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 RENEWED MOTION FOR SUMMARY JUDGMENT

Defendant, the United States Food and Drug Administration ("FDA"), through its undersigned counsel, respectfully moves this Court for summary judgment. FDA has released all responsive, non-exempt documents, or parts of documents, pursuant to the Freedom of Information Act, 5 U.S.C. § 552, et seq., as amended. As set forth in the attached Memorandum of Points and Authorities, there are no material facts in dispute and the government is entitled to judgment as a matter of law. Fed. R. Civ. P. 56.

Respectfully submitted,

_____/s/_____
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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S RENEWED MOTION FOR SUMMARY JUDGMENT

I. Introduction

Defendant, the United States Food and Drug Administration ("FDA"), respectfully submits this Memorandum of Points and Authorities in Support of its Renewed Motion for Summary Judgment. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, et seq., as amended, arising from Plaintiff's FOIA request of March 9, 2000, for records concerning xenotransplantation clinical trials. To date, FDA has produced approximately 1164 documents that are responsive to Plaintiff's modified FOIA request.[1] On July 23, 2001, this Court ordered FDA to provide to Plaintiff a sample Vaughn index, Campaign for Responsible Transplantation v. FDA, 180 F. Supp. 2d 29, 35 (D.D.C. 2001). On September 3, 2002, this

[1] Plaintiff's original FOIA request sought all records regarding (1) applications to conduct clinical trials in humans that involve xenotransplantation; and (2) past and present clinical trials involving xenotransplantation. Campaign for Responsible Transplantation v. FDA, 180 F. Supp. 2d 29, 31 (D.D.C. 2001). Plaintiff subsequently narrowed its FOIA request to include only FDA-generated records concerning xenotransplantation clinical trials involving pigs and/or non-human primates. Id.; see also Pl.'s Reply Mem. in Supp. of Pl.'s Mot. for Summ. J. and in Opp'n to the Government's Cross-Mot. for Summ. J. at 2, May 8, 2002 (citing Joint Stipulation, Dec. 20, 2001).

Court held that FDA's search for responsive documents was adequate, but ordered FDA to provide Plaintiff with a more detailed sample Vaughn index. Campaign for Responsible Transplantation v. FDA, 219 F. Supp. 2d 106, 116 (D.D.C. 2002). FDA thereafter provided Plaintiff with a New Sample Vaughn Index, describing the documents being withheld and setting forth the legal basis for each withholding.[2]

On December 2, 2003, this Court ruled that the parties' submissions failed to clearly state which of the requested documents remain at issue. Order at 1. The Court was unable to discern from the parties' briefs whether the parties were in agreement as to how many, and which, documents are still in contention. Id. at 3. The Court, therefore, struck both parties' motions for summary judgment and ordered that the parties either file a stipulation resolving the case or file new motions for summary judgment, with any new motions specifying the total number of documents that remain at issue, and, for each document still at issue, the document number and applicable exemption(s). Id. at 3-4.

FDA withheld the documents that remain in contention because they are exempt from disclosure pursuant to FOIA Exemptions 4 and/or 5. Accordingly, as set forth below, Defendant respectfully submits that no genuine issue of material facts exists and Defendant is entitled to judgment as a matter of law.

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[2] Although FDA provided the Vaughn index in two segments, one entitled "FDA-Generated Documents Concerning Xenotransplantation Clinical Trials in General," and the other entitled "FDA-Generated Documents in the IND 'G' File or Relating to IND 'G,'" for ease of understanding, they will be referred to herein collectively as "the New Sample Vaughn Index."

II. Documents Still in Contention

The parties are in agreement that only 16 documents remain at issue in the instant matter.[3] The number of documents at issue decreased as a result of Plaintiff further narrowing its FOIA request and FDA releasing many documents and parts thereof that it previously withheld. See Pl.'s Mem. in Supp. of Cross-Mot. for Summ. J. and in Opp'n to Def.'s Renewed Mot. for Summ. J. ("Pl.'s Mem."), Ex. 1; Reply Mem. of P. & A. in Supp. of Def's Renewed Mot. for Summ. J. and in Opp'n to Pl.'s Cross-Mot. for Summ. J. ("Def.'s Reply"), Ex. A. A third abbreviated New Sample Vaughn Index ("third Vaughn index") that references only those 16 documents is attached hereto as Exhibit A.[4]

The 16 documents that are currently in contention are (by document number): 201, 773, 1088, 1357, 1364, 1863, 1913, 2093, 2280, 2610, 2762, 3024, 3098, 3476, 3585, and 3591. Five documents, namely documents 2280, 2762, 3476, 3585, and 3591, were withheld, in part, pursuant to Exemption 4. Third Vaughn index. All 16 documents, namely documents 201, 773, 1088, 1357, 1364, 1863, 1913, 2093, 2280, 2610, 2762, 3024, 3098, 3476, 3585, and 3591, were withheld, in full or in part, pursuant to Exemption 5. Id.

