently detailed description of what it had not produced and why. *Francis v. FBI*, No.1:06cv0968, 2009 WL 1764990, *1 (E.D. Cal. June 19, 2009) (citing *Fiduccia v. U.S. Dep't of Justice*, 185 F.3d 1035 (9th Cir. 1999)). The "explanation of the exemption claim and the descriptions of withheld material need not be so detailed as to reveal that which the agency wishes to conceal, but . . . must be sufficiently specific to permit a reasoned

judgment as to whether the material is actually exempt under FOIA." *Founding Church of Scientology v. Bell*, 693 F.2d 945, 949 (D.C. Cir. 1979).

Given these standards, FOIA issues are often properly resolved on a motion for summary judgment. *Lane v. Department of Interior*, 523 F.3d 1128, 1134 (9th Cir. 2008) ("Generally, FOIA cases should be handled on motions for summary judgment. . . ," quoting *Miscavige v. IRS*, 2 F.3d 366, 369 (11th Cir. 1993)). To support a motion for summary judgment, an agency generally submits a *Vaughn* index, which correlates each document withheld to a specific FOIA exemption; this allows the court to review whether exemptions have been validly claimed without having to examine the withheld documents physically. See *Vaughn v. Rosen*, 484 F.2d 820, 827 (D.C. Cir. 1973). "A *Vaughn* Index must: (1) identify each document withheld; (2) state the statutory exemption claimed; and (3) explain how disclosure would damage the interests protected by the claimed exemption." *Citizens Comm'n on Human Rights v. FDA*, 45 F.3d 1325, 1326 n. 1 (9th Cir. 1995).

C. Whether the FDA Has Met its Burden of Justifying the Withholding of Records under Exemption 4

1. Legal Standard Under Exemption 4

Exemption 4 of FOIA exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). In the Ninth Circuit, a government agency invoking Exemption 4 must demonstrate that the information it seeks to protect is "(1) commercial [or] financial information, (2) obtained from a person or by the government, (3) that is privileged or confidential." *GC Micro Corp.*, 33 F.3d at 1112. The terms "commercial or financial" are given their ordinary meanings. *Watkins v. U.S. Bureau of Customs and Border Protection*, 643 F.3d 1189, 1194 (9th Cir. 2011) (citing *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983)).

"[C]ommercial or financial matter is 'confidential' for purposes of [Exemption 4] if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." *Id.* (citing

Nat'l Parks and Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974)). Competitive harm analysis is "limited to harm flowing from the affirmative use of proprietary information by *competitors*. Competitive harm should not be taken to mean simply any injury to competitive position." *Watkins*, 643 F.3d at 1195 (citing *Pub. Citizen Health Research Group,* 704 F.2d at 1291–92 & n. 30 (emphasis original)).

The party seeking to withhold information under Exemption 4 has the burden of proving that the information is protected from disclosure under FOIA. *GC Micro Corp.*, 33 F.3d at 1113. While a party need not show actual competitive harm, it must present specific evidence revealing (1) actual competition and (2) a likelihood of substantial competitive injury in order to prove that the information falls under Exemption 4. *Frazee v. U.S. Forest Service,* 97 F.3d 367, 371 (9th Cir. 1996). "Although the court need not conduct a sophisticated economic analysis of the likely effects of disclosure[,] . . . [c]onclusory and generalized allegations of substantial competitive harm . . . are unacceptable and cannot support an agency's decision to withhold requested documents." *Id.* (citing *Pub. Citizen Health Research Group,* 704 F.2d at 1291). Cf. *Bowen v. U.S. Food & Drug Admin.*, 925 F.2d 1225, 1227 (9th Cir. 1991) (affidavits that described documents withheld, the statutory exemptions claimed, and the specific reasons for the agency's withholding provided an adequate factual basis for application of "trade secrets" exemption).

2. Whether the FDA Has Shown That the Records Withheld Contain Confidential Information

AHF argues that the FDA has improperly withheld safety and efficacy data and data summaries ("safety and efficacy records") under Exemption 4.[36] The FDA argues that its *Vaughn*

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[36]AHF specifically challenges the FDA's withholding of records described by the FDA in its *Vaughn* indices as: "datasets" supporting Gilead's NDA, which pertain to its "efficacy analysis" (CDER Nos. 2-3, 391-96, 465-67, 465-67, 473-77, 1299, 1315-18, 1406, 1506-11, 149074-76, 149472-79, 155357, 155415, 155155); "datasets" supporting Gilead's NDA, pertaining to its "safety analysis" (CDER Nos. 432, 150300-02, 150304-06, 150312, 150670, 150671, 150672, 150774, 150775, 150783, 150785, 150787); "safety and efficacy information" and "efficacy and safety data" (CDER Nos. 1437-81, 148218-23, 1515-148185); "raw data" (CDER Nos. 1515-148185; "adherence data" (see, e.g., CDER Nos. 1515-148185); "study data" (CDER Nos. 410-18, 457-912, 1520-5521, 148202-10, 152416-19); and "diagnostic results"

indices and the declarations it has submitted in support of its motion for summary judgment show that its decision to withhold the safety and efficacy records was proper and made in good faith. It contends that the information withheld consists of confidential commercial or financial information. The FDA does not argue that disclosure will impair its ability to obtain information from Gilead in the future. Instead, it asserts that Gilead will suffer substantial competitive harm if the records are disclosed. AHF counters that the FDA has failed to show the records it withheld are "confidential" because it has not shown that there is actual competition in the market, nor that Gilead is likely to suffer "substantial competitive harm" from disclosure of the safety and efficacy records.

a. Actual Competition

As stated, an agency must present specific evidence revealing actual competition to establish competitive harm for purposes of FOIA Exemption 4. AHF asserts that the FDA has failed to adduce evidence of actual competition. It contends that the FDA's own evidence demonstrates that the market is not competitive with respect to Truvada, because Gilead has the exclusive right to manufacture and sell Truvada and owns the intellectual property rights to that drug, because no other drugs have been approved for PrEP, and because there appear to be no such drugs in clinical trials.[37]

The FDA counters that there is generalized actual competition in the drug industry, and that the market for HIV drugs, in particular, is "extremely competitive."[38] To support these assertions, the FDA proffers the declaration of David J. Pizzuti, Gilead's Vice President of Regulatory Affairs. As AHF correctly observes, Pizzuti's declaration establishes that Truvada currently faces no competition in the PrEP market, because no other drug has been approved by

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(CDER Nos. 1515-148185).

[37]Opp. at 10 (citing Declaration of David. J. Pizzuti, M.D., Docket No. 41-12 (Feb. 1, 2013), ¶ 1; *id.* ¶ 3; *id.*, ¶¶ 17-19; *id.*, ¶¶ 22-24).

[38]See Pizzuti Decl., ¶ 23.

the FDA for such use, and no such drugs are in advanced clinical trials.[39] The FDA argues, however, that other companies are in the process of studying drugs that will eventually compete with Truvada in the PrEP market. Other courts have held that an agency can show actual competition by adducing evidence that there will be future competition. See *General Elec. Co. v. Department of Air Force,* 648 F.Supp.2d 95, 103 (D.D.C. 2009) ("While there was technically no competition for these two contracts – since GE was awarded them on a sole source basis – GE has demonstrated that there remains actual competition over . . . future contracts with the Air Force. . . . Accordingly, the Air Force's actual competition argument fails"). Cf. *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 770-71 (D.C. Cir. 1974) ("Appellant argues that such a showing cannot be made in this case because the concessioners are monopolists, protected from competition during the term of their contracts and enjoying a statutory preference over other bidders at renewal time. In other words, appellant argues that disclosure cannot impair the concessioners' competitive position because they have no competition. While this argument is very compelling, we are reluctant to accept it without first providing appellee the opportunity to develop a fuller record in the district court. It might be shown, for example, that disclosure of information about concession activities will injure the concessioner's competitive position in a nonconcession enterprise. In that case disclosure would be improper").

