IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,	)	
Plaintiff,	)	
v.	)	Civil Action No. 00-2849 (RMU)
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
Defendant.	)	

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I. Introduction

Defendant, the U.S. Food and Drug Administration ("FDA"), respectfully submits this Memorandum of Points and Authorities in Opposition to Plaintiff's Motion for Summary Judgment. FDA has fulfilled its obligations under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, in response to Plaintiff's modified FOIA request. FDA withheld the sixteen documents that remain disputed because those documents are exempt from disclosure, in full or in part, under FOIA Exemptions 4 and/or 5, which protect trade secrets and confidential commercial information, as well as deliberative process information. 5 U.S.C. § 552(b)(4) - (5).

Plaintiff, in its Motion for Summary Judgment, attacked the sufficiency of FDA's Vaughn index and FDA's purported failure to adequately justify withholding the sixteen documents and parts thereof still at issue. FDA, however, has provided Plaintiff with a detailed Vaughn index and all responsive, non-exempt documents, withholding only those documents, in whole or in

part, that are exempt from disclosure. Accordingly, Defendant respectfully submits that no genuine issue of material fact exists and Defendant is entitled to judgment as a matter of law.

II. Argument

A. The Immediate Release of Documents Pertaining to Other INDs is not Warranted.

The parties have been litigating this case in stages, pursuant to this Court's order to use a representative sample Vaughn index. See Campaign for Responsible Transplantation v. FDA, 180 F. Supp. 2d 29, 35 (D.D.C. 2001). Plaintiff selected IND-G as the representative IND for which FDA was to produce a Vaughn index and, in accordance with the Court's July 23, 2001 opinion, FDA was to process the remaining responsive INDs consistent with the Court's subsequent rulings regarding IND-G. The current stage of litigation involves only the withholdings from two categories of documents listed in the FDA's "New Sample Vaughn Index." The first consists of "FDA-Generated Documents Concerning Xenotransplantation Clinical Trials in General," and the second consists of "FDA-Generated Documents in the IND 'G' File or Relating to IND 'G'." (The entirety of this index will be referred to throughout this brief, interchangeably, as the "New Sample Vaughn Index" or "FDA's Vaughn index.) Only sixteen of the thousands of documents listed in the New Sample Vaughn Index remain at issue, and FDA previously submitted an abbreviated index containing only those sixteen documents as an exhibit to the Court. See infra p. 6-7 (discussing the abbreviated Vaughn index).

There are a total of nineteen INDs that are responsive to Plaintiff's FOIA request. (Initially, 35 INDs were at issue in this case, but Plaintiff narrowed its request to xenotransplantation clinical trials involving pigs and/or non-human primates, leaving 19 INDs.) As previously explained, each IND contains an estimated average of 7,000 pages of documents.

See Def.'s Cross-Mot. to Permit a Sample Vaughn Index (June 12, 2001). FDA has not yet processed documents relating to any INDs other than IND-G. Reviewing all 126,000 pages in the eighteen INDs that FDA has yet to process will be a massive undertaking that could take more than a year, if not longer. Id. Accordingly, it always has been understood by the parties that the processing of these additional INDs would take place after the Court ruled on the parties' cross-motions for summary judgment. Indeed, this was the very purpose of the representative sample Vaughn index ordered by the Court, as it will allow the Court to "'extrapolate its conclusions from the representative sample to the larger group of withheld material.'" Campaign for Responsible Transplantation, 180 F. Supp. 2d at 33 (quoting Dowd v. Calabrese, 101 F.R.D. 427, 437 (D.D.C. 1984)). After the Court has ruled on Plaintiff's objections to FDA's withholdings pertaining to IND-G, the government (assuming it does not appeal any adverse decision) will begin processing the remaining INDs, in a manner consistent with those rulings.

In its Motion for Summary Judgment, Plaintiff now requests that the Court disregard this framework and compel FDA "immediately" to disclose to Plaintiff the documents pertaining to the other eighteen INDs. Plaintiff argues that because FDA has provided Plaintiff, during the course of this litigation, with many documents relating to IND-G, and because "those records are 'essentially uniform' in kind to the FDA-generated records that pertain to the other 18 INDs at issue in this case," the Court should order FDA to immediately release to Plaintiff all similar documents contained in the other eighteen INDs. See Mem. in Supp. of Pl.'s Mot. for Summ. Judg. ("Pl.'s Mem") at 12, 24. Plaintiff further suggests that FDA has been delinquent in not yet processing the other INDs and has failed to present an "argument or showing" as to why the documents relating to the other eighteen INDs are exempt from disclosure. Id. at 12.