III. Argument

Summary judgment is appropriate where "the pleadings . . . together with the declarations . . . show there is no genuine issue as to any material fact and that the moving party is entitled to

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[3] FDA sent a letter, dated December 4, 2003, to Plaintiff that listed the 16 documents FDA believed to still be at issue, and Plaintiff, on December 15, 2003, through counsel, concurred.

[4] The abbreviated Vaughn indices are merely condensed versions of FDA's New Sample Vaughn Index, with each abbreviated index containing details about only those documents that remain at issue.

a judgment as a matter of law." Fed. R. Civ. Proc. 56(c); see also Alyeska Pipeline Serv. Co. v. EPA, 856 F.2d 309, 313 (D.C. Cir. 1988); Miller v. Dep't of State, 779 F.2d 1378, 1382 (8th Cir. 1985). The standard governing summary judgment in FOIA cases is well established: "the agency must show, viewing the facts in the light most favorable to the requester, that there is no genuine issue of material fact." Steinberg v. Dep't of Justice, 23 F.3d 548, 551 (D.C. Cir. 1994); see also Burka v. HHS, 87 F.3d 508, 514 (D.C. Cir. 1996).

To demonstrate that summary judgment is appropriate in a FOIA matter, the agency may rely on declarations to show that its search was reasonable and that any withheld documents properly fall within the FOIA exemptions. Oglesby v. Dep't of the Army, 920 F.2d 57, 68 (D.C. Cir. 1990); Lewis v. IRS, 823 F.2d 375 (9th Cir. 1987). The agency's declarations will be sufficient for summary judgment if they are clear, specific, and reasonably detailed; if they describe the search and the withheld information in a factual and nonconclusory manner; and if there is no contradictory evidence on the record or evidence of agency bad faith. Miller v. Casey, 730 F.2d 773, 776 (D.C. Cir. 1984); Assassination Archives & Research Ctr. v. CIA, 177 F. Supp. 2d 1, 6 (D.D.C. 2001). Further, "[u]nless the [declarations] are deficient . . ., the court need inquire no further into their veracity," and will accord the declarations substantial weight. Taylor v. Dep't of the Army, 684 F.2d 99, 107 (D.C. Cir. 1982) (quoting Hayden v. NSA, 608 F.2d 1381, 1387 (D.C. Cir. 1979)).

FDA submitted several declarations in support of its Renewed Motion for Summary Judgment, and pursuant to the Court's December 2, 2003 Order, is relying on its previously submitted exhibits in support of the instant motion. One declaration was prepared by Beth Brockner Ryan, the Chief of the Access Litigation and Freedom of Information Branch of FDA's

Center for Biologics Evaluation and Research ("CBER"). Declaration of Beth Brockner Ryan, June 3, 2003 ("Second Brockner Ryan Decl."), ¶ 1 (Mem. of P. & A. in Supp. of Def.'s Mot. for Summ. J. ("Def.'s Mem."), Ex. H). Her duties include supervising the employees who process and respond to requests made pursuant to FOIA for documents in the possession of CBER, which response includes reviewing the documents and redacting any information that is exempt from disclosure. Id. Ms. Brockner Ryan's declaration sets forth the bases for FDA's withholding documents responsive to Plaintiff's modified FOIA request. Id. ¶ 5.

The second declaration, by Dr. Joyce Frey-Vasconcells, the Acting Deputy Office Director for CBER's Office of Cellular, Tissues, and Gene Therapies, describes the confidential and deliberative information generated in the course of FDA's review of investigational new drug application ("IND") submissions. Declaration of Joyce Frey-Vasconcells, Mar. 26, 2002 ("Second Frey-Vasconcells Decl.") (Def.'s Mem., Ex. I).[5] As part of her current duties, Dr. Frey-Vasconcells oversees the review process for xenotransplantation INDs submitted to CBER. Id. ¶ 1. Dr. Frey-Vasconcells' declaration shows that FDA properly withheld the confidential commercial, trade secret, and deliberative process information generated during FDA's IND review process. Id. ¶¶ 6-8, 10-12.