The FDA, however, does not adduce evidence indicating that there will be actual competition in the PrEP market in the future. Although Pizzuti asserts, "on information and belief," that other companies are working to develop drugs that "would be in direct competition with Truvada's FDA approved indication for PrEP," there is no foundation for this testimony. Pizzuti does not state that he has personal knowledge of the drug development efforts of companies other than his, or that his assertion rests on other reliable sources of information. A declaration used to support a motion for summary judgment must be based on personal knowledge. FED.R.CIV.PROC. 56(c)(4). Because Pizzuti has not shown that he has personal

[39] *Id.*, ¶ 24 ("Other than Truvada, there are no drugs approved for PrEP, and I am not aware of any drugs for PrEP that are presently in advanced clinical trials").

knowledge that other companies are actively studying drugs for PrEP, the court must disregard his testimony on that subject. *Id.* The FDA proffers no other evidence supporting its assertion that Truvada faces future competition. As a result, it has failed to adduce specific, admissible evidence of actual competition in the PrEP market.

The lack of competition in the market for PrEP drugs does not prove, however, that Gilead would not be harmed in some other, competitive market if the records at issue were disclosed. See *Morton*, 498 F.2d at 770-71. Pizzuti states that Truvada faces competition from other drugs being marketed as HIV treatment medications.[40] Citing the FDA's website, he asserts there are presently 36 branded and 18 generic medications approved for HIV treatment.[41] Pizzuti reports that these medications include best-selling drugs and other "nucleoside reverse transcriptaste inhibitors" that compete directly with Truvada.[42] AHF does not dispute this assertion and adduces no evidence controverting it. The FDA has thus adduced sufficient evidence showing that there is actual competition in the market for non-PrEP HIV treatment medications, and that that market includes Truvada. See *PETA v. U.S. Dep't of Agriculture*, No. Civ. 03 C 195-SBC, 2005 WL 1241141, *6 (D.D.C. May 24, 2005) ("Hunte's declaration describes actual competition Hunte faces in the puppy distribution industry. . . . Hunte's declaration describes the number of competitors in the puppy distribution business. His testimony is not speculative; it is based on his thirteen years of experience in the puppy distribution industry").

b. Substantial Competitive Harm

For the reasons stated, the FDA has failed to adduce evidence of actual competition in the PrEP market. It has, however, established that there is actual competition in the market for HIV

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[40] *Id.*, ¶ 23.

[41] *Id.* (citing FDA, Antiretroviral drugs used in the treatment of HIV infection, http://www.fda.gov/Forconsumers/byAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118915.htm (last accessed Jan. 17, 2013)). The court can take judicial notice of information appearing on an official government website. See, e.g., *Paralyzed Veterans of Am v. McPherson*, No. C 06-4670 SBA, 2008 WL 4183981, *5 (N.D. Cal. Sept. 8, 2008) (collecting cases).

[42] *Id.*, ¶ 23.

treatment medications. Accordingly, the FDA can show that the safety and efficacy records are "confidential" if it demonstrates that their disclosure would cause Gilead to suffer "substantial competitive harm" in the market for HIV treatment medications.

AHF argues that the FDA has failed to show that Gilead will suffer competitive harm if the safety and efficacy records are disclosed. It asserts that the FDA's motion focuses on categories of information it does not seek, such as Gilead's proprietary "methodologies, strategies and techniques." AHF contends that it seeks only the "data, data summaries and analyses pertaining to the efficacy and safety of Truvada,"[43] and that there has been no showing Gilead will suffer competitive harm from the disclosure of those items if the allegedly proprietary statistical methods and techniques it uses to analyze the data are not also disclosed.

The FDA counters that it has already produced the raw safety and efficacy data AHF seeks.[44] It represents that the safety and efficacy records it continues to withhold under Exemption 4 are Gilead's *summaries and analyses* of the raw data,[45] and reports that the summaries and analyses reveal Gilead's efforts to develop statistical methods to transform data gathered by third-party researchers into a format acceptable to the FDA.[46] The FDA contends that public disclosure of the records would reveal the statistical methods and analyses Gilead applied to the third-party data to obtain FDA approval, allowing its competitors to adopt the same techniques and methodologies to obtain PrEP approval for their drugs. It asserts that the declarations it filed in support of its motion offer detailed, instance-specific explanations as to how disclosing the summaries and analyses would likely cause Gilead competitive harm.[47]

In support of its argument that disclosure would cause Gilead substantial competitive harm,

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[43] *Id.*

[44] Reply at 6.

[45] *Id.*

[46] *Id.*

[47] *Id.*

the FDA proffers Pizutti's declaration, and the declarations of Nancy Sager, the Director of the FDA's Division of Information Disclosure Policy ("DIDP") for the Center for Drug Evaluation and Research ("CDER"), and Ann H. Wion, Deputy Chief Counsel for Program Review in the FDA's Office of the Chief Counsel ("OCC").[48] Sager's declaration provides little information showing how disclosure would cause Gilead competitive harm. It simply states that the FDA withheld records under Exemption 4 that would reveal, "among other things," Gilead's regulatory filing strategy and its "plan for meeting FDA's regulatory expectations with respect to the safe distribution and use of Truvada for PrEP."[49] She does not explain how revelation of

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[48]Declaration of Ann H. Wion, J.D. ("Wion Decl."), Docket No. 41-10 (Feb. 1, 2013).

[49]Sager Decl., ¶¶ 26-27. AHF objects to Sager's declaration on several grounds. First, it asserts that Sager fails to establish that she has personal knowledge of the subjects she addresses. Sager states that she is the Director of DIDP; that she has supervisory authority over the division; that DIDP processes and responds to FOIA requests directed to the CDER; that the CDER is the center within the FDA responsible for regulating most human drugs, including Truvada, and for reviewing INDs, NDAs, and sNDAs; that DIDP personnel search records systems under CDER's control for records responsive to particular FOIA requests at her direction; that the statements in her declaration are based on her personal knowledge and official records available to her in her capacity as Director of DIDP; that she is personally familiar with AHF's March 31, 2011 request and DIDP's handling of that request; that she is familiar with the records described in the *Vaughn* index submitted to the court; and that she is familiar with DIDP's handling of FOIA requests generally. (*Id.*, ¶¶ 1-5; see also *id.*, ¶ 24.) This suffices to demonstrate that Sager has personal knowledge of the matters set forth in her declaration, which describe the manner in which DIDP processed AHF's FOIA request.

AHF argues that Sager fails to establish that she has personal knowledge of the matters in her declaration because she "sets forth no evidence that she actually looked at any documents herself, trained the staff that conducted the document review, or even supervised the staff that conducted the document review for the March 11 Request." As an initial matter, the court finds Sager's statements sufficient to establish that she supervised the DIDP staff who processed the March 11 request. (See, e.g., *id.* ¶ 2 ("I have supervisory authority over DIDP, which process and responds to requests made under [FOIA]"; *id.*, ¶ 4 ("*At my direction*, DIDP personnel search records systems for documents . . . that may be responsive to particular FOIA requests" (emphasis added)).) Sager's declaration also suggests that she reviewed the documents. (See *id.*, ¶ 24 ("I am familiar with the records described in the CDER *Vaughn* index").) Sager's failure to state specifically that she personally reviewed documents or trained the staff who conducted the review does not demonstrate that she lacks personal knowledge about the processing of AHF's FOIA request. As the Ninth Circuit has recognized "'[a]n affidavit from an agency employee responsible for supervising a FOIA search is all that is needed to satisfy' the personal knowledge requirement