Plaintiff does not provide any explanation as to why the Court should abandon the framework for this litigation that it previously put in place. The immediate release of documents demanded by Plaintiff completely ignores the purpose of the sample Vaughn index and the Court's July 23, 2001 opinion, whereby FDA is to process the remaining responsive INDs consistent with the Court's rulings regarding IND-G. Moreover, the deadline proposed by Plaintiff -- "immediately"-- is not even close to feasible.

As discussed above, FDA estimates that there are 126,000 pages of documents that will need to be reviewed in processing the remaining eighteen responsive INDs. Once those documents are collected, it will be an extremely time-consuming process for FDA to review and process all of them.[1] Moreover, prior to release, it is likely that FDA will need to confer with the third-parties who have submitted the INDs and who may have interests in protecting trade secrets and confidential commercial information. Requiring FDA to release these documents immediately -- even if it were otherwise possible -- would prejudice these third-parties, who would be deprived of an opportunity to protect their legitimate FOIA Exemption 4 interests. This conferring with third-parties is likely to benefit Plaintiff as well--some of the documents pertaining to IND-G that FDA provided to Plaintiff would have been exempt from disclosure under Exemption 4, but for the consent to release by the entity that had submitted the information to FDA.

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[1] To process the documents for the remaining INDs, FDA first would need to consolidate the documents in one room for review. See Def.'s Cross-Mot. to Permit a Sample Vaughn Index (June 12, 2001) at 6. Responsive documents are housed in several different buildings in four Maryland cities. Id. To assemble the documents, FDA will have to coordinate several record managers in the various facilities with the reviewing personnel for xenotransplantation INDs, who would then search their files and send responsive documents to the FOIA processors. Id.

Additionally, processing the INDs in the manner which Plaintiff now seeks would require FDA to review all of the collected documents twice. In order to release all non-exempt documents to Plaintiff "immediately," FDA would first have to conduct an initial review of the documents for exempt information *before* the Court ruled on IND-G. Since that review would take place without the benefit of the Court's ruling regarding IND-G, FDA would then have to review all of the documents a second time once the Court issues its rulings, to ensure the remaining INDs were processed in accordance with the Court's rulings regarding IND-G. It should go without saying that avoiding this repetitive and unnecessary burden is the central reason for the litigation framework established by this Court.

The litigation framework established by this Court in its July 23, 2001 opinion is a logical and efficient manner in which to resolve issues regarding the production of the thousands of pages of remaining documents, and Plaintiff has failed to justify its demand that the Court abandon this plan.

B. FDA's Vaughn Index is Sufficient.

The purpose of a Vaughn index is to facilitate the court's review of the applicability of FOIA exemptions, and to give the requester sufficient information to challenge the agency's nondisclosure. Vaughn v. Rosen, 484 F.2d 820, 825, 827-28 (D.C. Cir. 1986); Cucci v. DEA, 871 F. Supp. 508, 514 (D.D.C. 1994). As this Court explained, "[t]he real test of a *Vaughn* index is whether it provides 'a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply.'" Campaign for Responsible Transplantation, 180 F. Supp. 2d at 33 (quoting Mead Data Central, Inc. v. Dep't of the Air Force, 566 F.2d 242, 251

(D.C. Cir. 1977)). The degree of specificity required of a Vaughn index varies based on the documents at issue and the exemptions being asserted. Info. Acquisition Corp. v. Dep't of Justice, 444 F. Supp. 458, 462 (D.D.C. 1978). FDA provided Plaintiff with a comprehensive New Sample Vaughn Index on December 20, 2002. See Mem. of P. & A. in Supp. of Def.'s Mot. for Summ. J. ("Def.'s Mem.") at 3, 6. It was accompanied by a declaration of Beth Brockner Ryan, an FDA employee whose duties include supervising the employees processing FOIA requests made of FDA's Center for Biologics Evaluation and Research. Id. at 4-5.

In spite of FDA's submission of Ms. Brockner Ryan's declaration, Plaintiff argues that FDA's "Vaughn index is not even a sworn document." Pl.'s Mem. at 15. If Plaintiff is referring to the initial, multi-volume New Sample Vaughn Index that FDA provided in December 2002, such clearly is a sworn document, as it was submitted as an exhibit to Ms. Brockner Ryan's declaration. The subsequent abbreviated Vaughn indices submitted by FDA are merely condensed segments of that original New Sample Vaughn Index, with each abbreviated index containing details about only those documents that remain at issue. See Def.'s Mem. at 3. FDA submitted the first two abbreviated indices for ease of both the Court's and the parties' understanding, and similarly attached a third abbreviated New Sample Vaughn Index ("third Vaughn index") as an exhibit to its Motion for Summary Judgment. Id. at 3, Ex. A.