As the declarations[6] and the third Vaughn index establish, and as set forth more fully below, FDA properly withheld certain documents and portions of documents from release. There

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[5] Until October 2002, Dr. Frey-Vasconcells was the Deputy Director of the Division of Cellular and Gene Therapies of CBER. Her duties for purposes of this litigation, however, remain the same.

[6] In addition to the two declarations described above, FDA submitted three of Defendant-Intervenors' previously filed declarations. See infra note 7.

is no contradictory evidence on the record or evidence of bad faith by FDA. Accordingly, summary judgment should be granted in favor of FDA.

A. FDA's Vaughn Index is Sufficient

On December 20, 2002, FDA provided Plaintiff with a New Sample Vaughn Index, containing a description of each document, the total number of pages in each document, the page number of each withholding, the authors' and recipients' names (if known), the date each document was created (if known), and the reason and legal authority for each withholding. The New Sample Vaughn Index was accompanied by a supporting declaration from Ms. Brockner Ryan that explained FDA's processing of Plaintiff's FOIA request and the Vaughn index, and set forth the detailed justifications for FDA's withholding documents or parts thereof. Decl. of Beth Brockner Ryan, Dec. 20, 2002, ¶ 4 (Def.'s Reply, Ex. C).

Neither the adequacy of FDA's search for responsive documents nor the adequacy of FDA's New Sample Vaughn Index are in dispute; rather the sole issue addressed in this Renewed Motion for Summary Judgment is whether FDA properly withheld the 16 documents and parts of documents that remain in contention. This Court has already ruled that FDA's search for responsive documents was adequate. Campaign for Responsible Transplantation v. FDA, 219 F. Supp. 2d 106, 111 (D.D.C. 2002) ("FDA has met its burden to demonstrate that it conducted a reasonable search to find all responsive documents"). Additionally, at the status hearing on October 16, 2002, this Court stated that it did "not expect that the parties will have to litigate the adequacy of a new Vaughn index and you may not do so without leave of the court." Tr. at 2, Pl.'s Mem., Ex. 16 (emphasis added). To date, Plaintiff has not requested leave of this Court, nor

has leave been granted to Plaintiff. Plaintiff, therefore, may not challenge the adequacy of FDA's New Sample Vaughn Index and Defendant is entitled to summary judgment on that issue.

B. FDA properly withheld information pursuant to Exemption 4

1. Exemption 4 of FOIA

Exemption 4 of FOIA protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). This exemption is intended to safeguard the interests of both the government and those submitting information to the government. Nat'l Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 767 (D.C. Cir. 1974). The exemption covers two categories of information in agency records: (1) trade secrets; and (2) information that is (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential. Id. at 766.

Information that relates to a business or trade is considered "commercial or financial." See Lepelletier v. FDIC, 977 F. Supp. 456, 459 (D.D.C. 1997) ("identities of business having unclaimed deposits" deemed "financial information"), aff'd in part, rev'd in part & remanded on other grounds, 164 F.3d 37 (D.C. Cir. 1999). Courts have held that the terms "commercial" and "financial" should be given their ordinary meanings. See, e.g., Judicial Watch, Inc. v. Export-Import Bank, 108 F. Supp. 2d 19, 28 (D.D.C. 2000) (citing Public Citizen, 704 F.2d at 1290; Washington Post Co. v. HHS, 690 F.2d 252, 266 (D.C. Cir. 1982)). If a submitter has a commercial interest in the information, it will be considered "commercial" for purposes of Exemption 4. Public Citizen, 704 F.2d at 1290.

The term "person" in Exemption 4 applies to a wide range of entities, including corporations, associations, and public or private organizations. See Judicial Watch, 108 F. Supp.

2d at 28; Allnet Communication Services, Inc. v. FCC, 800 F. Supp. 984, 988 (D.D.C. 1992), aff'd, No. 92-5351 (D.C. Cir. May 27, 1994). Information generated by the federal government is not "obtained from a person" and is thus excluded from Exemption 4. Allnet, 800 F. Supp. at 988. However, documents generated by the federal government that contain summaries or reformulations of information supplied by a source outside the government are protected by Exemption 4. See, e.g., Gulf & W. Indus., Inc. v. United States, 615 F.2d 527, 529-30 (D.C. Cir. 1979) (contractor information contained in agency audit report).