of Federal Rule of Civil Procedure 56(e)." *Lahr v. Nat'l Transp. Safety Bd.*, 569 F.3d 964, 990 (9th Cir. 2009) (citing *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 814 (2d Cir.1994); see also *Maynard v. CIA*, 986 F.2d 547, 559-60 (1st Cir. 1993)); see also *Spannaus v. U.S. Dep't of Justice*, 813 F.2d 1285, 1289 (4th Cir. 1987) ("Spannaus . . . contends [Special Agent Cook's] declaration does not meet the requirement of 'personal knowledge' under Federal Rule of Civil Procedure 56(e) because it does not state that Special Agent Cook was personally involved in the investigations but only that he was familiar with the handling of Spannaus's FOIA request. This contention is entirely without merit. In his declaration, Special Agent Cook attested to his personal knowledge of the procedures used in handling Spannaus's request and his familiarity with the documents in question. He has therefore demonstrated ample personal knowledge to render him competent to testify regarding the interference posed by disclosure"). Courts, moreover, routinely find that agency officials who hold supervisory positions analogous to Sager's have sufficient personal knowledge to testify about the processing of FOIA requests. See, e.g., *Carney*, 19 F.3d at 813-14 ("[T]he declaration of Nelson Hermilla indicates that he is the Chief of the FOIA/Privacy Act Branch of the Civil Rights Division and that he supervised the processing of Carney's requests to the Division. An affidavit from an agency employee responsible for supervising a FOIA search is all that is needed to satisfy Rule 56(e); there is no need for hte agnecy to supply affidavits from each individual who participated in the actual search. . . . The DOJ's submissions thus were proper"); *Am. Mgmt. Servs., LLC v. Dep't of the Army*, 842 F.Supp.2d 859, 867 (E.D. Va. 2012) ("Buchholz provides that, in his capacity as Associate Deputy General Counsel, he advises the Army on FOIA matters. . . . [I]t is clear that personal knowledge may be inferred from the affidavit itself by considering the affiant's 'position and job responsibilities' and other contextual factors," quoting *Center for Auto Safety v. National Highway Traffic Safety Admin.*, 93 F.Supp.2d 1, 11 (D.D.C. 2000)); *Russell v. Department of State*, No. CV 09–6050 PSG, 2011 WL 941334, *4 (C.D. Cal. Mar. 15, 2011) ("Ms. Grafeld's personal knowledge obtained in the course of official duties is all that is required, as it is not necessary for the agency employee who actually performed the search to provide an affidavit describing the search"); *Rosenfeld v. U.S. Dep't of* Justice, No. C 07-03240 MHP, 2008 WL 3925633, *12 (N.D. Cal. 2008) ("[T]he court finds that Hardy meets the personal knowledge requirement with respect ot the searches at FBIHQ because he supervises the division responsible for processing Rosenfeld's FOIA requetss"); *Berman v. C.I.A.,* 378 F.Supp.2d 1209, 1216 n.7 (E.D.Cal. 2005) ("[N]umerous cases allow[ ] an agency to submit a declaration from an agency official with responsibility for coordinating the agency's decisions on FOIA requests where that official has personal knowledge of the procedures used in handling the FOIA request at issue and is familiar with the documents in question. . . . Buroker is the Information Review Officer for the Director of Intelligence ("DI"). In that capacity, he is responsible for the final review of documents containing information implicating DI interests when such documents are requested under the FOIA. . . .The court finds Buroker competent to testify on these issues").

AHF also contends that Sager's declaration fails to establish that she has personal knowledge because she does not describe the search terms and key words utilized by the FDA. Sager's declaration describes in detail, however, the manner in which DIDP searched for records responsive to AHF's request. (See *id.*, ¶ 11-23.) The fact that she does not identify any "search

Gilead's regulatory filing strategy would cause it competitive harm. Nor does she describe the records withheld under Exemption 4 in sufficient detail to permit the court to determine whether her justifications pertain to the specific documents AHF seeks in its opposition, or whether there are particular documents that reveal Gilead's statistical methods and/or strategies. Sager's declaration, therefore, is not sufficiently specific to establish a likelihood of substantial competitive injury. See *Gov't Accountability Project v. United States*, 691 F.Supp.2d 170, 179 (D.D.C. 2010) ("Ms. Sager has not differentiated between the categories of information withheld in this case. Ms. Sager . . . has failed to discriminate between the types information at issue, instead broadly claiming that release of either category of information, without distinction, would likely result in substantial competitive injury. Such a blanket statement is wholly unpersuasive. Second, the explanation lacks any supporting detail demonstrating that a competitor could, in fact, use the withheld material to support its own new drug application without having to incur the time and expense involved in developing the information itself"); see also *Founding Church of Scientology*,

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terms and key words" does not render her statements so conclusory that it undermines her assertion she has personal knowledge of the processing of AHF's request. The court concludes, therefore, that Sager has adequately demonstrated that she has personal knowledge of the matters set forth in her declaration. For the same reasons, the court overrules AHF's hearsay objections to Sager's declaration (which are based on assertions that Sager's statements lack foundation). Sager states that she supervised the processing of AHF's request, that "the statements made in [her] declaration are based upon [her] personal knowledge *and official records available to [her] in [her] capacity of Director of DIDP*," and that she is familiar with the records described in the *Vaughn* index. (*id.*, ¶ 5 (emphasis added); *id.*, ¶ 24.) This is sufficient to establish that she has personal knowledge of the records described in her declaration, such that her statements concerning DIDP's positions with respect to those records do not constitute "inadmissible hearsay."

Finally, AHF objects to Sager's declaration on the ground that it is "[de]void of any information as to how DIDP would know that producing a particular document could cause a likelihood of substantial competitive injury." (Objections at 5.) As a result, it requests that the court disregard those portions of Sager's declaration reciting DIDP's conclusions that certain documents were properly withheld under FOIA Exemption 4. Whether or not records were properly withheld under FOIA is a legal question for the court. The court addresses whether the FDA's declarations provide sufficient evidence to support the withholding of particular records in the body of this order. It treats Sager's references to DIDP's conclusions regarding the applicability of particular FOIA exemptions as statements recounting the agency's position, not as dispositive evidence.

611 F.2d at 742 (the government can rely on detailed affidavits to establish that a document is exempt from disclosure, but only so long as the evidence offered enables the court to make an independent assessment of the government's claim of exemption).

Pizzuti's and Wion's declarations describe in more detail the competitive injury Gilead will purportedly suffer if the safety and efficacy records are disclosed. Wion states that disclosure of the documents at issue "could allow other pharmaceutical companies to adapt Gilead's techniques and methodologies used for submitting the Truvada for PrEP IND and sNDA to support PrEP approvals for their own products."[50] Pizzuti states that the study reports and correspondence Gilead submitted to the FDA in support of the Truvada for PrEP IND contain analyses of data sets generated by third-party researchers who conducted PrEP studies.[51] He asserts that the study reports contain extensive unpublished discussions of the statistical methods Gilead used to analyze the raw data generated in the studies supporting the Truvada for PrEP NDA Supplement.[52] As a consequence, Pizzuti contends, disclosure of the study reports and correspondence would reveal Gilead's approach and the statistical methodology it used to work with the unique data generated in third-party clinical trials for the PrEP NDA.[53]

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[50]Wion Decl., ¶ 15; see also *id.* ("[I]f publicly disclosed, Gilead's competitors could use such information in designing their own development plans for FDA approval of PrEP indications for their competing medications"). AHF objects to Wion's declaration on the same bases that it challenged Sager's declaration. The court overrules AHF's objections to Wion's declaration for substantially the same reasons that it earlier overruled its objections to Sager's declaration. Wion's declaration establishes that she has personal knowledge of the processing of AHF's request by the OCC, and of the records identified as responsive to the request and withheld by the agency. (See, e.g., *id.*, ¶¶ 1-4 (describing Wion's supervisory role and her familiarity with AHF's request); *id.*, ¶ 13 (describing Wion's familiarity with the records described in the OCC's *Vaughn* index).) As stated, the court addresses whether the FDA's declarations set forth sufficient facts to justify the withholding of particular records in the body of this order. It treats Wion's references to the OCC's conclusions regarding the applicability of FOIA exemptions as statements of the agency's position, not as dispositive evidence.