In several instances in its brief, Plaintiff purports to challenge FDA's withholdings pursuant to FOIA Exemptions 4 or 5, but in fact merely challenges the adequacy of FDA's Vaughn index. See, e.g., Pl.'s Mem. at 13, 15, 20. Before addressing the substance of any of those arguments, FDA once again objects to Plaintiff's attempt to challenge the adequacy of FDA's Vaughn index, in direct contravention of the Court's statement that Plaintiff must first

seek leave of the court in order to so challenge. See status hearing transcript at 2 (Oct. 16, 2002), Plaintiff's Ex. 16. To date, Plaintiff has not sought leave of this Court and Defendant is therefore entitled to summary judgment as to the adequacy of its New Sample Vaughn Index.

Even if the Court decides not to enforce its order to seek leave and instead considers the substance of Plaintiff's claims, FDA nonetheless is entitled to judgment as a matter of law. Plaintiff's contentions are not persuasive, as demonstrated below. In challenging the adequacy of FDA's Vaughn index, Plaintiff does not claim that "it was deprived of the opportunity to effectively present its case to the court because of the agency's inadequate description of the information withheld and exemptions claimed," Mead Data, 566 F.2d at 251. Instead, Plaintiff contends that FDA's Vaughn index is inadequate because it fails to (1) provide the "actual page on which the Exemption at issue pertains;" (2) adequately describe the justification for each Exemption 4 withholding; and (3) indicate the author, recipient, and/or date for some documents, and provide the titles or positions of the named authors and recipients. Pl.'s Mem. at 13, 15, 20.

1. FDA Properly Identified Page Numbers in the Withheld Documents.

Plaintiff first contends that in its New Sample Vaughn Index, FDA failed to indicate the page numbers on which information withheld pursuant to Exemption 4 can be found. Pl.'s Mem. at 13. In fact, however, the page numbers from which FDA withheld portions are identified in the New Sample Vaughn Index. See, e.g., third Vaughn index. Additionally, the specific items identified in each document as confidential commercial information are clearly labeled, indicating that the remainder of each document is being withheld pursuant to Exemption 5.[2]

[2] FDA acknowledges that some of the information identified in the third Vaughn index as confidential commercial information is no longer responsive, due to Plaintiff further narrowing its FOIA request. See Pl.'s Mem. at 15.

Third Vaughn index. For example, the description for document 3591 reads, in part, "CCI: names of sponsors, PERV testing, cells used, ...," and in the pages withheld column, the entry states, "pgs. 1-3: b(4) and b(5) throughout entire document." Id. at 9. The information FDA withheld in all of the other documents still at issue is similarly identified and correlated to the applicable FOIA exemption. Third Vaughn index; see also Keys v. Dep't of Justice, 830 F.2d 337, 349-50 (D.C. Cir. 1987) (finding a Vaughn index prepared by the government that used a similar "coding" system to be adequate).

2. The Descriptions in FDA's Vaughn Index are Sufficient.

Plaintiff also maintains that FDA's Vaughn index provides only "cursory" information about those documents withheld pursuant to Exemption 4 and fails to explain how disclosure of those documents "is likely to cause 'substantial competitive injury' to anyone." Pl.'s Mem. at 15. The Vaughn index and supporting declarations demonstrate that Plaintiff's characterizations are incorrect. In order to sustain its burden of justifying that withheld documents properly fall within the FOIA exemptions, an agency may rely on both its Vaughn index and supporting declarations. EPA v. Mink, 410 U.S. 73, 93 (1973) ("agency should be given the opportunity, by means of detailed affidavits or oral testimony, to establish to the satisfaction of the District Court that the documents sought fall clearly" within a FOIA exemption); Cucci v. DEA, 871 F. Supp. 508, 510 (D.D.C. 1994)(a court "may award summary judgment [to an agency in a FOIA case] solely on the information provided in affidavits or declarations that explain how the requested information falls within a claimed exemption if the affidavits or declarations are sufficiently detailed, nonconclusory and submitted in good faith"); Nishnic v. Dep't of Justice, 671 F. Supp. 776, 783 (D.D.C. 1987)(agency did not "rely exclusively on a *Vaughn* index to meet its burden of proof

under FOIA," but instead also submitted affidavits from an agency employee).