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, 498 F.2d at 770. These two tests apply when the submission of the information is "compelled" by the government. Critical Mass Energy Project v. NRC, 975 F.2d 871, 878 (D.C. Cir. 1992). In the instant matter, FDA regulations require sponsors to submit information, much of which is confidential, to FDA prior to commencing with a clinical trial of an investigational new drug; thus rendering their IND submissions "compelled" for purposes of FOIA. See 21 C.F.R. §§ 312.20-312.35. Under the second test outlined in National Parks, which is applicable in this case, 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, 108 F. Supp. 2d at 29 (quoting CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1152 (D.C. Cir. 1987)).

Consistent with Exemption 4 of FOIA, CBER regulations also protect the confidentiality of IND submissions. See 21 C.F.R. § 601.51; Second Brockner Ryan Decl. ¶ 8. Indeed, FDA

cannot even disclose the existence of an IND "before a biologics license application [BLA] has been approved unless it [the IND] has previously been publicly disclosed or acknowledged." 21 C.F.R. § 601.51(b). Further, no data or information contained in a CBER IND file is available for public disclosure "[i]f the existence of a biological product file has not been publicly disclosed or acknowledged," or if FDA has not approved a BLA. 21 C.F.R. §§ 601.51(c), (d)(1).

2. Documents withheld pursuant to Exemption 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. These documents are protected because they contain confidential commercial information. Second Brockner Ryan Decl. ¶ 9; see also 21 C.F.R. § 20.61. All INDs, including xenotransplantation INDs, contain confidential commercial information. Second Brockner Ryan Decl. ¶¶ 8, 9; Aff. of E. Michael Egan ("Egan Aff.") ¶¶ 17-22 (Ex. J); Decl. of John S. Logan ("Logan Decl.") ¶¶ 8, 9 (Ex. K); Decl. of Elizabeth Chen ("Chen Decl.") ¶ 5 (Ex. L).[7] Documents generated by FDA during the process of IND review include summaries or reformations of trade secret and confidential commercial information taken from the IND. Second Brockner Ryan Decl. ¶ 9; Egan Aff. ¶¶ 27-33; Logan Decl. ¶¶ 13, 14; Chen Decl. ¶ 10.

To date, FDA has not approved a BLA for any xenotransplantation product, including the product covered by IND "G." Second Brockner Ryan Decl. ¶ 10. Information from IND submissions that FDA recognizes as publicly released has already been produced to Plaintiff. Id. The information obtained from INDs that is contained in the documents that FDA continues to

[7] The Egan Affidavit, Logan Declaration, and Chen Declaration were originally filed as exhibits to Defendant-Intervenors' Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ("Int. Mem."), filed March 28, 2002.

withhold pursuant to Exemption 4 has not been disclosed to the public, and FDA regulations prohibit its release. Id. ¶¶ 8, 10. Disclosing such proprietary information would cause substantial competitive harm to a sponsor by giving a rival sponsor a competitive advantage. Id. ¶ 11; see also Int. Mem. at 15 ("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."); Egan Aff. ¶¶ 10-11, 17-22, 34-35; Logan Decl. ¶¶ 12, 14-16; Chen Decl. ¶¶ 11-13.

Documents 2280, 2762, 3476, 3585, and 3591 consist of charts, hand-written notes, and an e-mail, and the information FDA withheld from those five documents pursuant to Exemption 4, includes, but is not limited to, descriptions of sponsors' experiments, clinical trial details such as the number of patients enrolled and/or treated and the trial status, and the indications for which a product is being tested. Third Vaughn index at 3-6. As the government explained in its supporting declarations, disclosing such proprietary information would reveal confidential details about a sponsor's clinical trial that could be unfairly used by competitor sponsors to spend less money, time, and effort developing their own clinical trials. See Second Brockner Ryan Decl. ¶¶ 11-12; Int. Mem. at 15; 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 Summ. J. & Notice of Filing Decls., Exs. A & B); see also Public Citizen, 185 F.3d at 905-06 (finding affidavits with a similar level of detail to those FDA submitted in this case sufficient to support Exemption 4 withholdings); Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1291 (D.C. Cir. 1983).

If released, the withheld confidential commercial information could be utilized by other sponsors to the competitive disadvantage of the Defendant-Intervenors. Second Brockner Ryan Decl. ¶¶ 11-12; Egan Aff. ¶¶ 19, 21, 23, 29; Logan Decl. ¶¶ 9, 14; Chen Decl. ¶¶ 5, 11-13; see also Webb v. HHS, 696 F.2d 101, 103 (D.C. Cir. 1982) (discussing the competitive interest a drug manufacturer has in FDA maintaining the confidentiality of information submitted in conjunction with a new drug application ("NDA"), which is subject to a similar FDA review process as an IND: "If a manufacturer's competitor could obtain all the data in the manufacturer's NDA, it could utilize them [the data] in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently.").