[51]Pizzuti Decl., ¶ 30.

[52]*Id.*, ¶ 31.

[53]*Id.*, ¶ 30; see also *id.*, ¶ 29.

Pizzuti also reports that Gilead and the FDA discussed what datasets Gilead would submit in support of the Truvada for PrEP applications.[54] In addition, he states, Gilead had discussions with the FDA regarding other studies conducted with Truvada that contained unfavorable results.[55] Gilead and the FDA discussed how the safety and efficacy data proffered with Gilead's supplemental NDA was nonetheless sufficient to support approval.[56] Pizzuti reports that these discussions were memorialized in correspondence withheld by the FDA under Exemption 4,[57] and that disclosing the discussions would reveal how challenging PrEP study results can be successfully addressed, enabling competitors to craft successful PrEP applications that will cause Gilead competitive harm in the PrEP market.[58]

As can be seen, the only competitive harm addressed in the FDA's summary judgment declarations concerns the PrEP market. None of the declarations proffered by the FDA demonstrates that disclosure of the safety and efficacy records that have been withheld would likely cause Gilead to suffer competitive harm in the market for HIV treatment medications – the only market for which the FDA has established actual competition.[59] Because the FDA's only evidence of purported competitive harm concerns a market in which – on the present record – Gilead faces no actual competition, the court concludes that the FDA has failed to adduce evidence establishing a likelihood of substantial competitive injury. See *Watkins*, 643 F.3d at 1195 (holding that the competitive harm analysis is "limited to harm flowing from the affirmative use of proprietary information by *competitors*. Competitive harm should not be taken to mean simply any injury to competitive position," citing *Pub. Citizen Health Research Group,* 704 F.2d at

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[54] *Id.*, ¶ 30.

[55] *Id.*, ¶ 32.

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*, ¶ 32.

1291–92 & n. 30 (emphasis original)).

The FDA does not argue that the statistical methods and analyses Gilead has applied to the third-party data could be used by Gilead's competitors in a manner that would cause it substantial competitive injury in the market for HIV treatment medications. Even if it had made such an argument, moreover, the court would find the evidence insufficient to demonstrate such a fact. The FDA's evidence indicates that the third-party data at issue is unique to the PrEP context.[60] The FDA has adduced no evidence explaining how disclosure of Gilead's application of statistical methods it developed to analyze specific "non-traditional" datasets generated by third-party PrEP studies could be used by its competitors to its disadvantage outside the PrEP context. See *Gov't Accountability Project* , 691 F.Supp.2d at 178-81 ("Exemption 4 does not categorically exempt all information submitted in a drug application to the FDA; instead, the government retains the burden of demonstrating that the specific information withheld in any particular instance qualifies as confidential commercial information exempt under FOIA Exemption 4. Defendants . . . [do not] provide[ ] any . . . evidence to support their conclusory . . . position that a competitor could use the withheld information to support its own new drug application. Their failure to do so . . . illustrates the inadequacy of Defendants' explanation for withholding the material at issue"); *Physicians Committee For Responsible Med. v. Nat'l Inst. of Health*, 326 F.Supp.2d 19, 25-26 (D.D.C. 2004) ("Dr. Podell has submitted an affidavit stating that 'there is potential commercial harm or competitive disadvantage if the information is released in its entirety, as several laboratories are currently working on similar projects in the area of drug abuse and HIV infection.' These conclusory and generalized allegations [alone do not establish] substantial competitive harm, and thus are unacceptable and cannot support the defendant's decision to withhold requested documents. . . . Dr. Podell's affidavit . . . falls short of [showing] harm flowing from the affirmative use of proprietary information by competitors. Because defendants have not demonstrated substantial harm to Dr. Podell flowing from the affirmative use of

[60] *Id.*, ¶¶ 26-29 (distinguishing its PrEP application and the data underlying it from normal drug approval applications).

proprietary information, this Court concludes that the information . . . is not confidential information protected from disclosure by Exemption 4 of the FOIA" (internal quotation marks and citations omitted)). Accordingly, the court finds that the FDA has not established a likelihood that disclosure of the data summaries and analyses withheld under Exemption 4 would cause substantial competitive injury to Gilead.

As a result, it has failed to demonstrate that the safety and efficacy records that have been withheld are "confidential" financial and commercial records. Accordingly, the court denies the government's motion for summary judgment as to the documents withheld under Exemption 4, *sua sponte* grants summary judgment in favor of AHF, and orders the FDA to produce complete and unredacted copies of the safety and efficacy records to AHF. See *Gov't Accountability Project*, 691 F.Supp.2d at 172 ("Defendants' . . . motion for summary judgment, however, is DENIED–IN–PART and Plaintiff's . . . cross-motion for summary judgment is GRANTED with respect to the propriety of Defendants' withholdings pursuant to Exemption 4. Defendants are therefore directed to disclose to Plaintiff all information previously redacted as confidential consumer information under Exemption 4").

D. Whether FDA Has Met its Burden its Burden of Justifying the Withholding of Records under Exemption 5

1. Legal Standard Under Exemption 5

Exemption 5 provides that FOIA "does not apply to matters that are . . . 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." 5 U.S.C. § 552(b)(5); see also *Maricopa Audubon Soc'y v. U.S. Forest Serv.*, 108 F.3d 1089, 1092 (9th Cir. 1997) (quoting *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 148 (1975)). To qualify for protection from disclosure under Exemption 5, "a document must . . . satisfy two conditions: its source must be a Government agency, and it must fall within the ambit of a privilege against discovery under judicial standards that would govern litigation against the agency that holds it." *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001).

Exemption 5 protects documents covered by the executive deliberative process privilege.

Pacific Fisheries, Inc. v. United States, 539 F.3d 1143, 1148 (9th Cir. 2008). The purpose of the exemption is to allow agencies freely to explore possibilities, engage in internal debates, or play devil's advocate without fear of public scrutiny. *Assembly of State of Cal. v. U.S. Dept. of Commerce*, 968 F.2d 916, 920 (9th Cir. 1992). To qualify for Exemption 5 under the "deliberative process" privilege, a document must be both (1) "predecisional" or "antecedent to the adoption of agency policy," and (2) "deliberative," meaning "it must actually be related to the process by which policies are formulated." *Nat'l Wildlife Fed. v. U.S. Forest Serv.*, 861 F.2d 1114, 1117(9th Cir. 1988) (citing *Jordan v. U.S. Dep't of Justice*, 591 F.2d 753, 774 (D.C. Cir. 1978)). "A document can be characterized as predecisional if it . . . is a draft of what will become a final document." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980). A document is "deliberative" if disclosure of the material would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine its ability to perform its functions. *Lahr v. Nat'l Transp. Safety Bd.*, 569 F.3d 964, 982 (9th Cir. 2009). The "deliberative process" privilege "permits the government to withhold documents that reflect advisory opinions, recommendations and deliberations comprising part of a process by which government decisions and policies are formulated." *FTC v. Warner Communications Inc.*, 752 F.2d 1156, 1161 (9th Cir. 1984) (citing *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975)).

Factual portions of documents covered by the deliberative process privilege, however, must be segregated and disclosed unless they are "so interwoven with the deliberative material that" they cannot be segregated. *Pacific Fisheries*, 539 F.3d at 1148 (citing *United States v. Fernandez*, 231 F.3d 1240, 1247 (9th Cir. 2000)). "The burden is on the agency to establish that all reasonably segregable portions of a document have been segregated and disclosed." *Id.* (citing 5 U.S.C. § 552(a)(4)(B), (b)).

