

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE
TRANSPLANTATION,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant.

CIRCE BIOMEDICAL, INC., et al.,

Defendant-Intervenors.

Civil Action No. 00-2849 (RMU)

**DEFENDANT'S REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND
IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

ROSCOE C. HOWARD, JR.,
United States Attorney.

MARK E. NAGLE,
BRIAN J. SONFIELD,
Assistant United States Attorneys.

OF COUNSEL:

DANIEL E. TROY,
Chief Counsel.

CANDACE K. AMBROSE,
Assistant Chief Counsel for Enforcement
United States Food and Drug Administration.

June 10, 2002

TABLE OF CONTENTS

INTRODUCTION	1
ARGUMENT.....	1
I. Defendant's Sample Vaughn Index and Declarations Provide Sufficient Justification for Nondisclosure.	1
II. FDA Has Lawfully Withheld Information Pursuant to Exemption 4	3
III. FDA Has Lawfully Withheld Information Pursuant to Exemption 5	6
IV. FDA Has Lawfully Withheld Information Pursuant to Exemption 6	8
V. FDA Has Released Reasonably Segregable Portions of the Documents	9
VI. FDA Conducted a Reasonable Search for Responsive Documents.	12
VII. FDA Has Lawfully Withheld Documents Containing Marginalia	17
VII. Discovery Is Not Appropriate in a FOIA Case	18
IX. Immediate Release of the Documents Is Not Appropriate	20
CONCLUSION	20

TABLE OF AUTHORITIES

FEDERAL CASES

<u>Ashley v. United States Dep't of Labor</u> , 589 F. Supp. 901 (D.D.C. 1983)	6
<u>Bay Area Lawyers Alliance for Nuclear Arms Control v. Dep't of State</u> , 818 F. Supp. 1291 (N.D. Cal. 1992)	16
<u>British Airports Auth. v. Civil Aeronautics Bd.</u> , 531 F. Supp. 408 (D.D.C. 1982)	17
<u>Bureau of Nat'l Affairs v. Dep't of Justice</u> , 742 F.2d 1484 (D.C. Cir. 1984)	18
<u>Campbell v. United States Dep't of Justice</u> , 164 F.3d 20 (D.C. Cir. 1998)	13, 20
<u>Carney v. United States Dep't of Justice</u> , 19 F.3d 807 (2d Cir. 1994)	17, 19
<u>Chamberlain v. United States Dep't of Justice</u> , 957 F. Supp. 292 (D.D.C.)	15
<u>Coastal States Gas Corp. v. Dep't of Energy</u> , 617 F.2d 854 (D.C. Cir. 1980)	6, 9
<u>Dep't of Justice v. Tax Analysts</u> , 492 U.S. 136 (1989)	17
<u>Exxon Corp. v. FTC</u> , 384 F. Supp. 755 (D.D.C. 1974)	18
<u>Forsham v. Harris</u> , 445 U.S. 169 (1980)	17
<u>Founding Church of Scientology v. Marshals Serv.</u> , 516 F. Supp. 151 (D.D.C. 1980)	19
<u>Gallant v. Nat'l Labor Relations Bd.</u> , 26 F.3d 168 (D.C. Cir. 1994)	17
<u>Goland v. CIA</u> , 607 F.2d 339 (D.C. Cir. 1978), <u>vacated in part, reh'g denied</u> , 607 F.2d 367 (D.C. Cir. 1979)	19
<u>Greene v. Dalton</u> , 164 F.3d 671 (D.C. Cir. 1999)	5
<u>Hunt v. United States Marine Corps</u> , 935 F. Supp. 46 (D.D.C. 1996)	19
<u>Jordan v. United States Dep't of Justice</u> , 591 F.2d 753 (D.C. Cir. 1978)	9
<u>Judicial Watch v. United States Dep't of Commerce</u> , 83 F. Supp. 2d 105 (D.D.C. 1999)	20
<u>Katzman v. Freeh</u> , 926 F. Supp. 316 (EDNY 1996)	18
<u>Kowalczyk v. Dep't of Justice</u> , 73 F.3d 386 (D.C. Cir. 1996)	13
<u>Marks v. Dep't of Justice</u> , 578 F.2d 261 (9th Cir. 1978)	13
<u>Maynard v. CIA</u> , 986 F.2d 547 (1st Cir. 1993)	15
<u>Mead Data Cent., Inc. v. United States Dep't of the Air Force</u> , 566 F.2d 242 (D.C. Cir. 1977)	1

<u>Meeropol v. Meese</u> , 790 F.2d 942 (D.C. Cir. 1986)	12, 15
<u>Military Audit Project v. Casey</u> , 656 F.2d 724 (D.C. Cir. 1981)	19
<u>NLRB v. Sears, Roebuck & Co.</u> , 421 U.S. 132 (1975)	6
<u>NTEU v. Customs</u> , 802 F.2d 525 (D.C. Cir. 1986)	1
<u>Nat'l Magazine v. United States Customs Serv.</u> , 71 F.3d 885 (D.C. Cir. 1995)	12
<u>Oglesby v. United States Dep't of the Army</u> , 920 F.2d 57 (D.C. Cir. 1990)	12, 15
<u>Public Citizen Health Research Group v. FDA</u> , 997 F. Supp. 56 (D.D.C. 1998), 185 F.3d 898 (D.C. Cir. 1999)	18
<u>Russell v. Dep't of the Air Force</u> , 682 F.2d 1045 (D.C. Cir. 1982)	9
<u>SafeCard Servs. v. SEC</u> , 926 F.2d 1197 (D.C. Cir. 1991)	19
<u>Schaffer v. Kissinger</u> , 505 F.2d 389 (D.C. Cir. 1974)	18
<u>Schell v. HHS</u> , 843 F.2d 933 (6th Cir. 1988)	6
<u>Steinberg v. United States Dep't of Justice</u> , 23 F.3d 548 (D.C. Cir. 1994)	12, 16
<u>Valencia-Lucena v. United States Coast Guard</u> , 180 F.3d 321 (D.C. Cir. 1999)	13
<u>Vaughn v. Rosen</u> , 484 F.2d 820 (D.C. Cir. 1973), <u>cert. denied</u> , 415 U.S. 977 (1974)	Passim
<u>Weisberg v. Dep't of Justice</u> , 627 F.2d 365 (D.C. Cir. 1980)	18

FEDERAL REGULATIONS

21 C.F.R. § 601.51	4
--------------------------	---

INTRODUCTION

Defendant, the United States Food and Drug Administration ("FDA"), through its undersigned counsel, respectfully submits this reply memorandum of points and authorities in support of its motion for summary judgment. FDA has released to Plaintiff all reasonably segregable, non-exempt information in response to Plaintiff's request under the Freedom of Information Act ("FOIA"). FDA is lawfully withholding the remainder of the responsive information pursuant to Exemptions 4, 5, and 6 of the FOIA.