Additionally, it has been established in this Circuit that the type of information contained in documents 2762, 3476, 3585, and 3591, namely side effects, adverse events, and certain testing/assays, is exempt from disclosure pursuant to Exemption 4. Public Citizen Health Research Group v. FDA, 539 F. Supp. 1320, 1327 (D.D.C. 1982), rev'd on other grounds, 704 F.2d 1280, 1291-92 (D.C. Cir. 1983). Both documents 2762 and 3476 consist of charts that contain detailed information concerning specific, albeit unnamed, sponsors, which is in sharp contrast to the general summaries deemed discloseable in Public Citizen.[8]

All of the documents and parts thereof still at issue that FDA withheld pursuant to Exemption 4 contain confidential commercial information. FDA, therefore, properly withheld, in whole or in part, the five documents listed in the third Vaughn index as exempt from disclosure pursuant to Exemption 4.

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[8] Documents 2762 and 3476 were both released in part to Plaintiff and were previously submitted as exhibits to this Court. Def.'s Reply, Ex. E.

C. FDA properly withheld information pursuant to Exemption 5

1. Exemption 5 of FOIA

Exemption 5 of FOIA 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). Courts have construed this language to exempt from release documents that would not ordinarily be available to an agency's opponent in civil discovery, and to incorporate all evidentiary privileges that would be available in that context. United States v. Weber Aircraft Corp., 465 U.S. 792, 799 (1984); Martin v. Office of Special Counsel, 819 F.2d 1181 (D.C. Cir. 1987).

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). The purpose of this privilege is to protect the "quality of agency decisions." Id. at 151. The privilege is intended to encourage open, frank discussions of policy matters between subordinates and supervisors, to protect against premature disclosure of proposed policies before they are finalized, and to protect against public confusion that could result from disclosing reasons and rationales that were not the ultimate grounds for the agency's action. Russell v. Dep't of the Air Force, 682 F.2d 1045, 1048 (D.C. Cir. 1982); Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980); Jordan v. Dep't of Justice, 591 F.2d 753, 772-73 (D.C. Cir. 1978) (en banc). The privilege protects "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, 617 F.2d at 866; see also Pies v. IRS, 668 F.2d 1350, 1353-54 (D.C. Cir. 1981) (holding draft proposed regulations and a draft transmittal memorandum exempt from disclosure

pursuant to Exemption 5). The deliberative process privilege also protects the process by which a "draft" document becomes a "final" document. See, e.g., Marzen v. HHS, 825 F.2d 1148, 1155 (7th Cir. 1987) ("[E]xemption protects not only the opinions, comments and recommendations in the draft, but also the process itself.").

The deliberative process privilege protects information that is both predecisional and deliberative. See Mapother v. Dep't of Justice, 3 F.3d 1533, 1537 (D.C. Cir. 1993). A document is predecisional if "it was generated before the adoption of an agency policy." Coastal States, 617 F.2d at 866. A document is deliberative if "it reflects the give-and-take of the consultative process." Id. The government has the burden of proving that the information in question satisfies both requirements. Id. at 868.

The existence of predecisional 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. DOJ, 238 F. Supp. 2d 284, 292 (D.D.C. 2003) (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 applies as 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 so 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. DOJ, 182 F. Supp. 2d 1, 7 (D.D.C. 2000).

2. Documents withheld pursuant to Exemption 5

FDA withheld all 16 documents, or parts thereof, that currently remain at issue pursuant to Exemption 5. FDA has relied on the deliberative process privilege incorporated within Exemption 5 for documents that are reviews of INDs, and that develop FDA policy on xenotransplantation-related issues, including screening methods and the feasibility of rationale for clinical holds. In conjunction with its Renewed Motion for Summary Judgment, FDA submitted the declaration of Dr. Joyce Frey-Vasconcells, which describes the sensitive and deliberative nature of the information generated in the course of FDA's review of IND submissions. Second Frey-Vasconcells Decl., Def.'s Mem., Ex. I.