2. Whether the FDA Improperly Withheld Correspondence with Non-Governmental Entities

AHF argues that the FDA has improperly withheld correspondence with non-governmental entities under Exemption 5. Specifically, it challenges the FDA's withholding of (1) portions of

a letter the FDA sent Gilead that provided comments concerning the minutes of a meeting,[61] and (2) parts of a "fax sent to Gilead containing the review team comments to questions posed by a sponsor."[62]

The FDA contends that these records were properly withheld under Exemption 5 because they are predecisional drafts of correspondence.[63] Predecisional drafts, which "inaccurately reflect or prematurely disclose the view of the agency," are exempt from disclosure under the "deliberative process" exemption. *Nat'l Wildlife Fed'n*, 861 F.2d at 1120 (working drafts of forest plans and environmental impact statements were exempt from disclosure under Exemption 5); see also *Marin Inst. for Prevention of Drug and Other Alcohol Problems v. U.S. Dep't of Health & Human Servs.*, 229 F.3d 1158, 2000 WL 964620, *1 (9th Cir. July 11, 2000) (Unpub. Disp.) (the draft of an agency report evaluating attempts to privatize state alcohol systems was exempt from disclosure under Exemption 5). Courts have held that draft correspondence and comments on draft correspondence can fall within the scope of Exemption 5. *Krikorian v. Dep't of State*, 984 F.2d 461, 466 (D.C. Cir. 1993) ("Document 97 includes two draft letters proposing two options for replies to public inquiries about the Article and the Note. . . . Neither option was ultimately used by the Department but the letters reflect advisory opinions that are important to the deliberative process. . . . Accordingly, the district court correctly held both documents exempt from disclosure"); *Island Film, S.A. v. Dep't of the Treasury*, 869 F.Supp.2d 123, 135 (D.D.C. 2012) (concluding that draft correspondence and documents were exempt from disclosure under the deliberative process privilege); *Styrene Info. & Research Ctr., Inc. v. Sebelius,* 851

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[61]CDER Nos. 151137-151142.

[62]CDER Nos. 151167-151172.

[63]AHF asserts it is "not interested" in draft language withheld under Exemption 5. (Opp. at 17 ("Plaintiff is not interested in seeing how draft language differs from final language in the records, Plaintiff seeks factual data regarding safety and efficacy and summaries of that factual data").) Because it specifically challenges the FDA's withholding of these documents in its opposition, however, the court addresses the FDA's redactions of the letter and fax under Exemption 5.

F.Supp.2d 57, 67 (D.D.C. 2012) ("The Court finds that the drafts of the Portier Letter and any correspondence relating to that letter are both predecisional and deliberative"); see also *Blue Lake Forest Prods., Inc. v. United States*, Nos. 01-570C, 01-627C, 04-501C, 2007 WL 5161595, *8 (Fed. Cl. Mar. 29, 2007) ("These documents are covered by the deliberative process privilege in that they are draft, predecisional, proposed comments on a draft letter").

The FDA's *Vaughn* index indicates that the redacted portions of the letter and fax contain "language different from the final version reflecting the opinions and suggestions of FDA personnel regarding Gilead's proposed submission of its NDA, dataset and REMS."[64] This description clearly indicates that the redacted portions reflect predecisional content, insofar as they did not reflect "final versions" of the agency's opinions. It also indicates with reasonable specificity that the challenged redactions concern a deliberative process, inasmuch as it specifies that the redacted language concerns the FDA's decisions on Gilead's application for PrEP approval and the information needed to secure such approval. The court therefore finds the *Vaughn* index entries related to the redacted draft correspondence sufficient to support the conclusion that the portions redacted under Exemption 5 fall within the "deliberative process" privilege. See *Island Film*, 869 F.Supp.2d at 135 ("Treasury has indicated with reasonable specificity that it has redacted . . . draft correspondence and documents that it claims are part of OFAC's deliberative process. . . . The description of the withheld records provided by the Vaughn index and agency affidavit sufficiently support the conclusion that the records were made to facilitate the agency's policy determination about how to respond to license applications. . . . Treasury properly redacted these portions of documents under Exemption 5").

The court's own review of the redacted documents, which provide context for judging the redactions, confirms that they concern the agency's responses to certain proposals Gilead made regarding its PrEP application. This supports the inference that the challenged redactions were part of the deliberative process.[65] See *Casad v. U.S. Dep't of Healt h& Human Servs.*, 301 F.3d

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[64] *Vaughn* Index at 84.

[65] See Filing of Redacted Documents (Volume IV of V), Docket No. 51 (June 26, 2013).

1247, 1252 (10th Cir. 2002) ("Redacted material from summary statement reflecting scientific review group's thoughts and conclusions about grant applications, was predecisional memorandum protected from disclosure under deliberative process privilege"); *ICM Registry LLC v. U.S. Dep't of Commerce*, 538 F.Supp.2d 130, 134-38 (D.D.C. 2008) (documents reflecting government's consideration of various responses to approval of plaintiff's application for a new .xxx Internet domain were protected from disclosure by deliberative process privilege).

The court concludes, therefore, that the FDA has met its burden of showing that it properly withheld the redacted portions of the draft correspondence under Exemption 5.

3. Whether the FDA Improperly Withheld the Opinions of Other Agencies

AHF next contends that the FDA improperly withheld portions of records that reflect the opinions of third parties because it did not show that there was any relation between the opinions and the FDA's decisionmaking process. Specifically, AHF challenges the FDA's redaction of records reflecting the opinions of the Centers for Disease Control and Prevention ("CDC"), the National Institute of Health ("NIH"), and the United States Department of Health and Human Services.[66] AHF argues that these opinions cannot be withheld under Exemption 5, which protects only "inter and intra-agency" memoranda that are deliberative.

The FDA represents that the withheld documents contain inter- and intra-agency discussions related to the development of a Morbidity and Mortality Report ("MMWR") that discusses the results of a Truvada for PrEP clinical study ("the MMWR documents").[67] It asserts that the redactions of the MMWR documents pertain to discussions that took place within the FDA and between the FDA and its sister agencies in the Department of Health and Human Services concerning development of the MMWR. It contends the redacted discussions are subject to the

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[66]See Opp. at 15 (challenging the withholding of CDER 150171-150756, 150183, 150185, 150200-150206, 150208-150214, 150224, 150231-150232, 150233-150234, 150491-150497, and 150500-150506).

[67]See Reply at 8 (addressing CDER 150171-150176, 150183, and 150185); see also *Vaughn* Index at 65-67 (addressing CDER 150200-150206, 150208-150214, 150224, 150231-150232, and 150233-150234); *id.* at 71 (addressing CDER 150491-150497, and 150500-150506)

deliberative process privilege because they reflect the give-and-take of the consultations and concern inter-agency deliberations.[68]

The *Vaughn* index entries for the MMWR documents describe them as pages of an "FDA internal email regarding pre-clearance comments of draft of PrEP MMWR, w/ attachment of the current draft documents of PrEP MMWR";[69] "FDA internal email string[s] regarding comments to the draft PrEP MMWR";[70] and e-mails between the FDA and CDC concerning PrEP Interim Guidance.[71] The justification offered for the redactions made is that those portions of the emails contain "draft language different from the final version online reflecting the opinions and suggestions of [FDA, CDC, NIH, and HHS] personnel for a MMWR regarding the upcoming release of Truvada for PrEP study results."[72] The *Vaughn* index entries establish that the redactions were made to protect predecisional content; they concern "pre-clearance comments," drafts, and "draft language different from the final version." AHF contends, however, that the *Vaughn* index descriptions do not sufficiently establish that portions of the MMWR documents are protected by the deliberative process privilege.

To determine whether a document concerns the deliberative process, the court asks "whether the document is recommendatory in nature or is a draft of what will become a final document, and whether the document is deliberative in nature, weighing the pros and cons of agency adoption of one viewpoint or another." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980). The deliberative process exemption "covers recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency." *Id.*; *Assembly of State of*

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[68]Reply at 9.