The New Sample Vaughn Index contains, for each document, a description of the document, the number of pages, the page number of each withholding, the authors' and recipients' names (if known), the date of creation (if known), and the legal authority for each withholding. See third Vaughn index. FDA submitted several declarations that address, *inter alia*, the potential competitive harm from disclosure of the material withheld under Exemption 4. Indeed, three of the declarations explain that disclosing details of the sponsor's clinical trials would reveal confidential information that could be unfairly used by competitors to spend less money, time, and effort developing their own clinical trials. See Def.'s Mem. at 10; Second Brockner Ryan Decl. ¶¶ 11-12; Stewart/Egan Decl., Dec. 16, 2002, ¶ 4, Egan Decl., June 4, 2003, ¶ 3 (Intervenor-Def. Diacrin/Genayme LLC's Mem. in Supp. of Def. FDA's Ren. Mot. for Sum. J. & Not. Filing Decls., Exs. A & B). These descriptions are "sufficiently specific to support the exemptions claimed." Cucci, 871 F. Supp. at 514; see also Oglesby v. Dep't of the Army, 79 F.3d 1172, 1178 (D.C. Cir. 1996) ("If an affidavit submitted by an agency contains sufficient detail to forge the 'logical connection between the information [withheld] and the claimed exemption,' then the court will accord that affidavit substantial weight and consider the agency's 'unique insights into what adverse effects might occur as a result of public disclosure.'") (quoting Goldberg v. Dep't of State, 818 F.3d 71, 78 (D.C. Cir. 1987)).

3. Names, Titles, and Positions are not Essential to a Valid Vaughn Index.

Plaintiff also contends that by failing to provide authors, recipients, dates, positions, and titles for all of the withheld documents, FDA produced an inadequate Vaughn index. Pl.'s Mem. at 20-21. Plaintiff fails, however, to cite any authority requiring a Vaughn index to identify

authors, recipients, and dates (let alone when such information is unavailable). To the contrary, the caselaw in this Circuit clearly establishes no pre-set format for a Vaughn index--it must describe, in as much detail as possible, the withheld information and specify the reasons for each withholding. See, e.g., Mead Data, 566 F.2d at 251; Campaign for Responsible Transplantation v. FDA, 219 F. Supp. 2d 106, 112-13 (D.D.C. 2002); see also Keys, 830 F.2d at 349 ("As our post-Vaughn opinions make clear, it is the function, not the form, of the index that is important."). Indeed, much of the information that Plaintiff seeks, such as names and titles, was not withheld; it was simply unavailable.

One of the cases that Plaintiff cites as support for its proposition, Animal Legal Defense Fund, Inc. v. Dep't of the Air Force, notes in dicta that the Air Force's Vaughn index failed to include dates, and author and recipient titles. Animal Legal Defense, 44 F. Supp. 2d 295, 301 (D.D.C. 1999). But the court's holding, that the documents at issue were not exempt from disclosure, turned on the fact that "the Air Force offers not a single description of any of the withheld documents," not that the agency failed to include the authors' and recipients' titles and positions. Id. at 299-300. Plaintiff's reliance on this case, therefore, is misplaced.

For the majority of documents, FDA provided Plaintiff with the names of the authors and recipients, as well as the dates. For the others, FDA does not have the identity of the authors or recipients, nor the date on which the document was created, and therefore cannot provide such details to Plaintiff. For all such documents, FDA entered "unknown" in the appropriate column of the Vaughn index. See third Vaughn index. Though Plaintiff argues to the contrary, the names of the authors and recipients are unnecessary for ascertaining whether Exemptions 4 and/or 5 apply in this case. The descriptions of the documents in the Vaughn index provide

sufficient detail to demonstrate that the documents at issue are being properly withheld.

FDA's Vaughn Index contains all of the required elements and satisfies the "relatively detailed justification" test set forth in Mead Data: FDA's Vaughn index is one complete document, includes a detailed description of each document, identifies the statutory and regulatory authority for nondisclosure, and matches the pages withheld to the relevant authority. Third Vaughn index. The descriptions in FDA's Vaughn index allow Plaintiff a meaningful opportunity to challenge the withholdings and permit the Court to review their appropriateness.

C. FDA Properly Withheld Portions of Five Documents Pursuant to Exemption 4.

Exemption 4 protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The only five documents that FDA is withholding, in part, pursuant to Exemption 4 that remain at issue are: 2280, 2762, 3476, 3585, and 3591.[3] These documents are protected because they contain confidential commercial information and, as explained in the declarations previously submitted by the government, disclosing such proprietary information would reveal confidential details about a sponsor's clinical trial that could be unfairly used by competing sponsors to spend less money, time, and effort developing their own clinical trials. 2d Brockner Ryan Decl. ¶¶ 9, 11-12; Stewart/Egan Decl., Dec. 16, 2002, ¶ 4, Egan Decl., June 4, 2003, ¶ 3 (Intervenor-Def. Diacrin/Genayme LLC's Mem. in Supp. of Def. FDA's Renewed Mot. for Sum. J. & Not. of Filing Decls., Exs. A & B).