ARGUMENT

I. Defendant's Sample Vaughn Index and Declarations Provide Sufficient Justification for Nondisclosure.

Defendant's Sample Vaughn Index and the declarations are more than sufficient "to permit adequate adversary testing of the agency's claimed right to an exemption." See Def.'s Mem. in Opp'n to Pl.'s Mot. for Summ. J. and in Supp. of Def.'s Cross-Mot. for Summ. J. ("Def.'s Mem.") at 14, quoting NTEU v. Customs, 802 F.2d 525, 527 (D.C. Cir. 1986), citing Mead Data Cent., Inc. v. United States Dep't of the Air Force, 566 F.2d 242, 252 (D.C. Cir. 1977), and Vaughn v. Rosen, 484 F.2d 820, 828 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974). As addressed in FDA's motion for summary judgment, the Sample Vaughn Index provided to Plaintiff describes each document and correlates the pages and paragraphs of the information withheld with the appropriate FOIA exemptions. See Def.'s Mem. at 15, 17. The declaration submitted with the Sample Vaughn Index provides the legal basis for withholding the documents therein. Id. at 15; see also Second Declaration of Lesia M. Banks ("Second Banks Decl."), Aug. 30, 2001, Attachment, Notice of Filing, Aug. 30, 2001. FDA also prepared supplemental

declarations of Lesia Banks and Joyce Frey-Vasconcells which elaborate on the applicability of Exemptions 4, 5, and 6 of the FOIA to the information withheld. See Fourth Declaration of Lesia M. Banks ("Fourth Banks Decl."), Mar. 27, 2002, and Second Declaration of Joyce Frey-Vasconcells ("Second Frey-Vasconcells Decl."), Mar. 26, 2002, Attachments, Def.'s Mem. FDA's supplemental declarations make clear that the specific documents raised by Plaintiff, as well as the other documents listed in the Sample Vaughn Index, are exempt from disclosure under the FOIA. See Def.'s Mem. at 23; see also Fourth Banks Decl. ¶ 31.

Plaintiff asserts that FDA is required to disclose the names of the authors and recipients of the documents. See Pl.'s Reply at 8-9. The names of the authors and recipients of the documents have been provided to plaintiff where the documents were produced in redacted form; they simply do not appear on the Sample Vaughn Index. See, e.g., Exhibit O (some examples of redacted documents where the names of the authors and recipients of the documents were provided). Of course, such information was also provided to Plaintiff in connection with the documents that were released in their entirety. It is only in regard to the documents that were withheld in their entirety that the names of the authors and recipients of the documents have not been provided. As previously explained in FDA's motion for summary judgment, it is not necessary to put these names in the Sample Vaughn Index to demonstrate that these documents were properly withheld. The descriptions of the documents and declarations are adequate enough to demonstrate that the documents listed in the Sample Vaughn Index are being properly withheld pursuant to the FOIA. See Def.'s Mem. at 18-19.

There are tens of thousands of documents at issue in this case. Revising the Sample Vaughn Index is totally unnecessary and would require a tremendous amount of time and

resources. Plaintiff has refused FDA's numerous attempts to propose reasonable ways to narrow Plaintiff's request.¹ Plaintiff's FOIA request is still extremely broad despite Plaintiff's narrowing of it. Because Plaintiff's FOIA request is so broad, revising the Sample Vaughn Index would impose an unreasonable burden on FDA.

II. FDA has Lawfully Withheld Information Pursuant to Exemption 4.

The documents in the Sample Vaughn Index for which FDA has asserted Exemption 4 are protected because they contain trade secret and/or confidential commercial information. See Def.'s Mem. at 27. Plaintiff complains that FDA has not made clear whether the information being withheld pursuant to Exemption 4 is "trade secret" or "confidential commercial information." See Pl.'s Reply at 10. However, FDA justifiably has not differentiated between whether the information is trade secret or confidential commercial information. See Fifth Declaration of Lesia M. Banks ("Fifth Banks Decl.") ¶ 4, June 10, 2002, Attachment. Distinguishing between trade secret and confidential commercial information would have required a more detailed analysis than was conducted when FDA created the Sample Vaughn Index. Id. If FDA had to distinguish between trade secret and confidential commercial information it would have taken FDA much longer to produce the Sample Vaughn Index. Id. This would not have been time well spent considering that both trade secret and confidential commercial information are protected from disclosure under Exemption 4. Id. Both types of information are contained in the documents that are being withheld under Exemption 4. Id.

¹ Plaintiff appears to now focus on documents pertaining to FDA's 1997 decision to place all porcine xenotransplantation clinical trials on hold. See 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. ("Pl.'s Reply") at 12. If this was the focus of Plaintiff's request, Plaintiff should have originally made this request, rather than taxing FDA's resources with an enormously broad FOIA request.

As pointed out in FDA's motion for summary judgment, the Center for Biologics Evaluation and Research ("CBER") regulations protect the confidentiality of investigational new drug application ("IND") submissions. See Def.'s Mem. at 27; see also 21 C.F.R. § 601.51; Fifth Banks Decl. ¶ 4. Xenotransplantation INDs contain both trade secret and confidential commercial information. See Fifth Banks Decl. ¶ 4; Affidavit of E. Michael Egan ("Egan Aff.") ¶¶ 17-22, Mar. 28, 2002, Exhibit A, Def. Intervenor's Mem. in Opp'n to Pl.'s Mot. for Summ. J. ("Int. Mem."); Declaration of John S. Logan ("Logan Decl.") ¶¶ 8, 9, Mar. 28, 2002, Exhibit B, Int. Mem.; Declaration of Elizabeth Chen ("Chen Decl.") ¶ 5, Mar. 29, 2002, Exhibit C, Int. Mem. Documents generated by FDA during the process of reviewing INDs necessarily include summaries or reformulations of the trade secret and confidential commercial information taken from the sponsor's IND so that issues concerning the IND can be addressed. See Def.'s Mem. at 29; see also Fifth Banks Decl. ¶ 4; Egan Aff. ¶¶ 27-33; Logan Decl. ¶¶ 13, 14; Chen Decl. ¶ 10. Disclosing such proprietary information would cause substantial competitive harm to a sponsor by giving a rival sponsor a competitive advantage. See 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."); see also Egan Aff. ¶¶ 17-22, 34-35; Logan Decl. ¶¶ 12, 14-16; Chen Decl. ¶¶ 11-13. Therefore, the trade secret and confidential commercial information in the documents is being properly withheld from disclosure.

Plaintiff asserts that Exemption 4 does not apply because the sponsors have disclosed much of the withheld information to the public. See Pl.'s Reply at 10-12. But CBER has

released to Plaintiff all of the information that CBER is aware has been publicly released. See Def.'s Mem. at 20. Although sponsors have disclosed to the public information about xenotransplantation and the clinical trials, sponsors have not disclosed the specific types of information being withheld under Exemption 4. See Egan Aff. ¶ 24 ([Sponsors have] "made conscientious, required public disclosures to [their] shareholders and to the public regarding xenotransplantation and [their] clinical trials. But [they have] carefully limited these disclosures, and . . . do[] not customarily release detailed information of the type contained in [their] IND submissions."). Additionally, sponsors enter into confidentiality agreements with their employees and other individuals involved with their xenotransplantation products barring disclosure of trade secret and confidential commercial information. See Egan Aff. ¶ 23; Logan Decl. ¶ 10; Chen Decl. ¶ 8. In short, FDA has released all information that it believes to have been publicly disclosed by the sponsors. Plaintiff's conclusory assertion to the contrary is insufficient to defeat FDA's motion for summary judgment. See Greene v. Dalton, 164 F.3d 671, 675 (D.C. Cir. 1999).

Plaintiff complains that FDA has withheld in its entirety under Exemption 4 a "form letter" concerning FDA's decision to place all porcine xenotransplantation clinical trials on hold. See Pl.'s Reply at 12. But FDA has released the "form letter" to Plaintiff. See Fifth Banks Decl. ¶ 5. The only information concerning the "form letter" that FDA has withheld under Exemption 4 is the IND number, the IND title, the sponsor's name, and the sponsor's address. Id. Plaintiff has received the substantive contents of the "form letter;" its release is a moot issue.

Plaintiff also suggests that documents may have been withheld from disclosure under Exemption 4 because they were "publicly embarrassing" to a company. See Pl.'s Reply at 13.