[69]*Vaughn* Index at 64.

[70]*Id.* at 65-67.

[71]*Id.* at 72.

[72]*Id.* at 64; *id.* at 72;

Cal. v. U.S. Dep't of Commerce, 968 F.2d 916, 920 (9th Cir. 1992).

The justifications set forth in the *Vaughn* index for the redacted portions of the MMWR documents indicate that they contain recommendations from other agencies to the FDA regarding its development of the MMWR. The justifications also indicate that the redacted discussions contain "draft language" included in a later, final online publication. The *Vaughn* index entries suggest that the MMWR documents were deliberative in nature, insofar as they contained comments from other agencies suggesting that the FDA adopt certain positions. They indicate that the redacted portions of the documents contain the opinions and suggestions of agencies other than the FDA regarding the FDA's preparation of the MMWR. They thus indicate that the redacted portions of the documents reflect the opinions of other agencies and/or their employees, rather than the policy of the FDA. As a result, public disclosure of the opinions and suggestions could stifle honest and frank communication between agencies in the Department of Health and Human Services. As a consequence, considering the *Vaughn* index entries in light of the factors identified in *Coastal States,* the court concludes that the redacted portions of the MMWR documents pertain to a deliberative process and were properly withheld under Exemption 5.[73]

4. Whether FDA Improperly Withheld Interpretations of Submitted Data

AHF asserts that the FDA improperly invoked Exemption 5 in withholding records reflecting its "interpretation of submitted data" ("data interpretation records")[74] because Exemption 5 cannot be invoked to withhold purely factual material. AHF contends that the FDA has not made a sufficient showing that interpretative portions of the documents cannot be segregated from factual matter. See 5 U.S.C. § 552(b) (requiring disclosure of any reasonable segregable portion of a record after deletion of exempt portions). In support of this argument,

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[73]The Ninth Circuit has cited *Coastal States* in identifying factors that indicate whether a given document is "deliberative." See, e.g., *Maricopa Audubon Soc'y*, 108 F.3d at 1095; *Assembly of State of Cal.*, 968 F.2d at 920.

[74]Opp. at 16 (citing CDER Nos. 149465, 149472-149749, 149987-149988,149990-149993, 150298-150306,150311, 150312, 150316-150318, 150538-150542, 150774, 150775, and 151556-151564).

AHF cites cases holding that an agency may not withhold data under the deliberative process exemption. See, e.g., *Carter v. U.S. Dep't of Commerce*, 307 F.3d 1084, 1085 (9th Cir. 2002) (an agency cannot withhold "statistically adjusted data" as deliberative); *Vaughn*, 523 F.2d at 1145 (an agency cannot withhold "the raw data upon which decisions can be made" since "they are not themselves a part of the decisional process").

FDA asserts that the data interpretation records reflect the internal deliberations of agency employees regarding data submitted by Gilead in support of the Truvada for PrEP IND. It represents that the records were redacted not because they contain safety and efficacy data, but because they contain "draft language different from the final version reflecting the opinions and suggestions of FDA personnel regarding the interpretation of submitted data as they tr[ied] to determine the acceptability of the [Truvada for PrEP] IND submission."[75]

While the rule articulated in the cases cited by AHF in its opposition may entitle it to disclosure of any raw data contained in the data interpretation records, AHF is not entitled to disclosure of predecisional, deliberative draft language reflecting the opinions and suggestions of FDA employees concerning that data. Such opinions and suggestions would "themselves [be] a part of the decisional process," making them exempt from disclosure under the deliberative process privilege. *Vaughn*, 523 F.2d at 1145. The court's review of the redacted data interpretation records confirms that they appear to be drafts of agency memoranda and correspondence summarizing and/or analyzing data submitted by Gilead in support of its PrEP application; none of the documents appears, on its face, to be tables or other records containing only raw data.[76] Rather, the unredacted portions of the documents contain salutations and

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[75]Reply at 10; see also *Vaughn* Index at 51-101.

[76]Although Sager states that her staff conducted a "careful page-by-page, line-by-line review" of all records containing information responsive to AHF's March 2011 request to ensure that any reasonably segregable factual information in the records was disclosed (Sager Decl., ¶ 35), this generalized statement is too broad and conclusory to provide independent support for the FDA's motion for summary judgment relative to the data interpretation records.

signature lines indicating that they are correspondence;[77] prefatory language describing the redacted portions of the document as "comments reproduced below" "questions in bold font" and "responses" to those questions;[78] headers that indicate the redacted portions of the documents contain "discussion",[79] "background,"[80] and "action items"[81]; and headers identifying the redacted content as "meeting minutes."[82]

It is possible, however, that there is purely factual matter — i.e., data — included within the data interpretation records that could be segregated from the FDA's analyses and interpretations of that data. The court cannot determine, from its review of the redacted records, whether or not this is the case. The FDA has redacted full pages of the data interpretation records. The *Vaughn* index entries for the records do not state that no purely factual matter has been redacted. As a consequence, the court cannot find that the FDA has adequately demonstrated that the data interpretation records do not include segregable factual material. See *NRDC v. U.S. Dep't of Defense*, 442 F.Supp.2d 857, 872-73, 876-77 (C.D. Cal. 2006). The court therefore directs the FDA to produce the unredacted versions of the data interpretation records for the court's *in camera* inspection.[83] See *Lahr v. Nat'l Transp. Safety Bd.*, 569 F.3d 964, 982 n. 16 (9th Cir. 2009) ("As the government's *Vaughn* index did not supply sufficient information for us to determine whether the documents fell within the privilege, and because the content-specific nature of the inquiry makes it unlikely that a more specific *Vaughn* index would have aided our review, we ordered the government to produce these documents for our in camera inspection");

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[77]See, e.g., CDER No. 149472, 149476

[78]See, e.g., CDER No. 149472,

[79]See, e.g., CDER 150298, 150316, 150538, 151556

[80]See, e.g., CDER 149465, 150303, 150311

[81]CDER 150304, 150312

[82]CDER No. 150303

[83]CDER 151471-151482.

see also *Favish v. Office of Independent Counsel*, 217 F.3d 1168, 1177(9th Cir. 2000) ("Generally speaking, *in camera* inspection would be appropriate where a FOIA request specifies only the kind of information sought and the *Vaughn* index provides insufficient detail for the district court to determine whether the withheld documents qualify for the claimed exemption"); *People of California v. E.P.A.*, No. C 07-2055 JSW, 2008 WL 5384623, *9 (N.D. Cal. Dec. 22, 2008) ("[T]his Court read both the affidavits and the *Vaughn* Index and then, if neither of these provided a sufficient basis to decide whether factual material was reasonably segregable from deliberative material, the court reviewed the documents *in camera*").

In similar vein, AHF argues that the FDA improperly withheld documents containing "interpretations of submitted data prepared to assist the Agency in preparing meeting minutes to provide Gilead" (the "meeting minutes documents")[84] without showing that the preparation of meeting minutes was part of a deliberative process. The *Vaughn* index entry for the meeting minutes documents describes them as a "memorandum of meeting minutes for Feb. 10, 2011" that was attached to an email.[85] The *Vaughn* index justification for withholding the documents states that they "contain[ ] draft language different from the final version reflecting the opinions and suggestions of agency personnel regarding the interpretation of submitted data, prepared to assist the Agency in preparing meeting minutes to provide Gilead."[86]

The *Vaughn* index entry does not identify the purpose of the meeting for which minutes were being prepared, the individuals or entities present at the meeting, or the purpose of providing the minutes to Gilead. Sager does not address the documents in her declaration, and there is no other evidence showing the purpose of the meeting or the meeting minutes. The versions of the meeting minutes given to the court consist of two fully redacted pages. As a consequence, the court cannot determine on the record before it whether the documents pertain to an agency decisionmaking process.