[3] Plaintiff states that document 773 was also withheld pursuant to Exemption 4, but since Plaintiff is no longer seeking the information that FDA previously withheld from document 773, FDA is not currently withholding any portion of document 773 pursuant to Exemption 4. As a result, portions of only five of the documents still at issue were withheld under Exemption 4.

For documents containing information whose submission the government compelled, as is the case for the documents still at issue, information is confidential for purposes of Exemption 4 if its disclosure is likely "(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." Nat'l Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); see also Critical Mass Energy Project v. NRC, 975 F.2d 871, 878 (D.C. Cir. 1992). Under the second prong of the National Parks test, Exemption 4 protects information whenever there is evidence of "actual competition and a likelihood of substantial competitive injury" to the provider of that information. Judicial Watch, Inc. v. Export-Import Bank, 108 F. Supp. 2d 19, 29 (D.D.C. 2000). The party opposing disclosure does not need to demonstrate actual competitive harm, and "the court need not conduct a sophisticated economic analysis of the likely effects of disclosure." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1291 (D.C. Cir. 1983).

Plaintiff contends that FDA failed to demonstrate the likelihood of substantial competitive harm that would result from disclosure of the five documents still at issue that FDA is withholding pursuant to Exemption 4. Pl.'s Mem. at 16-17. FDA has repeatedly explained, in prior briefs and through declarations, that details concerning clinical trials, if released, would cause substantial competitive harm to the Defendant-Intervenors by giving rival sponsors a competitive advantage in designing their own clinical trials. See Def.'s Mem. at 9-11; Second Brockner Ryan Decl. ¶ 11; Def.-Intervenors' Mem. in Opp'n to Pl.'s Mot. for Summ. J. at 15 (March 28, 2002) ("Disclosure of this data and information would allow competitors to bypass scientific dead-ends encountered by a particular sponsor without the same expenditures of time,

effort, risk, and resources. Competitors could also use IND data and materials to understand a sponsor's future xenotransplantation development efforts."). The declarations submitted to the Court by FDA and the Defendant-Intervenors, along with the Vaughn index, provide ample justification for FDA withholding portions of five documents pursuant to Exemption 4. See Public Citizen Health Research Group v. FDA, 185 F.3d 898, 905-06 (D.C. Cir. 1999) (finding affidavits with a similar level of detail to those FDA submitted in this case sufficient to support Exemption 4 withholdings); Public Citizen, 704 F.2d at 1291.

Plaintiff also argues that some of the information FDA identified as confidential commercial information has already been publicly disclosed, and must therefore be released. Pl.'s Mem. at 17-18. FDA agrees that information in the public domain is not "confidential" for purposes of Exemption 4. Plaintiff incorrectly suggests, however, that since "sponsors of xenotransplantation INDs have willingly shared with investors and other members of the public vast amounts of information about their products," the parts of documents FDA has withheld pursuant to Exemption 4 are no longer confidential. It is well-established that "the party favoring disclosure has the burden of demonstrating that the information sought is identical to information already publicly available." Center for Auto Safety v. Nat'l Highway Traffic Safety Admin., 244 F.3d 144, 151 (D.C. Cir. 2001) (emphasis in original); see also Assassination Archives & Research Ctr. v. CIA, 334 F.3d 55, 60-61 (D.D.C. 2003). Plaintiff has not made such a showing.

Plaintiff contends that "FDA has never stated that it has reviewed those records [provided by Plaintiff to FDA] to ascertain whether any of the information it continues to withhold under Exemption 4 has already been publicly disclosed." Pl.'s Mem. at 18. To the contrary, however, FDA previously reviewed all of the exhibits that Plaintiff provided in its attempt to demonstrate

that certain withheld documents have been publicly disclosed and, after reviewing the materials, FDA concluded that all responsive, non-exempt, reasonably segregable information was provided to Plaintiff. See, e.g., Second Brockner Ryan Decl. ¶¶ 5, 10. The burden is not on FDA to disprove that the withheld information has previously been made public; rather the burden is on Plaintiff "to point to 'specific' information identical to that being withheld." Davis v. Dep't of Justice, 968 F.2d 1276, 1280 (D.C. Cir. 1992). Plaintiff has failed to present publicly disclosed information identical to that being withheld, and thus Plaintiff's argument that FDA has improperly withheld Exemption 4-protected documents must fail.