Plaintiff's suggestion is wholly unsupported by the facts of this case. There is nothing in the record that even remotely suggests that FDA has withheld information under Exemption 4 because it may be "publicly embarrassing" to a company. The only information that FDA has withheld under Exemption 4 is trade secret and confidential commercial information.²

III. FDA has Lawfully Withheld Information Pursuant to Exemption 5.

FDA has lawfully withheld documents under the deliberative process privilege of Exemption 5. The deliberative process privilege applies if the document was predecisional – "generated before the adoption of an agency policy" – and deliberative – "reflects the give-and-take of the consultative process." See Def.'s Mem. at 30, quoting Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980). The privilege "applies as long as the document is generated as part of a continuing process of agency decisionmaking." Def.'s Mem. at 31; see also Ashley v. United States Dep't of Labor, 589 F. Supp. 901, 908-09 (D.D.C. 1983).

Plaintiff argues that FDA has not identified any "discrete agency policy decision" or single "'guidance,' rule,' or policy'" to which the documents protected under Exemption 5 apply. See Pl.'s Reply at 14-15. Plaintiff's argument is without merit. First, the applicability of the deliberative process privilege document does not depend on whether the agency can identify a specific policy decision regarding the document that was prepared. See NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 n. 18 (1975); see also Schell v. HHS, 843 F.2d 933, 941 (6th Cir.

² Plaintiff asserts that FDA did not rely on the intervenors' declarations to support the withholding of documents pursuant to Exemption 4. See Pl.'s Reply to Def.-Intervenors' Mem. in Opp'n to Pl.'s Mot. for Summ. J. at 1. At the time FDA filed its motion for summary judgment, FDA did not have a copy of the intervenors' declarations. Further, FDA did not know that Diacrin would reveal that IND"G" concerns Diacrin until FDA received the Affidavit of E. Michael Egan.

1988). Second, FDA has listed numerous documents in the Sample Vaughn Index concerning xenotransplantation in general that identify a "guidance, rule, or policy."

Many of the documents that reflect FDA's "guidances, rules, or policies" are listed in the Sample Vaughn Index as draft documents. Draft documents based on the opinions of the writers are clearly protected by the deliberative process privilege. See Def.'s Mem. at 30 ("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.'" (quoting Coastal States, 617 F.2d at 866 (emphasis added))). For example, document number 72 is listed in the Sample Vaughn Index as a draft proposed rule on public disclosure of gene therapy and xenotransplantation clinical trials. Document number 830 is listed in the Sample Vaughn Index as a document about FDA xenotransplantation policy development and xenotransplantation preclinical/clinical issues. Document number 1550 is listed in the Sample Vaughn Index as a draft PHS ("Public Health Service") guideline on infectious disease issues in xenotransplantation. Document number 3262 is listed in the Sample Vaughn Index as a draft guidance for industry regarding public health issues posed by the use of non-human primate xenografts in humans. These documents, as well as other documents listed in the Sample Vaughn Index for which Exemption 5 has been asserted, clearly relate to FDA decisionmaking. Accordingly, these documents are properly being withheld from disclosure under the deliberative process privilege.

Plaintiff incorrectly argues that FDA may have waived its privilege regarding Exemption 5 because certain documents have been "shared with the sponsors of INDs." See Pl.'s Reply at 16. The documents for which Exemption 5 has been asserted are all internal documents that are

protected from disclosure under the deliberative process privilege. Thus, these documents have not been shared with the sponsors or with any other person who is not an employee of FDA. See Egan Aff. ¶ 28 ("[The sponsors are] not allowed to read the documents that are generated by the FDA . . . The FDA keeps its deliberations secret from the IND Sponsor, and secret from everyone else."). As noted in FDA's motion for summary judgment, IND reviewers and managers exchange documents with each other to address various issues concerning a specific xenotransplantation IND and xenotransplantation in general. See Def.'s Mem. at 20-22. The documents for which the deliberative process privilege of Exemption 5 has been asserted are all internal documents and are being appropriately withheld.

IV. FDA has Lawfully Withheld Information Pursuant to Exemption 6.

Plaintiff has pointed to some documents in the Sample Vaughn Index for which it believes Exemption 6 does not apply. See Pl.'s Reply at 17. Upon review, FDA acknowledges that Exemption 6 was inadvertently applied to the following documents: 1218, 2054, and 3288. See Fifth Banks Decl. ¶ 6. However, these mistakes are inconsequential because these documents are protected from disclosure in their entirety under Exemption 4 or 5. Id. Document numbers 1218 and 2052 are protected from disclosure in their entirety under the deliberative process privilege of Exemption 5. Document number 3288 is protected from disclosure in its entirety under Exemption 4. Id. FDA has determined that document number 746 should not have been listed in the Sample Vaughn Index because it concerns an IND other than IND"G." Id.

Information being withheld pursuant to Exemption 6 should be a moot issue. Plaintiff has made clear that it is not interested in the names of patients participating in the xenotransplantation clinical trials or any information that identifies the patients. See Pl.'s Mem.

in Supp. of Mot. for Summ. J. at 39. FDA has properly withheld such information pursuant to Exemption 6. See Def.'s Mem. at 34.

V. FDA has Released Reasonably Segregable Portions of the Documents.

Plaintiff asserts that FDA has not disclosed all segregable, nonexempt information. See Pl.'s Reply at 18. FDA has disclosed all reasonably segregable, non-exempt information to Plaintiff. See Def.'s Mem. at 38.

Plaintiff argues that FDA could have disclosed more information concerning the documents withheld under Exemption 5. But, FDA has disclosed to Plaintiff all of the information that is releasable under Exemption 5; the remaining information consists entirely of information protected under the deliberative process privilege. The documents for which the deliberative process privilege has been asserted reflect the opinions of their authors and the development of FDA policy concerning xenotransplantation. See Def.'s Mem. at 31; see also Fourth Banks Decl. ¶¶ 15, 16; Second Frey-Vasconcells Decl. ¶¶ 7, 8. Many of these documents are in draft form, as discussed above. It would be inappropriate and bad policy for FDA to release information that reflects FDA's internal deliberations. "The policy underlying this privilege is to encourage open, frank discussions of policy matters between subordinates and supervisors, to protect against premature disclosure of proposed policies before they become final, and to protect against public confusion by disclosing reasons and rationales that were not in fact 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, 617 F.2d at 866; Jordan v. United States Dep't of Justice, 591 F.2d 753, 772-73 (D.C. Cir. 1978) (en banc). Disclosing these documents would

hinder frank discussions regarding policy matters among FDA personnel. See Def.'s Mem. at 32; see also Fourth Banks Decl. ¶ 17.

Plaintiff argues that FDA has not segregated out and released the names of the authors and recipients of the documents. See Pl.'s Reply at 18. Plaintiff is not correct; as discussed above, the names were included in the documents released to Plaintiff. With regard to documents that were released in part, FDA segregated the names of the authors and recipients and released the names to Plaintiff. The names of the authors and recipients of the documents were also obviously included in the documents that were released in their entirety.³

Plaintiff also complains that FDA has failed to "correlate claimed exemptions with particular passages." See Pl.'s Reply at 19. Again, Plaintiff is incorrect. The majority of the entries within the Sample Vaughn Index provided to Plaintiff correlate a specific exemption with the particular page and/or paragraph being redacted or withheld. See Fifth Banks Decl. ¶ 7; see, e.g., document numbers 128, 465, 926, 927, 991, 1104, 1171, 1342, and 3508. In a few of the documents listed in the Sample Vaughn Index, the exemptions were not correlated to particular pages and paragraphs because multiple exemptions were inextricably intertwined with each other in one document. See Fifth Banks Decl. ¶ 7; see, e.g., document numbers 1482 and 1501.