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[84]Opp. at 18 (citing CDER Nos. 150774, 150775).

[85]*Vaughn* Index at 78.

[86]*Id.*

The court therefore directs the FDA to submit a more detailed affidavit and/or *Vaughn* index describing the meeting minutes documents and why they are covered by the deliberative process exception.[87] See *Gerstein v. C.I.A.*, No. C-06-4643 MMC, 2008 WL 4415080, *13 (N.D. Cal. Sept. 26, 2008) ("Where an agency's affidavit is determined to be insufficient, and it appears that a more detailed affidavit could be presented, the court should permit the agency to provide a more detailed affidavit. . . . In the instant case, because it appears the CIA could provide a more detailed affidavit with respect to the fourteen documents referred by the DOJ, the Court will, in this instance, afford CIA the opportunity to do so. Such greater detail would both afford Gerstein a meaningful opportunity to either accept or object to such withholding and permit the Court to determine, if later called upon to so rule, whether such documents were properly withheld," citing *Wiener v. FBI*, 943 F.2d 972, 979 (9th Cir. 1991)); *South Yuba River Citizens League v. National Marine Fisheries Service,* No. CIV. S-06-2845 LKK/JFM, 2008 WL 2523819, *10 (E.D. Cal. June 20, 2008) ("[D]efendants have not shown that each of the documents is deliberative in nature. Defendants' *Vaughn* declaration describes each withheld item only cursorily and with only occasional references to the opinions and recommendations contained therein. . . . None of the withheld items [is] explained in adequate detail to sufficiently show that it contains the types of analysis, recommendations and opinions that the privilege is created to protect. . . . Put directly, the *Vaughn* declaration does not offer enough facts to permit the court to conclude that disclosure of the documents would chill intra- and inter-agency communications so as to impede the agency's functioning. . . . As a remedy, the court has discretion to order defendants to produce more detailed *Vaughn* declarations or indexes or order an *in camera* review of the withheld documents. . . . Generally, ordering *in camera* review is only appropriate after the defendants have been ordered to produce as detailed a *Vaughn* index as possible, and that has been found inadequate. . . . Accordingly, the court orders the NMFS to produce a *Vaughn* index or declaration justifying their withholding of the documents at issue").

[87]CDER 151471-151482.

5. Whether FDA Improperly Withheld Other Information That Does Not Reflect a Deliberative Process

a. The MedGuides Emails

AHF asserts that the FDA improperly withheld information related to the overall "implementation of new internal procedures for MedGuides and REMS" ("the MedGuides emails")[88] It contends the FDA has not shown that the development and implementation of these procedures involved a "deliberative process" such that the documents need not be disclosed under Exemption 5. The *Vaughn* index entry for one of MedGuides emails describes it as an "email informing staff of a new guidance" that contains "discussion of the PrEP submission."[89] The FDA's justification for redacting the email is that the redacted portions contain the "thoughts and opinions of FDA personnel . . . discussing the implementation of new internal procedures."[90] The *Vaughn* index entry concerning the other MedGuides email describes it as an "email attaching medical officers' review with track changes."[91] It states that the redacted portions of the email contain "draft language that reflects the opinions and suggestions of Agency personnel regarding the proposed protocol."[92]

The Ninth Circuit has held that a document is deliberative in nature if it contains "opinions, recommendations, or advice about agency policies." *Warner*, 742 F.2d at 1161. As stated, "recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency" are deliberative. *Assembly of State of Cal.*, 968 F.2d at 920. The *Vaughn* index justification for withholding the Medguides emails states that they reflect the personal opinions and suggestions

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[88]See Opp. at 18 (citing CDER Nos 150686; Nos. 151471-151482).

[89]*Vaughn* Index at 77.

[90]*Id.*

[91]*Vaughn* Index at 98,

[92]*Id.*

of individual FDA employees, and do not reflect the policy of the agency. They thus support a conclusion that the redactions contain deliberative material.

The court's review of the redacted documents confirms that the first MedGuides email sets forth the opinions of individual employees, rather than of the agency, regarding potential implementation of a new internal protocol. Based on the *Vaughn* index entry for this email and the court's review of the redacted document, it concludes that the FDA has demonstrated that the redactions fall within the deliberative process privilege and thus within Exemption 5. *Judicial Watch, Inc. v. U.S. Dept. of Homeland Sec.*, No. 11–00604, 2013 WL 753437, *9 (D.D.C. Feb. 28, 2013) (a *Vaughn* index's explanation that redacted portions of an email discussed the procedures for filing motions to dismiss in several Chief Counsel offices, including one employee's personal opinion as to whether or not the implementation of a certain procedure was appropriate, was sufficient to justify redactions pursuant to the deliberative process privilege); *Techserve Alliance v. Napolitano*, 803 F.Supp.2d 16, 27 (D.D.C. 2011) (holding that USCIS properly withheld "e-mail exchanges between various agency officials regarding the possible implementation of changes to processing fraud matters involving H–1B visas, and stating: "While these recommendations do not identify a specific agency decision, they reflect on-going discussions and debate regarding a change to current processing. If the Court were to order the release of this commentary, it would stymie the consultative process because employees might hesitate to express their opinions for fear of public disclosure").

The court cannot, however, reach the same conclusion regarding the redacted portions of the second MedGuides email. The court's review of the document indicates that the redactions include a section of the medical officer's review titled "Background and Rationale."[93] This caption suggests that the redacted information may include background facts and other information that does not "reflect the opinions and suggestions of Agency personnel regarding . . . proposed protocol," and/or that it consists of purely factual matter. The FDA has failed, moreover, to

[93]See Filing of Redacted Documents (Volume V of V), Docket No. 52-1 (June 27, 2013), at 19.

produce the email that attached the medical officer's review, or to provide any information regarding the purpose of a "Medical Officer's Review of New Protocol" at the FDA. The court cannot determine, therefore, whether the redacted content is deliberative, nor whether it reflects the opinions and suggestions of an individual medical officer rather than the position of the agency as a whole. The court therefore directs the FDA to produce an unredacted version of the second Medguides email for its *in camera* inspection.[94] See *Lahr*, 569 F.3d at 982 n. 16; *People of California*, 2008 WL 5384623 at *9.

b. Elements for Safe Use

AHF next asserts that the FDA improperly withheld several portions of documents relating to the "thoughts and ideas" of FDA personnel concerning the [Elements to Assure Safe Use ("ETASU")] of a third-party's drug (the "ETASU documents").[95] AHF maintains that the FDA has failed to demonstrate that the "thoughts and ideas" contained in the redacted portions of the ETASU documents were part of a deliberative process.

The *Vaughn* entries for the ETASU documents state that the redacted portions are an "internal exchange of thoughts and ideas by FDA personnel regarding the effectiveness and issues with enforcing a current ETASU for a third[ ]party's unrelated drug."[96] As noted, a document is deliberative in nature if it contains "opinions, recommendations, or advice about agency policies." *Warner*, 742 F.2d at 1161. "[S]ubjective documents which reflect the personal opinions of the writer rather than the policy of the agency" are also deliberative. *Assembly of State of Cal.*, 968 F.2d at 920.

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[94]CDER 151471-151482.

[95]Opp. at 19 (citing CDER Nos. 151499, 151500, 151505, 151512, 151514, 151516, 151518, 151520, 151522, 151707, 151717, 152876, 152896, 152914, 152948, 152959, 152988, 152999, 153006, 153022, 153054, 153081, 153092, 153227). ETASUs are guidance that can be included in a medication guide distributed with the medication at FDA direction. See FDA, "Questions and Answers on Guidance for Industry: Medication Guides – Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)," http://www.fda.gov/Drugs/DrugSafety/ucm248459.htm (last visited June 28, 2013).

[96]See, e.g., *Vaughn* Index at 99.