In her declaration, Dr. Frey-Vasconcells explains that FDA's IND review process involves the exchange of documents and discussions between managers and reviewers; communications by e-mail, internal memoranda, teleconferences, and meetings among reviewers from different disciplines; and drafts and summaries prepared by reviewers for managers, all of which may concern either individual INDs or classes of INDs. Second Frey-Vasconcells Decl. ¶¶ 5-11. All of the documents generated during the IND review process are pre-decisional, because there is no "final" decision on an IND until a letter is sent to the sponsor: "After a decision is made by all of the managers regarding the scientific and safety issues raised by the IND, FDA's regulations and policies, and how to proceed with the clinical trial," a letter reflecting FDA's decision is sent to the sponsor. Id. at ¶ 9; see also Hamilton Sec. Group, 106 F. Supp. 2d at 29-31 (finding that documents created as part of a review process similar to FDA's review satisfied the first prong of the deliberative process privilege).

The following are representative examples of documents, or parts thereof, withheld pursuant to Exemption 5:

1) Document 201 is a two page, internal FDA memorandum concerning procedures potentially appropriate for use with xenotransplantation patients. 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. Id. These opinions were provided to the recipients in order to assist their decision-making on the issue. It is well-settled that documents containing agency employee recommendations that are part of the agency's decision-making process are protected by the deliberative process privilege. See, e.g., Dep't of the Interior & Bureau of Indian Affairs v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8-9 (2001) ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news."); NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975). Here, document 201 consists of internal advice from one FDA employee to her FDA colleagues as part of the give-and-take of FDA's decision-making process, rendering it exempt from disclosure pursuant to Exemption 5. See Wolfe v. HHS, 839 F.2d 768, 774 (D.C. Cir. 1988) ("advice and recommendations may be withheld [pursuant to Exemption 5]");

2) Document 1088 consists of an e-mail exchange between FDA employees. Third Vaughn index at 1. The e-mails discuss what, if any, long-term requirements FDA ought to impose on sponsors who withdraw INDs relating to xenotransplantation. Id. 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). And 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 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);

3) Document 1364 contains internal memoranda that discuss potential solutions to problems concerning PERV screening. Third Vaughn index at 2. Because the withheld portion of document 1364 involves the author employee's judgment in her contribution to FDA's attempt to resolve issues concerning PERV screening, it is exempt from disclosure under Exemption 5 and was properly withheld by FDA. See Klamath Water Users Protective Ass'n, 532 U.S. at 8-9 ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news").

Document 1364 also consists, 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. DOJ, 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;

4) Both documents 1863 and 2610 are comprised of internal e-mail discussions about the laws and/or regulations that may be applicable to xenotransplantation. Third Vaughn index at 2, 4. The e-mails express the authors' personal thoughts and opinions, rather than final agency policy. One of the purposes of the deliberative process privilege is to protect "subordinates' willingness to provide decision-makers with frank opinions and recommendations." Wolfe, 839 F.2d at 775. Documents that "discuss the wisdom or merits of a particular agency policy, or recommend new agency policy" are protected by the deliberative process privilege. Coastal States Gas Corp., 617 F.2d at 869. Requiring the disclosure of documents such as these e-mails would have a chilling effect on employees' willingness to express personal opinions and would force FDA to operate in the sort of "fishbowl" Congress aimed to avoid by enacting Exemption 5. See, e.g., Second Brockner Ryan Decl. ¶ 14; Wolfe, 839 F.2d at 775-76;

5) Document 3585 is a single page of hand-written notes. Third Vaughn index at 5. The notes describe a telephone conference between FDA employees and a sponsor regarding a clinical trial issue. Id. The notes represent the author employee's personal impressions and thoughts, and do not constitute a final agency position. Documents that contain personal opinions as opposed to final agency views are protected from disclosure by Exemption 5. Coastal States Gas Corp., 617 F.2d at 866. The disclosure of documents such as document 3585 would negatively impact the frank, open discussions within agencies that Exemption 5 was designed to protect. Wolfe, 839 F.2d at 775-76.

In sum, the deliberative process privilege contained in Exemption 5 is intended to encourage frank, open discussions of policy matters among agency employees. NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975). Draft documents, recommendations, and other documents containing authors' personal opinions, rather than those of the agency, are exempt from disclosure. Coastal States Gas Corp., 617 F.2d at 866. The IND review process entails the exchange of many opinions, recommendations, drafts, and other documents among FDA employees, prior to any final agency decision regarding the IND. Second Frey-Vasconcells Decl. ¶¶ 5-12. This exchange of information and opinions among FDA employees is critical to the IND review process, and the review process itself is characterized by its predecisional and deliberative nature. Id. ¶¶ 5-8. As explained above, all 16 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 documents or parts thereof are therefore exempt from disclosure and FDA properly withheld them pursuant to Exemption 5 of FOIA.