In these documents, the entire document is protected from disclosure under one FOIA exemption. Id. These documents also contain a vast amount of information that is interspersed throughout the document that is protected from disclosure under another FOIA exemption. Id.

³ The final category of documents are those withheld in their entirety. With respect to those documents it would be ridiculous and unduly burdensome to release the names of the authors and recipients of those documents because the documents would be blank documents with nothing but the names of FDA personnel on them. This information could not possibly be useful to Plaintiff.

To correlate the exempted information with specific exemptions, FDA would have had to list the majority of the words, sentences, or paragraphs in those documents. Id. This would have been a useless task since the document is protected in its entirety under another exemption. Id.

For example, Plaintiff references document numbers 1482 and 1501 in the Sample Vaughn Index. See Pl.'s Reply at 19. Document number 1482 is exempt from disclosure in its entirety under Exemption 5. See Fifth Banks Decl. ¶ 8. It is a draft memorandum of an interview involving a clinical trial that is protected by the deliberative process privilege of Exemption 5. Id. Document 1482 also contains information that is protected from disclosure under Exemption 4. Id. The types of trade secret and/or confidential commercial information in this document are the sponsor's name, the IND number, the title of the IND, the disease being studied, the data derived from the assay, the number of patients in the clinical study, and the length of the clinical study. Id. This information appears throughout this entire document. Id. Accordingly, to correlate the Exemption 4 information in this document, FDA would have had to list most of the paragraphs on every page of this document. Id.

Similarly, document number 1501 is protected in its entirety under the deliberative process privilege of Exemption 5 because it is a draft memorandum of an interview concerning a clinical trial. Id. Document number 1501 also contains information that is exempt from disclosure under Exemption 4. Id. The types of trade secret and/or confidential commercial information contained in this document include the number of the IND, the location of the clinical trial, the disease being studied, the names of the treating physicians, and the number of patients in the clinical study. Id. This information is interspersed throughout the entire

document. Id. To correlate the Exemption 4 information in this document, FDA would have had to list most of the paragraphs on every page of this document. Id.

In short, there is no more information that could reasonably be segregated out and provided to Plaintiff. Id. FDA has disclosed to Plaintiff all reasonably segregable information that is not exempt from disclosure under Exemptions 4, 5, and 6 of the FOIA.

VI. FDA Conducted a Reasonable Search for Responsive Documents.

Plaintiff continues to assert that FDA has not conducted an adequate search for responsive records. See Pl.'s Reply at 20-23. FDA has made a good faith effort to search for all documents responsive to Plaintiff's FOIA request. See Fifth Banks Decl. ¶ 9.

To demonstrate that an adequate search was conducted, the agency "must show that it made a good faith effort to conduct a search for the requested records, using methods which can be reasonably expected to produce the information requested." Oglesby v. United States Dep't of the Army, 920 F.2d 57, 68 (D.C. Cir. 1990). The fundamental question is whether the search for responsive documents was adequate, not whether any other responsive documents may possibly exist. See Steinberg v. United States Dep't of Justice, 23 F.3d 548, 551 (D.C. Cir. 1994) (quoting Weisberg v. United States Dep't of Justice, 745 F.2d 1476, 1485 (D.C. Cir. 1984)); Nat'l Magazine v. United States Customs Serv., 71 F.3d 885, 892 n.7 (D.C. Cir. 1995) ("there is no requirement that an agency [locate] all responsive documents"); Meeropol v. Meese, 790 F.2d 942, 952-53 (D.C. Cir. 1986) ("[A] search is not unreasonable simply because it fails to produce all relevant material; no search of this [large] size . . . will be free from error.").

CBER is comprised of nine offices within which are a total of twenty-one divisions. CBER's divisions are responsible for regulating various biological products. See Fifth Banks

Decl. ¶ 10. Xenotransplantation products are classified by FDA as biological products and are, thus, regulated by CBER. Id. CBER personnel are responsible for reviewing most xenotransplantation INDs and clinical trials.⁴ Id. Because Plaintiff's FOIA request concerned clinical trials involving xenotransplantation, CBER was the most logical place to search for responsive documents. Id. All twenty-one of CBER's divisions were instructed to search for documents potentially responsive to Plaintiff's FOIA request. Id. FDA received responsive documents from five of CBER's divisions.⁵ Id.

The FOIA does not require that an agency search every division or field office in response to a FOIA request when responsive documents are likely to be located in one place. Marks v. Dep't of Justice, 578 F.2d 261, 263 (9th Cir. 1978). "When a request does not specify the locations in which an agency should search, the agency has discretion to confine its inquiry to a central filing system if additional searches are unlikely to produce any marginal return; in other words, the agency generally need not 'search every record system.'" Campbell v. United States Dep't of Justice, 164 F.3d 20, 28 (D.C. Cir. 1998) (quoting Oglesby, 920 F.2d at 68). "The agency is not required to speculate about potential leads" to the location of responsive documents, Kowalczyk v. Dep't of Justice, 73 F.3d 386, 389 (D.C. Cir. 1996), although it is required "to follow through on obvious leads to discover requested documents." Valencia-Lucena v. United States Coast Guard, 180 F.3d 321, 325 (D.C. Cir. 1999).

⁴ The Center for Devices and Radiological Health regulates a small number of non-porcine and non-human primate xenotransplantation INDs and clinical trials that are no longer responsive to Plaintiff's FOIA request.

⁵ CBER also received responsive documents from the Scientific Advisory Committee Staff, which advises FDA on issues concerning xenotransplantation. See Fourth Banks Decl. ¶ 5.

The case law above indicates that FDA could have limited its search to CBER. Plaintiff nevertheless argues that the Office of the Commissioner, Office of the Chief Counsel ("OCC"), Office of Regulatory Affairs ("ORA"), or "some other office" should have been included in FDA's search for responsive records. See Pl.'s Reply at 22. The Office of the Commissioner was included in the search for responsive documents. See Fifth Banks Decl. ¶ 11. The Ombudsman's Office, which is a component of the Commissioner's Office, determines what center should regulate a particular product. Id. The Ombudsman's Office did not locate any documents responsive to Plaintiff's request. Id. OCC, which is also a component of the Commissioner's Office, was not included in the search for responsive documents because OCC has no role in reviewing xenotransplantation clinical trials. Id. ORA advises FDA's Commissioner on enforcement and compliance matters, usually involving FDA inspections. Id. ORA is not usually included in a search for documents involving INDs. Id. ORA is not likely to have documents concerning INDs because the sites where the clinical trials are conducted are not typically inspected unless the Center regulating the product requests an inspection of the site of the clinical trial. Id. None of the INDs concerning Plaintiff's FOIA request were inspected. Id. Therefore, ORA is unlikely to have any responsive documents. Id. Furthermore, Plaintiff's FOIA request did not specify a particular office within FDA to be searched. Id. Since Plaintiff did not name a particular office in its FOIA request, FDA searched for responsive documents in the most reasonable places. Id.

The first time CBER became aware that Plaintiff was specifically interested in documents pertaining to FDA's decision to place all porcine xenotransplantation clinical trials on hold, the resumption of the trials, the development of assays, and adverse events in connection with the

trials was when Plaintiff filed its motion for summary judgment. Id. ¶ 12. Although many of such documents had already been located and included in the Sample Vaughn Index, CBER, in good faith, conducted another search for responsive documents that focused primarily on such information. Id. In so doing, CBER discovered fifty-five more documents to add to the thousands of other documents previously indexed or released. Id. Some of these documents were released in their entirety, and others were released with information redacted pursuant to Exemptions 4 and 5 of FOIA. Id.