The *Vaughn* index entries for the ETASU documents indicate that the redactions AHF challenges are portions of emails between FDA employees that communicated their personal opinions regarding agency policy. They thus support a conclusion that the redactions constitute deliberative material. The court's review of the redacted ETASU documents indicates that they appear to be emails exchanged by individual FDA employees that communicated their own views, rather than those of the agency in the context of a discussion about the FDA's approach to PrEP in the future.[97] The court finds, consequently, that the FDA has adequately shown that the ETASU documents are protected by the deliberative process privilege.

c. Other Items Withheld Under Exemption 5

Additionally, AHF argues that the FDA's *Vaughn* index is not sufficiently detailed to permit it to determine whether the following information the agency withheld is protected by the deliberative process privilege:[98]

- "redacted portions of meeting notes from a Truvada regulatory briefing rehearsal, iPrEx study slides and the agenda for the Center Director Decisional Briefing on July 14, 2011;[99] and
- portions of an "FDA internal email re: 3rd party IND with attached draft Clinical Microbiology Review."[100]

AHF asserts that the *Vaughn* index lacks basic information concerning the alleged decision to which each record pertains, including the titles/roles of the authors and recipients of the documents, the precise decision to which each pertains, and the role each played in a particular

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[97]See Filing of Redacted Documents (Volume V of V), Docket No. 52-1 (June 27, 2013), at 20.

[98]The court has already addressed some of the records that AHF contends are in this category. Accordingly, the court discusses here the adequacy of the FDA's showing with respect to CDER 150774, 150775, 149465

[99]*Vaughn* Index at 164; Opp. at 21 (citing CDER Nos. 153993, 153994).

[100]*Id.* (citing CDER Nos. 149309-149311, 149508-149511, 149514-149516, 150624-150632).

agency policy decision. It contends that all of this information is crucial to enable the court to determine whether the information falls within the deliberative process privilege and Exemption 5. AHF also argues that the FDA's descriptions provide only "a vague hint at the possible contents of the documents," and that this is insufficient to give either AHF or the court "the necessary functional description of the documents at issue."[101]

AHF correctly notes that the *Vaughn* index entry for the briefing rehearsal documents does not identify the author or recipient of the document. It does indicate, however, that the redacted portions of the meeting notes reflect the "thoughts and ideas of Agency employees in drafting language to include in education slides for use in a future briefing and which language was not used in final slides."[102] The unredacted portions of the document reveal, moreover, that the redacted information concerns a specific FDA policy decision: whether to hold a "Part 15 hearing" regarding the use of Truvada for PrEP.[103]

Because the *Vaughn* index and the unredacted portions of the briefing rehearsal documents show that the redactions contain draft language pertaining to the FDA's deliberations about whether to engage in certain agency action (i.e., whether to hold a "Part 15 hearing" concerning the use of Truvada for PrEP), the record adequately supports the FDA's invocation of the deliberative process exemption. See *NAACP Legal Defense and Ed. Fund, Inc. v. U.S. Dep't of Housing and Urban Dev.*, No. 07 Civ. 3378(GEL), 2007 WL 4233008, *11 (S.D.N.Y. Nov. 30, 2007) ("[A]lthough OIG's *Vaughn* index and accompanying declaration are perhaps not as full as might be ideal, they nevertheless provides a sufficient basis for making a 'reasoned judgment' that the documents fall within the scope of the deliberative process privilege. . . . [T]he withheld records are made up, not of final analyses, but of 'draft' reports and 'proposed slides to use in

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[101] *Id.* at 22 (quoting *Campaign for Responsible Transplantation v. FDA*, 219 F.Supp.2d 106, 112 (D.D.C. 2002)).

[102] *Vaughn* Index at 164.

[103] Notice of Lodging 2nd Attachment for Volume 5 of 5 of Redacted Documents, Docket No. 53 (June 27, 2013), at 20-21.

making internal presentations,' which involve the consideration of certain issues preceding the release of the OIG's final audit report. Draft documents, by their very nature, are typically predecisional and deliberative. . . . The withheld pages represent OIG's internal analysis of what the agency ought to report, or what actions it should take in the future. . . . Accordingly, the non-disclosed pages were protected by the deliberative process privilege"); see also *Marin Inst. for Prevention of Drug and Other Alcohol Problems*, 2000 WL 964620 at *1 (finding the draft of an agency report evaluating attempts to privatize state alcohol systems was exempt from disclosure under Exemption 5).

The *Vaughn* index entry for the FDA internal email lists the author of the email and the recipient. It also states that the redacted portions of the email contain "proposed protocol for PrEP study from a third-party that was not relied upon by the FDA for approval of Truvada for PrEP," and that it contains "draft language different from the final version reflecting the opinions and suggestions of FDA personnel regarding the proposed protocol . . . to determine acceptability of the IND submission."[104] The *Vaughn* index description of the redactions is sufficient to demonstrate that the withheld information falls within the scope of the deliberative process privilege. It reveals that the redactions contain draft language reflecting the personal opinions of FDA employees, which they exchanged in the course of deliberations concerning a specific prospective agency decision – whether or not to accept a proposed protocol to determine the acceptability of a third-party's IND submission. The index thus provides a sufficient basis for the court to determine that the language redacted from the FDA's internal email concerning the third-party IND falls within the deliberative process exemption. *Id.*; see also *Assembly of State of Cal.*, 968 F.2d at 920 (holding that the deliberative process exemption "covers recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency"); *Judicial Watch, Inc.*, 2013 WL 753437 at *9 (a *Vaughn* index's explanation that redacted portions of an email contained an employee's personal opinions as to whether or not the implementation of a certain procedure was

[104] *Vaughn* Index at 42.

appropriate was sufficient to justify redactions under the deliberative process exemption).

III. CONCLUSION

For the reasons stated, the FDA's motion for summary judgment is denied with respect the documents withheld under Exemption 4. The court directs the FDA to produce complete and unredacted copies of the documents withheld under Exemption 4 to AHF.

With respect to documents withheld under Exemption 5, the court grants the FDA's motion as to its draft correspondence,[105] the first MedGuides e-mail,[106] the MMWR documents,[107] the ETASU documents,[108] the Truvada regulatory briefing rehearsal slides,[109] and the FDA's internal email on the third-party IND.[110]

The court defers ruling on the second MedGuides email[111] the data interpretation records,[112] and the meeting minutes documents.[113] The FDA is directed to produce the second MedGuides email and the data interpretation records for *in camera* inspection by the court. It also directs the FDA to submit a more detailed affidavit and/or *Vaughn* index describing the meeting minutes

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[105]CDER Nos. 151137-151142; CDER Nos. 151167-151172.

[106]CDER No. 150686.

[107]CDER Nos. 150171-150756, 150183, 150185, 150200-150206, 150208-150214, 150224, 150231-150232, 150233-150234, 150491-150497, and 150500-150506.

[108]CDER Nos. 151499, 151500, 151505, 151512, 151514, 151516, 151518, 151520, 151522, 151707, 151717, 152876, 152896, 152914, 152948, 152959, 152988, 152999, 153006, 153022, 153054, 153081, 153092, 153227.

[109]CDER Nos. 153993, 153994.

[110]CDER Nos. 149309-149311, 149508-149511, 149514-149516, 150624-150632.

[111]CDER No. 150686.

[112]CDER Nos. 149465, 149472-149749, 149987-149988,149990-149993, 150298-150306,150311, 150312, 150316-150318, 150538-150542, 150774-150775, and 151556-151564.

[113]CDER Nos. 150774, 150775.

documents and why the deliberative process exemption applies to them. The FDA is directed to submit these materials within **five days of the date of this order** so that the court can make a final determination of the issues in dispute. AHF may file a response to the more detailed affidavit/*Vaughn* index within **five days of its filing.**

DATED: August 6, 2013

MARGARET M. MORROW
UNITED STATES DISTRICT JUDGE