In conclusion, FDA has shown that all five of the documents still at issue that FDA withheld in part pursuant to Exemption 4 contain confidential commercial information. FDA, therefore, properly withheld portions of the five documents listed in the third Vaughn index as exempt from disclosure pursuant to Exemption 4.

D. FDA Properly Withheld all Sixteen Documents Pursuant to Exemption 5.

Exemption 5 protects "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). The deliberative process privilege is one of the evidentiary privileges incorporated within Exemption 5. NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975); see also Def.'s Mem. at 11-12. The privilege protects documents that are both pre-decisional and deliberative, including "recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency." Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980). The existence

of Exemption 5-protected documents does not depend on the agency's ability to identify a specific decision to which the documents relate. Sears, 421 U.S. at 151 n.18; see also Vaughn, 523 F.2d at 1146; Gutman v. Dep't of Justice, 238 F. Supp. 2d 284, 292 (D.D.C. 2003) (citing Coastal States, 617 F.2d at 868).

FDA asserted the deliberative process privilege for all sixteen of the documents that remain in contention pursuant to Exemption 5.[4] Two documents have been entirely withheld on this basis and fourteen documents have been partially withheld. Plaintiff claims that FDA failed to demonstrate that the withheld documents are pre-decisional and deliberative. Pl.'s Mem. at 20-22. All sixteen of the documents, or parts thereof, that FDA withheld pursuant to Exemption 5, however, were created during FDA's process of reviewing xenotransplantation INDs and/or creating policy on xenotransplantation-related issues in clinical trials, before any final agency position was established. Def.'s Mem. at 14. Contrary to Plaintiff's assertions that the documents were part of FDA's "'continuing process of agency self-evaluation,'" Pl.'s Mem. at 22, the withheld documents, or parts thereof, reflect FDA's efforts to finalize agency positions on xenotransplantation, are both pre-decisional and deliberative, and are therefore exempt from disclosure pursuant to Exemption 5. Def.'s Mem. at 14-18; see also Petroleum Info. Corp. v. Dep't of the Interior, 976 F.2d 1429, 1434 (D.C. Cir. 1992)("The deliberative process privilege,

[4] Plaintiff notes that, based on the entry in the Vaughn index, document 3024 appears to have been created by a sponsor, and FDA cannot therefore withhold it pursuant to the deliberative process privilege of Exemption 5. Pl.'s Mem. at 20. In fact, the author of document 3024 is an unknown agency employee, and the column in the Vaughn index should have been labeled "unknown" rather than "sponsor." Additionally, by Plaintiff's own modification of its FOIA request, Plaintiff seeks only FDA-generated documents, so even if document 3024 was created by a sponsor, it would be non-responsive.

we underscore, is centrally concerned with protecting the process by which *policy* is formulated.") (emphasis in original).

1. The Documents FDA Withheld are Pre-decisional.

Plaintiff maintains that for every document FDA withheld pursuant to Exemption 5, FDA must "pinpoint" a particular agency decision to which the document relates. Pl.'s Mem. at 19. The existence of pre-decisional documents, however, does not depend on the agency's ability to identify a specific decision to which the documents relate. See Sears, 421 U.S. at 151 n.18; Vaughn, 523 F.2d at 1146; Gutman, 238 F. Supp. 2d at 292 (citing Coastal States, 617 F.2d at 868); Hamilton Sec. Group Inc. v. HUD, 106 F. Supp. 2d 23, 30 (D.D.C. 2000). The deliberative process privilege contained in Exemption 5 is applicable so long as the document is generated as part of a continuing process of agency decision-making. Ashley v. Dep't of Labor, 589 F. Supp. 901, 908-09 (D.D.C. 1983) (holding that documents containing agency self-evaluations need not be shown to be part of a clear process leading up to an "assured" final decision as long as the agency can demonstrate that the documents were part of some deliberative process); see also Montrose Chemical Corp. of California v. Train, 491 F.2d 63, 71 (D.C. Cir. 1974) ("Exemption 5 was intended to protect not simply deliberative material, but also the deliberative process of agencies."); Heggestad v. Dep't of Justice, 182 F. Supp. 2d 1, 7 (D.D.C. 2000).