Courts have accepted an agency's subsequent discovery of additional documents as evidence of the agency's good-faith efforts. See Maynard v. CIA, 986 F.2d 547, 565 (1st Cir. 1993); Meeropol, 790 F.2d at 953. Without clear evidence of bad faith, the veracity of the government's submissions in this case should not be questioned. "It is well established that '[a]gency affidavits enjoy a presumption of good faith that withstand[s] purely speculative claims about the existence and discoverability of other documents.'" Chamberlain v. United States Dep't of Justice, 957 F. Supp. 292, 294 (D.D.C.) (quoting Albuquerque Publ'g Co. v. United States Dep't of Justice, 726 F. Supp. 851, 860 (D.D.C. 1989)). The sufficiency of an agency's search is not put in question by a requester's claim that a piece of information might exist. "Hypothetical assertions are insufficient to raise a material question of fact with respect to the adequacy of the agency's search." Oglesby, 920 F.2d at 67 n.13. The presumption of an adequate search can only be rebutted by showing evidence of bad faith. Maynard, 986 F.2d at 560 (citing Miller v. United States Dep't of State, 779 F.2d 1378, 1383 (8th Cir. 1985); Carney v. United States Dep't of Justice, 19 F.3d 807, 812 (2d Cir. 1994); Chamberlain v. United States Dep't of Justice, 957 F. Supp. 292, 294 (D.D.C. 1997)).

Plaintiff contends that FDA has not conducted an adequate search for documents because there are only ten documents listed in the Sample Vaughn Index concerning "adverse events." See Pl.'s Reply at 23. Plaintiff is mistaken. See Fifth Banks Decl. ¶ 13. The Sample Vaughn Index provided to Plaintiff in August 2001 lists additional documents concerning adverse events in connection with the clinical trials, as well as FDA's decision to place all porcine xenotransplantation clinical trials on hold, the resumption of the trials, and the development of assays. Id. The particular documents noted in FDA's motion for summary judgment were specific examples of such documents from the Sample Vaughn Index. Id. Those documents were not an exhaustive list. Id.

In short, FDA's declarations adequately demonstrate that FDA, in good faith, has searched every record system that could contain the records sought by Plaintiff, and that FDA has turned over all responsive records. Plaintiff's speculation that additional documents may exist is not sufficient to rebut the assertions in the Banks declarations that all responsive documents have been produced. See Steinberg v. United States Dep't of Justice, 23 F.3d 548, 552 (D.C. Cir. 1994) ("Mere speculation that as yet uncovered documents may exist does not undermine the finding that the agency conducted a reasonable search for them."); see also Bay Area Lawyers Alliance for Nuclear Arms Control v. Dep't of State, 818 F. Supp. 1291, 1295 (N.D. Cal. 1992) ("Plaintiff's incredulity at the fact that no responsive documents were uncovered . . . does not constitute evidence of unreasonableness or bad faith."). Because FDA has demonstrated that it made a good faith effort to conduct a reasonable search using reasonable methods, its search was more than adequate under the applicable case law.

VII. FDA has Lawfully Withheld Documents Containing Marginalia.

Plaintiff wrongly insists that the personal, handwritten notes in margins of documents submitted by IND sponsors are agency records. See Pl.'s Reply at 23-24. In so doing, Plaintiff relies on Dep't of Justice v. Tax Analysts, 492 U.S. 136 (1989). Id. The Court in Tax Analysts does not address the issue presented in this case: whether personal, handwritten notes constitute agency records. Even assuming arguendo that Tax Analysts is on point, this case states that an "agency record" exists only if an agency "either create[s] or obtain[s]" the materials and is "in control" of them. Tax Analysts, 492 U.S. at 144-45. Here, the personal "notes are kept in the author's own personal files until they are discarded when review of an IND is complete." Def.'s Mem. at 36-37 (emphasis added); see also Fourth Banks Decl. ¶ 19. Accordingly, the notes are not within the FDA's control and are, therefore, not agency records.

Plaintiff also asserts that the notes "fall squarely within the Tax Analysts definition" because they were created "in the course of reviewing the INDs." See Pl.'s Reply at 24. But the mere fact that a record relates to the agency's business does not make the record an "agency record." See Def.'s Mem. at 36; see also Gallant v. Nat'l Labor Relations Bd., 26 F.3d 168, 172 n.2 (D.C. Cir. 1994). Tax Analysts did not overrule Kissinger and Forsham which held that "personal materials" are not agency records. See Tax Analysts, 492 U.S. at 145 (citing Kissinger v. Reporters Comm. for Freedom of the Press, 445 U.S. 136, 157 (1980) ("[T]he term "agency records" is not so broad as to include personal materials in an employee's possession")); see also Forsham v. Harris, 445 U.S. 169 (1980).

As addressed in FDA's motion for summary judgment, British Airports is the case most on point. See British Airports Auth. v. Civil Aeronautics Bd., 531 F. Supp. 408 (D.D.C. 1982);

see also Def.'s Mem. at 35. This case held that under the FOIA personal, handwritten notes do not constitute agency records, and therefore, are not subject to disclosure. Id. This holding is consistent with that of the Court of Appeals in the Bureau of Nat'l Affairs case. See Bureau of Nat'l Affairs v. Dep't of Justice, 742 F.2d 1484 (D.C. Cir. 1984). Both British Airports and Bureau of Nat'l Affairs are still good case law.

In short, the personal notes written by FDA employees in the margins of the sponsors' documents were intended solely for the convenience of the writer of the note. See Def.'s Mem. at 37; see also Fourth Banks Decl. ¶ 19. The notes were not intended to be circulated to other FDA employees. Id. Thus, the notes are not agency records subject to disclosure under the FOIA and are being properly withheld by FDA.⁶

VIII. Discovery is Not Appropriate in a FOIA case.

Plaintiff repeatedly asserts that it needs to "take discovery" regarding the information being withheld by FDA. See Pl.'s Reply. at 9, 14, 17, 18, 20, 23, 24, and 25. Discovery, however, is extremely restricted in FOIA actions. See 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); Katzman v. Freeh, 926 F. Supp. 316, 319 (EDNY 1996). Although discovery is sometimes permitted with respect to the scope of an agency's search, its indexing and classification procedures, and similar factual matters, see Weisberg v. Dep't of Justice, 627 F.2d 365, 371 (D.C. Cir. 1980); Schaffer v. Kissinger, 505 F.2d 389, 391 (D.C. Cir. 1974); Exxon Corp. v. FTC, 384 F. Supp. 755, 760

⁶ Even if the personal notes were agency records, the notes would not be subject to disclosure under Exemptions 4 and 5 of the FOIA. See Def.'s Mem. at 37; see also Fourth Banks Decl. ¶ 20.

(D.D.C. 1974), the government must first be permitted to submit its dispositive motion and supporting affidavits and have an opportunity to rebut allegations that its affidavits are insufficient. Military Audit Project v. Casey, 656 F.2d 724, 750 (D.C. Cir. 1981); Founding Church of Scientology v. Marshals Serv., 516 F. Supp. 151, 156 (D.D.C. 1980). Discovery is only permissible if the plaintiff raises sufficient questions concerning the agency's good faith in its processing or search. See, e.g., Carney, 19 F.3d at 812. Discovery should be denied altogether if the Court is satisfied from the agency's affidavits that no factual disputes remain. Goland v. CIA, 607 F.2d 339, 352 (D.C. Cir. 1978), vacated in part, reh'g denied, 607 F.2d 367 (D.C. Cir. 1979). Discovery should also be denied when the affidavits are sufficiently detailed and submitted in good faith. See SafeCard Servs. v. SEC, 926 F.2d 1197, 1200-02 (D.C. Cir. 1991); Military Audit Project, 656 F.2d at 751; Hunt v. United States Marine Corps, 935 F. Supp. 46, 50 (D.D.C. 1996).