III. Conclusion

FDA has complied with its obligations in response to Plaintiff's FOIA request.[9] 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

[9] Plaintiff is not entitled to the disclosure of documents from any of the other responsive INDs because those INDs are to be processed in accordance with the Court's rulings on IND "G," all of which rulings have not yet been issued.

documents and parts thereof, and the 16 documents that remain at issue in this case are exempt from disclosure pursuant to FOIA Exemptions 4 and/or 5. Third Vaughn index.

For the reasons set forth above and in Defendant's previously submitted documents, Defendant's renewed motion for summary judgment should be granted.

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 SUPPLEMENTAL STATEMENT OF MATERIAL FACTS

Pursuant to Local Rule 7.1(h), Defendant United States Food and Drug Administration ("FDA") submits this supplemental statement of material facts as to which there is no genuine issue.

1. On December 20, 2002, pursuant to this Court's Order of September 3, 2002, FDA filed, and provided Plaintiff with, a New Sample Vaughn Index, divided into two segments: one entitled "FDA-Generated Documents Concerning Xenotransplantation Clinical Trials in General," consisting of fourteen (14) volumes, and the other entitled "FDA-Generated Documents in the IND 'G' File or Relating to IND 'G,'" consisting of four (4) volumes (hereinafter, collectively, the "New Sample Vaughn Index"). See Letter from Ambrose to All Parties' Counsel of 12/20/02 (Mem. of P. & A. in Supp. of Def.'s Mot. for Summ. J., Ex. A).

2. FDA's New Sample Vaughn Index lists, for each document, the document number, the page and paragraph range of information that was withheld, the total number of pages, a description, and an explanation and legal authority for each withholding. See, e.g., Third Abbreviated New Sample Vaughn Index ("third Vaughn index") (Ex. A).

3. The parties are in agreement that only 16 documents responsive to Plaintiff's modified FOIA request remain at issue in the instant matter. Those 16 documents, by document number, are: 201, 773, 1088, 1357, 1364, 1863, 1913, 2093, 2280, 2610, 2762, 3024, 3098, 3476, 3585, and 3591. Third Vaughn index.

4. Five documents, namely documents 2280, 2762, 3476, 3585, and 3591, were withheld, in part, pursuant to Exemption 4. Third Vaughn index.

5. All 16 documents, namely documents 201, 773, 1088, 1357, 1364, 1863, 1913, 2093, 2280, 2610, 2762, 3024, 3098, 3476, 3585, and 3591, were withheld, in full or in part, pursuant to Exemption 5. Third Vaughn index.

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Defendant's 3rd Abbreviated New Sample Vaughn Index

Including

FDA-Generated Documents Concerning Xenotransplantation Clinical Trials in General

and

FDA-Generated Documents Contained in the IND "G" File or Relating to IND "G"

Doc #	Description	Type	Pages Withheld	To:	From:	Date	Reasons For Withholding	Statutory Authority
201	General: Internal Memo re: Effects of Xenotransplantation in Humans. Comments by author are draft in nature.	2	pgs. 1-2: releasable with b(5) redactions	Amy Patterson, James Kaiser	Carolyn Wilson	09/10/97	DPP	5 USC 552(b)(5)
773	IND G: The document contains pharm / tox comments. The document contains questions to ask the sponsor to establish the validity and scientific merit of the toxicity study. The document also contains a description of a non-hold issue. CCI: IND number, name of the clinical study.	2	pgs. 1-2: b(5) with sponsor info b(4) throughout entire document	Unknown	Unknown	01/10/95	CCI, DPP	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)
1088	General: Internal Email re: Life long xenotransplantation requirements if sponsor withdraws from IND. Non-responsive sponsor name and IND number. (i.e. not a porcine or non-human primate xenotransplantation sponsor)	2	pgs. 1-2:releasable with b(5) and non-responsive redactions	Philip Noguchi	Thomas Eggerman	09/28/99	DPP, Non-responsive	5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons for Withholding	Statutory Authority
1357	IND G: Internal Memo re: Holds For Lack of Assays. The memo addresses a numbered regulation in relation to a clinical hold. The memo discusses a numbered regulation in relation to an assay.	1	pg. 1: releasable with b(5) redactions	Amy Patterson	Bette Goldman	06/10/97	DPP	5 USC 552(b)(5)
1364	General: Internal Memos from various sources and various dates re: draft comments on solutions to problems regarding PERV Screening and an interpretation of data on PERV	2	pgs. 1-2: releasable with b(5) redactions	Tina Moulton	Amy Patterson	10/16/97	DPP	5 USC 552(b)(5)
1863	General: Internal Email re: Revised Questionnaire for Council of Europe. Email discussion on what Regulations and Laws apply to xenotransplantation in order to answer a Council of Europe questionnaire.	2	pgs. 1-2:releasable with b(5) redactions	Joseph A. Foster	Eda Bloom	02/01/00	DPP	5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
1913	General: Memo re: detection of eperythrozoon. The memos provides comments on porcine eperythrozoon.	1	pg. 1: b(5)	Amy Patterson	Philip Snoy	04/10/95	DPP	5 USC 552(b)(5)
2093	General: Internal Memo that discusses steps to inactivate a virus.	1	pg. 1: releasable with b(5) redactions	Robin Biswas	Carolyn A. Wilson	04/07/95	DPP	5 USC 552(b)(5)
2280	General: Internal Memo contains a USDA contact for xenotransplantation issues. The memo discusses the importation of transgenic animals from the UK to set up breeding facilities. Memo discusses non-responsive sponsors and responsive sponsors. Non-responsive because the sponsor's IND is not responsive to the narrowed FOIA request. CCI: The memo contains the name of the sponsor and a brief description of experiments.	4	pgs. 1-4: non-responsive, b(4), and b(5).	Thomas Eggerman	Steven Bauer	05/14/97	Non-Responsive, DPP, CCI	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)