Plaintiff also contends that FDA has withheld documents concerning decisions that were already made, meaning that those documents are not pre-decisional and therefore not protected by Exemption 5. Pl.'s Mem. at 22-23. All of the documents FDA withheld pursuant to Exemption 5, however, are pre-decisional. Plaintiff specifically identifies document 1088 as an example of a document that FDA improperly withheld. Pl.'s Mem. at 22. Document 1088

consists of an e-mail exchange that discusses what, if any, long-term requirements FDA ought to impose on sponsors who withdraw INDs relating to xenotransplantation. Third Vaughn index at 1. As of the dates of the e-mails, no final policy on the issue had yet been established. Documents containing advice that is used by the agency to reach a decision is "precisely the kind of predecisional and deliberative advice and recommendations contemplated by Exemption 5 which must remain uninhibited and thus undisclosed." Renegotiation Bd. v. Grumman Aircraft Engineering Corp., 421 U.S. 168, 190 (1975). Further, even after FDA policy is established, documents such as document 1088 remain exempt from disclosure: "documents shielded by executive privilege remain privileged even after the decision to which they pertain may have been effected, since disclosure at any time could inhibit the free flow of advice, including analysis, reports, and expression of opinion within the agency." Fed. Open Mkt. Comm. of the Fed. Reserve Sys. v. Merrill, 443 U.S. 340, 360 (1979).

2. The Documents FDA Withheld are Deliberative.

Plaintiff asserts that some of the documents FDA claims are protected by Exemption 5 are not deliberative but instead contain purely factual material. Pl.'s Mem. at 23. While early court decisions evaluating the deliberative process privilege relied heavily on the distinction between "factual" and "deliberative" material, "[t]he fact/opinion distinction, however, is not always dispositive; in some instances, 'the disclosure of even purely factual material may so expose the deliberative process within an agency ' that the material is appropriately held privileged." Petroleum Info. Corp., 976 F.2d at 1434 (quoting Mead Data, 566 F.2d at 242). The focus in Exemption 5 cases "became whether the disclosure of 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." Dudman Communications Corp. v. Dep't of the Air Force, 815 F.2d 1565, 1568 (D.C. Cir. 1987).

Plaintiff states that documents 201, 2093, and 1364 are examples of documents that FDA improperly withheld pursuant to Exemption 5 because those documents contain purely factual material. Pl.'s Mem. at 23. Document 201 is a two page, internal FDA memorandum concerning the effects of xenotransplantation in humans. Third Vaughn index at 1. The only portions withheld from document 201 contain the author's opinion regarding an issue involving xenotransplantation in human subjects, which opinions were provided to the recipients in order to assist their decision-making on the issue. Id. The withheld parts of document 201 were not purely factual as stated by Plaintiff, but instead consist of internal advice from one FDA employee to her FDA colleagues as part of the give-and-take of FDA's decision-making process.

Plaintiff maintains that FDA wrongly withheld factual information, namely an "interpretation of data," from document 1364. Pl.'s Mem. at 23. Document 1364 does consist, in part, of an interpretation of data. Third Vaughn index at 2. This data interpretation, however, is very different from the purely factual materials that courts have found must be disclosed pursuant to FOIA. See, e.g., Mapother v. Dep't of Justice, 3 F.3d 1533, 1539-40 (D.C. Cir. 1993) (holding that the portion of a report that merely listed an individual's promotions, ranks, and leaves from active duty was not exempt from disclosure). As one court aptly explained, "[t]he draft audit report [at issue] does not merely involve the collection and compilation of publicly available data. It involves judgments about what to collect, how to collect it, and how to present it." Hamilton Sec. Group, 106 F. Supp. 2d at 32. Similarly, the interpretation of data from document 1364 that FDA withheld reflects agency scientists' judgments, and is not merely raw data.

The final document cited by Plaintiff as containing disclosable factual information is document 2093. Document 2093 is an internal memorandum "that discusses steps to inactivate a virus," and both the author and recipient are agency employees. Third Vaughn index at 3. The document contains the author's personal opinion regarding a recommendation made by the recipient concerning inactivation steps, before any final decision had been made on the matter. Documents that contain views that are not yet final agency policy are deliberative and protected from disclosure by Exemption 5. Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980). As such, document 2093 is deliberative in nature, rather than a mere recitation of facts as Plaintiff contends, and was properly withheld by FDA pursuant to Exemption 5.

As explained above, all sixteen of the documents still at issue that FDA withheld, in full or in part, pursuant to Exemption 5 were or are part of FDA's decision-making process and are deliberative in nature. The disclosure of such documents would have a chilling effect on the frank, open discussions that Exemption 5 was designed to protect. Wolfe v. HHS, 839 F.2d 768, 775-76 (D.C. Cir. 1988). The documents or parts thereof are therefore exempt from disclosure and FDA properly withheld them pursuant to Exemption 5.