There are tens of thousands of responsive documents at issue in this case. The FDA has made a good faith effort to comply with its obligations under the FOIA; there is no evidence to the contrary. In response to the plaintiff's FOIA request, FDA has produced to Plaintiff thousands of pages of responsive documents. FDA has provided Plaintiff with a Sample Vaughn Index that lists 2,583 documents concerning xenotransplantation clinical trial in general and 639 documents from the IND"G" file. FDA has also provided Plaintiff with two addenda to the Sample Vaughn Index, as well as several declarations that describe in detail the information that is exempt from disclosure.

In light of FDA's good faith effort, the Vaughn indices, and the supporting declarations, discovery is not appropriate and should be denied. If this Court is not satisfied that FDA,

through its enormous effort, has met its burden under the FOIA, this Court should order FDA to provide additional declarations, not discovery. See, e.g., Judicial Watch v. United States Dep't of Commerce, 83 F. Supp. 2d 105, 111 (D.D.C. 1999); Campbell, 164 F.2d at 31.

IX. Immediate Release of the Documents is Not Appropriate.

Finally, Plaintiff asserts that if this Court determines that the FDA has not sufficiently justified its withholdings, then the documents at issue should be immediately released. See Pl.'s Reply Mem. at 25. Immediate release of the documents is not appropriate. Again, there are tens of thousands of documents at issue here. Much of the information at issue is confidential commercial information in which the intervening defendants have important interests. See Int. Mem. at 12-16. Plaintiff has not demonstrated any sort of urgency or bad faith on the part of the FDA that would require this Court to deviate from normal practices and order immediate release of the documents. FDA has made a good faith effort to comply with its obligations under the FOIA. There is no evidence on the record to the contrary.⁷ If this Court is not satisfied that FDA is properly withholding information pursuant to Exemptions 4, 5, and 6 of FOIA, this Court should order FDA to provide additional declarations. See, e.g., Judicial Watch, 83 F. Supp. 2d at 111; Campbell, 164 F.2d at 31.

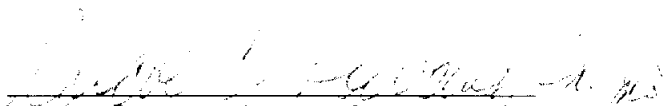
CONCLUSION

As demonstrated above, FDA has conducted a reasonable search for documents responsive to Plaintiff's FOIA request. FDA has produced to Plaintiff all reasonably segregable

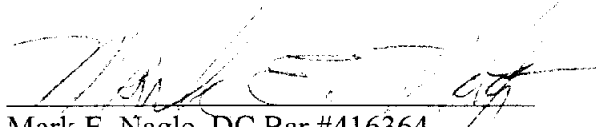
⁷ If any bad faith exists, it is on the part of Plaintiff. As pointed out in FDA's motion for summary judgment, Plaintiff has unreasonably rejected FDA's attempts to resolve this case more expeditiously by failing to further narrow the scope of its FOIA request. See Def.'s Mem. at 3-5.

portions of documents that are not exempt from disclosure under the FOIA. FDA has also released thousands of pages of documents in their entirety. FDA has provided Plaintiff with a Sample Vaughn Index that, together with the declarations, adequately describes the information being withheld pursuant to Exemptions 4, 5, and 6 of the FOIA. Accordingly, FDA's motion for summary judgment should be granted.

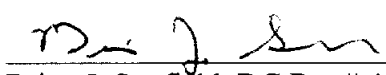
Respectfully submitted,



Roscoe C. Howard, Jr., DC Bar #246470
United States Attorney



Mark E. Nagle, DC Bar #416364
Assistant United States Attorney



Brian J. Sonfield, DC Bar # 449098
Assistant United States Attorney
Judiciary Center Building
555 4th Street, NW
Washington, D.C. 20530
202-514-7143

OF COUNSEL:

Daniel E. Troy
Chief Counsel

Candace K. Ambrose
Assistant Chief Counsel for Enforcement
United States Food and Drug Administration
5600 Fishers Lane, Room 6-71
Rockville, MD 20857
301-827-3099

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE)
TRANSPLANTATION,)

Plaintiff,)

v.)

UNITED STATES FOOD AND DRUG)
ADMINISTRATION,)

Defendant.)

CIRCE BIOMEDICAL, INC., et al.,)

Defendant-Intervenors.)

Civil Action No. 00-2849 (RMU)

FIFTH DECLARATION OF LESIA M. BANKS

I, LESIA M. BANKS, hereby declare as follows:

1. I am the Chief of the Access Litigation and Freedom of Information Branch (ALFOI) of the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) located in Rockville, Maryland. My duties include supervising the branch that processes and responds to requests made pursuant to the Freedom of Information Act (FOIA) for documents in the possession of CBER. In my first declaration in this case, dated June 12, 2001, I explained in detail my experience in handling FOIA matters and ALFOI's role in processing and responding to FOIA requests submitted to CBER. See Declaration of Lesia M. Banks, June 12, 2001 (hereinafter "Banks Decl."), Exhibit G, Def.'s Mem. in Opp'n to Pl.'s Mot. Requesting a Vaughn Index and in Supp. of Def.'s Cross-Mot. for a Sample Vaughn Index. In my second declaration, dated August 30, 2001, I explained the types of FDA-generated documents contained in the Sample Vaughn Index sent to Plaintiff on August 30, 2001, and the

justifications for withholding certain types of documents listed therein. See Second Declaration of Lesia M. Banks, Aug. 30, 2001 (hereinafter "Second Banks Decl."), Attachment, Notice of Filing, Aug. 30, 2001. In my third declaration, dated March 13, 2002, I explained the additional types of FDA-generated documents contained in the second addendum to the Sample Vaughn Index sent to Plaintiff on March 15, 2002, and the justifications for withholding those documents in whole or in part. See Third Declaration of Lesia M. Banks, Mar. 13, 2002 (hereinafter "Third Banks Decl."), Attachment, Notice of Filing, Mar. 15, 2002. In my fourth declaration, dated March 27, 2002, I described the search conducted by CBER which resulted in the responsive documents listed in the Sample Vaughn Index, explained the method used for describing the documents listed therein, and discussed the withholding of certain classes of documents listed in the Sample Vaughn Index. See Fourth Declaration of Lesia M. Banks, Mar. 27, 2002 (hereinafter "Fourth Banks Decl."), Attachment, Def.'s Mem. in Opp'n to Pl.'s Mot. for Summ. J. and in Supp. of Def.'s Cross-Mot. for Summ. J. (hereinafter "Def.'s Mem."), Mar. 29, 2002.

2. The statements made in this declaration are based upon my personal knowledge, upon information made known to me in my official capacity, and upon information available to me in my official capacity and about which I have become knowledgeable.

3. I submit this declaration in support of Defendant's Reply in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Defendant's Cross-Motion for Summary Judgment. The purpose of this declaration is to further discuss the withholding of information listed in the Sample Vaughn Index and describe the search conducted by FDA which resulted in the responsive documents listed in the Sample Vaughn Index.