Doc #	Description	Total Pages	Pages Withheld	To:	From:	Date	Reasons For Withholding	Statutory Authority
2610	General: Internal email Exchange re: Laws applying to the use of animals in xenotransplantation. The non-responsive portions are non-FDA generated.	2	pgs. 1-2: releasable with b(5) and non-responsive redactions	Eda Bloom, R. Riseberg	Robert Lanman	01/28/00	DPP, Non-responsive	5 USC 552(b)(5)
2762	General: Internal Chart re: Xenotransplantation clinical trials. Chart contains non-responsive sponsors and responsive sponsor information, product and clinical indications, clinical trial statuses, outcomes, and comments Non-responsive because the sponsor's IND is not responsive to the narrowed FOIA request. CCI: names of sponsors; cells studied; diseases studied; clinical trial; IND numbers; number of patients; types of side effects; survival rates of patients	3	pgs. 1-3 releasable with b(4) and b(5) redactions	Unknown	Unknown	06/30/97	DPP, CCI	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)
3024	General: Document on a clinical trial re: Xenogeneic cells for implantation in patients	5	pgs. 1-5: b(5)	Unknown	Sponsor	Undated	DPP	5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
3098	IND G: Internal Email Exchange re: Species and strains for xeno database. The non-responsive pages discuss non-responsive sponsors. Non-responsive because the sponsor's IND is not responsive to the narrowed FOIA request. CCI: Non-IND G sponsor names	40 (originally stated as 15 pages)	pgs. 3-7: releasable with b(5) and non-responsive redactions; pgs. 1-2, 8-40: non-responsive	Thomas Eggerman, Austine Moulton	Phillip Snoy	02/23/00	Non-Responsive, DPP	5 USC 552(b)(5)
3476	General: CCI: The document contains a chart showing the IND number / sponsor, the product name, indications, status, patients enrolled / treated, adverse events attributed to xenotransport, and comments / review team.	4	pgs. 1-4: releasable with b(4) and b(5) redactions	Unknown	Unknown	Undated	CCI, DPP	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61, 5 USC 552(b)(5)
3585	IND G: handwritten notes of telecon between FDA and sponsor re: PERV CCI: PERV testing, sponsors' names, clinical trial	1	pg. 1: b(4) and b(5) throughout entire document	Unknown	Unknown	Undated	CCI, DPP	5 USC 552 (b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To	From	Date	Reasons For Withholding	Statutory Provision(s)
3591	General: Internal Email, re: Review of Sponsor Xenotransplantation Interim Regulatory Authority meeting (closed meeting) CCI: names of sponsors, PERV testing, cells used, PERT assay	3	pgs. 1-3: b(4) and b(5) throughout entire document	Philip Noguchi, Amy Patterson,	Carolyn Wilson	08/12/98	CCI, DPP	5 USC 552 (b)(4); 21 CFR 601.51; 21 CFR 20.6; 5 USC 552 (b)(5)