E. Discovery is not Appropriate in this Case.

Plaintiff asserts, in a footnote, that it should be "provided limited discovery" regarding the basis for FDA's withholdings. Pl.'s Mem. n.2. Discovery, however, is rarely permitted in FOIA cases. Public Citizen Health Research Group v. FDA, 997 F. Supp. 56, 72 (D.D.C. 1998) ("Discovery is to be sparingly granted in FOIA actions."), aff'd in part, rev'd in part & remanded, 185 F.3d 898 (D.C. Cir. 1999); Schrecker v. Dep't of Justice, 217 F. Supp. 2d 29, 35 (D.D.C. 2002) ("Discovery in FOIA is rare and should be denied where an agency's declarations are

reasonably detailed, submitted in good faith and the court is satisfied that no factual dispute remains."). Discovery may be had if a plaintiff raises sufficient questions concerning the agency's good faith in the processing of its Vaughn index or its search for responsive documents, Judicial Watch, Inc. v. Export-Import Bank, 108 F. Supp. 2d 19, 25 (D.D.C. 2000), but discovery in FOIA cases is "typically limited to the scope of an agency's search, its indexing and classification procedures, and similar factual matters." Cent. for Nat'l Sec. Studies v. Dep't of Justice, No. 01-2500 (GK), 2002 U.S. Dist. LEXIS 2983, at *4 (D.D.C. Feb. 21, 2002). The adequacy of FDA's search was definitively established by this Court, Campaign for Responsible Transplantation v. FDA, 219 F. Supp.2d 106, 111 (D.D.C. 2002), and thereby is not at issue, and Plaintiff has not questioned FDA's good faith in processing Plaintiff's FOIA request. As a result, Plaintiff's request for discovery lacks merit and should be denied.

Conclusion

FDA has complied with its obligations in response to Plaintiff's FOIA request. FDA has reviewed hundreds of thousands of pages of documents, released thousands of responsive documents or parts thereof, produced a detailed Vaughn index that describes the withheld information and justifies each withholding, and provided supporting declarations from FDA employees. FDA has provided Plaintiff with all reasonably segregable, non-exempt, responsive documents and parts thereof, and the sixteen documents that remain at issue in this case are exempt from disclosure pursuant to FOIA Exemptions 4 and/or 5. For the reasons set forth above and in Defendant's previous pleadings, Defendant's renewed motion for summary judgment should be granted and Plaintiff's motion for summary judgment should be denied.

February 5, 2004

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,	)	
Plaintiff,	)	
v.	)	Civil Action No. 00-2849 (RMU)
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
Defendant.	)	

DEFENDANT'S RESPONSE TO PLAINTIFF'S STATEMENT OF MATERIAL FACTS

Pursuant to Local Rule 7(h), Defendant, the United States Food and Drug Administration ("FDA"), responds to Plaintiff's Statement of Material Facts ("Statement"). Although Defendant disputes certain assertions contained in Plaintiff's Statement, Defendant does not believe that those disputes present any genuine issues of fact that are material to the resolution of this case. Accordingly, Defendant avers that there are no genuine issues of material fact in dispute and that judgment should be entered in favor of Defendant.

1. Defendant does not dispute this statement.

2-3. The statements in these paragraphs are not relevant or material. At issue in the instant matter is whether FDA has provided Plaintiff with all reasonably segregable documents that are not exempt from disclosure under the Freedom of Information Act ("FOIA") in response to Plaintiff's FOIA request. Plaintiff's statements, however, concern the alleged health risks posed by xenotransplantation and FDA's duty to inform the public. The statements in paragraphs 2 and 3 allege facts that are clearly immaterial to the instant motion.

4. Defendant does not dispute this statement.

5. Defendant does not agree that these statements are material. The paragraph alleges facts regarding xenotransplantation in patients in clinical trials, which facts are irrelevant and immaterial to this FOIA litigation.

6. Defendant disputes this statement. Defendant lacks the knowledge as to the reasons Plaintiff attached exhibits to its March 9, 2000 FOIA request. Defendant also denies that the exhibits to Plaintiff's FOIA request are identical to the documents being withheld by Defendant in this case. See Second Brockner Ryan Decl. ¶ 10.

7. Defendant disputes this statement. As FDA has repeatedly stated, information that FDA is aware has been publicly disclosed has been produced to Plaintiff. See, e.g., Def.'s Mem. of P. & A. in Opp'n to Pl.'s Mot. for Summ. J.; Second Brockner Ryan Decl. ¶ 10. Defendant does not dispute the remainder of this statement.

8-9. Defendant does not dispute these statements.

Respectfully submitted,

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