EXEMPTION 4

4. I have reviewed Plaintiff's Reply Memorandum in Support of Plaintiff's Motion for Summary Judgment and In Opposition to the Government's Cross-Motion for Summary Judgment ("Pl.'s Reply"). Plaintiff complains that FDA has not made clear whether the information being withheld pursuant to Exemption 4 is "trade secret" or "confidential commercial information." See Pl.'s Reply at 10. However, FDA justifiably has not differentiated between whether the information is trade secret or confidential commercial information. Distinguishing between trade secret and confidential commercial information would have required a more detailed analysis than was conducted when CBER created the Sample Vaughn Index. If ALFOI had to distinguish between trade secret and confidential commercial information it would have taken ALFOI much longer to produce the Sample Vaughn Index. This would not have been time well spent considering that both trade secret and confidential commercial information are protected from disclosure under Exemption 4. Both types of information are contained in the documents that are being withheld under Exemption 4. CBER regulations protect the confidentiality of investigational new drug applications ("INDs") submissions. See 21 C.F.R. § 601.51. Documents generated by FDA during the process of reviewing INDs necessarily include summaries or reformations of the trade secret and confidential commercial information taken from the sponsor's IND so that issues concerning the IND can be addressed. See Fourth Banks Decl. ¶ 12. Disclosing such proprietary information could cause substantial competitive harm to a sponsor by giving a rival sponsor a competitive advantage. Id.

5. Plaintiff complains that FDA has withheld in its entirety under Exemption 4 a "form letter" concerning FDA's decision to place all porcine xenotransplantation clinical trials on hold. See Pl.'s Reply at 12. But FDA has released the "form letter" to Plaintiff. The only information concerning the "form letter" that FDA has withheld under Exemption 4 is the IND number, the IND title, the sponsor's name, and the sponsor's address.

EXEMPTION 6

6. Plaintiff has pointed to some documents in the Sample Vaughn Index to which it believes Exemption 6 does not apply. See Pl.'s Reply at 17. Upon review, ALFOI acknowledges that Exemption 6 was inadvertently applied to the following documents: 1218, 2054, and 3288. However, these mistakes are inconsequential because these documents are protected from disclosure in their entirety under Exemption 4 or 5. Document numbers 1218 and 2052 are protected from disclosure in their entirety under the deliberative process privilege of Exemption 5, and document number 3288 is protected from disclosure in its entirety under Exemption 4. ALFOI has also determined that document number 746 should not have been listed in the Sample Vaughn Index because it concerns an IND other than IND"G."

SEGREGABILITY

7. Plaintiff asserts that FDA has not segregated out and correlated exemptions within particular documents. See Pl.'s Reply at 19. The majority of the entries within the Sample Vaughn Index provided to Plaintiff correlate the exempted information with the particular page and/or paragraph in each document. See, e.g., Document numbers 128, 465, 926, 927, 991, 1104, 1171, 1342, and 3508. In a few of the documents listed in the Sample Vaughn Index, the information exempt from disclosure was not correlated to particular pages and paragraphs

because multiple exemptions were inextricably intertwined with each other in one document. See, e.g., 1482 and 1501. In these documents, the entire document is protected from disclosure under one FOIA exemption. These documents also contain a vast amount of information that is interspersed throughout the document that is protected from disclosure under another FOIA exemption. To correlate the exempted information, ALFOI would have had to correlate the majority of the words, sentences, or paragraphs in those documents. This would have been a useless task since the document is protected in its entirety under another exemption.

8. Plaintiff references document numbers 1482 and 1501 in the Sample Vaughn Index. See Pl.'s Reply at 19. Document number 1482 is exempt from disclosure in its entirety under Exemption 5. It is a draft memorandum of an interview involving a clinical trial that is protected by the deliberative process privilege of Exemption 5. Document 1482 also contains information throughout the entire document that is protected from disclosure under Exemption 4. The types of trade secret and/or confidential commercial information in this document are the sponsor's name, the IND number, the title of the IND, the disease being studied, the data derived from the assay, the number of patients in the clinical study, and the length of the clinical study. This information appears throughout this document. To correlate the Exemption 4 information in this document, ALFOI would have had to list most of the paragraphs on every page of this document. Document number 1501 is also protected under the deliberative process privilege of Exemption 5 because it is a draft memorandum of an interview concerning a clinical trial. Document number 1501 also contains information that is exempt from disclosure under Exemption 4 interspersed throughout the entire document. The types of trade secret and/or confidential commercial information contained in this document include the number of the IND,

the location of the clinical trial, the disease being studied, the names of the treating physicians, and the number of patients in the clinical study. To correlate the Exemption 4 information in this document, ALFOI would have had to list most of the paragraphs on every page of this document. There is no more information concerning the documents listed in the Sample Vaughn Index that could reasonably be segregated out and provided to Plaintiff.

ADEQUACY OF SEARCH

9. Plaintiff continues to assert that FDA has not conducted an adequate search for responsive records. See Pl.'s Reply at 20-23. FDA has made a good faith effort to search for all documents responsive to Plaintiff's FOIA request.

10. CBER is comprised of nine offices, within which are a total of twenty-one divisions. CBER's divisions are responsible for regulating various biological products. See Fourth Banks Decl. at ¶ 5. Xenotransplantation products are classified by FDA as biological products and are, thus, regulated by CBER. CBER personnel are responsible for reviewing most xenotransplantation INDs and clinical trials.¹ Because Plaintiff's FOIA request concerned clinical trials involving xenotransplantation, CBER was the most logical place to search for responsive documents. All twenty-one of CBER's divisions were instructed to search for documents potentially responsive to Plaintiff's FOIA request. Id. ALFOI received responsive documents from five of CBER's divisions.² Id.

¹ The Center for Devices and Radiological Health regulates a small number of non-porcine, non-primate xenotransplantation clinical trials that are no longer responsive to Plaintiff's FOIA request.

² CBER also received responsive documents from the Scientific Advisory Committee Staff, which advises FDA on issues concerning xenotransplantation. See Fourth Banks Decl. ¶ 5.

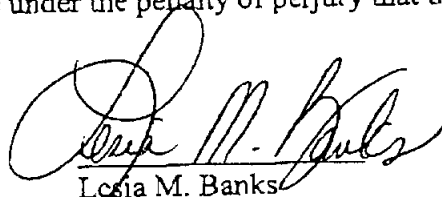
11. Plaintiff argues that the Office of the Commissioner, Office of the Chief Counsel ("OCC"), Office of Regulatory Affairs ("ORA"), or "some other office" should have been included in FDA's search for responsive records. See Pl.'s Reply at 22. The Office of the Commissioner was included in the search for responsive documents. The Ombudsman's Office, which is a component of the Commissioner's Office, determines what center should regulate a particular product. The Ombudsman's Office did not locate any documents responsive to Plaintiff's request. OCC, which is also a component of the Commissioner's Office, was not included in the search for responsive documents because OCC has no role in reviewing xenotransplantation clinical trials. ORA advises FDA's Commissioner on enforcement and compliance matters, usually involving FDA inspections. ORA is not usually included in a search for documents involving INDs. ORA is not likely to have documents concerning INDs because the sites where the clinical trials are conducted are not typically inspected unless the Center regulating the product requests an inspection of the site of the clinical trial. None of the INDs concerning Plaintiff's FOIA request were inspected; therefore, ORA is unlikely to have any responsive documents. Furthermore, Plaintiff's FOIA request did not specify a particular office within FDA to be searched. Since Plaintiff did not name a particular office in its FOIA request, FDA searched for responsive documents in the most reasonable places.

12. The first time CBER became aware that Plaintiff was specifically interested in documents pertaining to FDA's decision to place all porcine xenotransplantation clinical trials on hold, the resumption of the trials; the development of assays, and adverse events in connection with the trials was when Plaintiff filed its motion for summary judgment. Although many of such documents had already been located and included in the Sample Vaughn Index, CBER, in

good faith, conducted another search for responsive documents that focused primarily on such information. See Fourth Banks Decl. at ¶¶ 7-8. In so doing, CBER discovered fifty-five more documents to add to the thousands of other documents previously indexed or released. Id. at ¶ 8. Some of these documents were released in their entirety, and others were released with information redacted pursuant to Exemptions 4 and 5 of FOIA. Id.

13. Plaintiff contends that FDA has not conducted an adequate search for documents because there are only ten documents listed in the Sample Vaughn Index concerning "adverse events." See Pl.'s Reply at 23. Plaintiff is mistaken. The Sample Vaughn Index provided to Plaintiff in August 2001 lists additional documents concerning adverse events in connection with the clinical trials, as well as FDA's decision to place all porcine xenotransplantation clinical trials on hold, the resumption of the trials, and the development of assays. The particular documents noted in my previous declaration were specific examples of such documents from the Sample Vaughn Index. Those documents were not an exhaustive list. FDA has conducted a reasonable search for documents responsive to Plaintiff's FOIA request.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.



Lesia M. Banks
Chief, Access Litigation and Freedom of
Information Branch, CBER

Executed on June 10, 2002

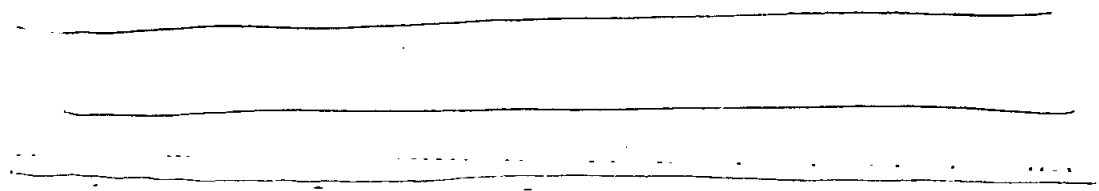
EXHIBIT O

Minutes of the Xenograft IND Reviewer Focus Group meeting March 17, 1999

Attendees: Darin Weber, Cynthia Rask, Malcolm Moos, Ellis Unger, Estella Jones, Jeanne Delasko, Dina Stolman, Donald Find, Kamela Evans-Davis, Steve Bauer, Phil Snoy, Carolyn Wilson, David Essayan, Eda Bloom
Estella Jones and Kamela Evans-Davis have joined Phil Snoy's group.

Agenda Items:

- 1) IND update



Action Items:

- 1) Check Xeno Guidance to Industry for the use of imported animals
- 2) List of 'agents to be considered' - rabbit, monkey, pigs, cows and mice - bacteria, viruses and fungus

2) Xeno Action Plan update

Guidance for Industry – current draft has been circulated to working group for review. Working group will meet in April.

Proposed Rule on Public Disclosure – work in progress. Draft document is being reviewed by working group

Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts – sent out for clearance.

National Xenotransplantation Database – Surveillance Officers are completing pilot evaluation questionnaires. Phase II will begin in April.

Xenotransplantation Advisory Subcommittee Meeting – has been expanded to two days (June 3 & 4) to include discussions on clinical indications, levels of risk, current definition and other issues.

Next meeting of the Xenograft IND Reviewer Focus Group is May 5, 1999. Dr. Purcell/NIH will give a presentation on Porcine Hepatitis E at 1:30 in conference room 29A-1A09.

Brammer, Sandy

#969

From: Falter, Steven
Sent: Monday, August 30, 1999 9:52 AM
To: Bloom, Eda
Subject: RE: petition response

I'll look more closely in a bit but I would think we need to identify the docket number since the petition was filed under that docket and the petitioner gets a letter asking that they identify any future correspondence with "CP[DOCKET NUMBER]" I see no problem with the administrative responsibility being placed with FDA as long as the sign-off is at a higher level. This follows the mechanism used to issue the guidance and the up-coming guidance, i.e., FDA does the dirty work and DHHS signs it.

Brammer, Sandy

970

From: Falter, Steven
Sent: Monday, August 30, 1999 10:17 AM
To: Bloom, Eda
Subject: RE: petition response

As I recall the petition was specifically sent to FDA for administrative handling so I don't think any one else has it logged in. We have the most formal mechanism ofr handling such things so it is usual that we get stuck with it.

-----Original Message-----

From: Bloom, Eda
Sent: Monday, August 30, 1999 9:44 AM
To: Falter, Steven
Subject: RE: petition response

Fine by me. It was a question raised by one of those OTHER agencies (three guesses which). Should we also find out if it was filed in public dockets by other agencies or DHHS too?? I somehow doubt it, but you never know.

-----Original Message-----

From: Falter, Steven
Sent: Monday, August 30, 1999 9:52 AM
To: Bloom, Eda
Subject: RE: petition response

I'll look more closely in a bit but I would think we need to identify the docket number since the petition was filed under that docket and the petitioner gets a letter asking that they identify any future correspondence with "CP [DOCKET NUMBER]" I see no problem with the administrative responsibility being placed with FDA as long as the sign-off is at a higher level. This follows the mechanism used to issue the guidance and the up-coming guidance, i.e., FDA does the dirty work and DHHS signs it.

Date: 22-May-1997 05:46pm EST
From: Dr. Amy P. Patterson, M.D.
PATTERSONA
Dept: HFM-518 N29B 2NN12
Tel No: 301-827-0706 FAX 301-827-0449

1149

TO: See Below

Subject: porcine ERU protocol

1. A copy of the _____ protocol for porcine ERU testing by PCR has been placed in your mailbox for your review.

- Please review this protocol with an eye toward framing questions/points to consider that could be presented later this year at an advisory committee meeting on xenograft recipient monitoring: Optimizing diagnostic tools and informed consent.

- ALSO:

For those of you attending the _____ meeting on clinical issues May 29, this assay system will be discussed; data from patient samples will be presented. I am drafting a set of questions for the sponsor so if you have any thoughts on this protocol please e-mail by 5/27.

2. Please provide names and/OR areas of expertise for individuals to be considered for membership on the newly formed Xenotransplantation Subcommittee. This subcommittee will advise the agency, as the BRMAC does. In addition, some of its members will also sit on the NATIONAL Xenotransplantation Advisory Committee. Do not worry about numbers of people - names as many people as you think would add value at this point.

Distribution:

TO: Dr. Thomas L. Eggerman, M.D., Ph.D. (EGGERMAN)
TO: Carolyn A. Wilson, Ph.D. (WILSONC)
TO: Parris Burd, Ph.D. (BURD)
TO: Steven Russell Bauer, Ph.D. (BAUER)
TO: Eda Bloom, Ph.D. (BLOOM)
TO: John G. Bishop, Ph.D. (BISHOPJ)



February 2, 1996

Ms. Mary Pendergast, Esq.
FDA

COPY

Dear Ms. Pendergast,

Please find attached several documents that map the developmental process of the PHS Guideline on Xenotransplantation. Included for your reference are the following attachments:

- (1.) The initial memo and attachment from Dr. Phil Lee, Assistant Secretary of Health, DHHS requesting information from federal agencies regarding the infectious disease issues in xenotransplantation and the memo from Walt Osborne re-iterating this request.
- (2.) A timeline delineating the major milestones of our agency's role in developing a consensus regarding the public health issues inherent in xenotransplantation.
- (3.) The agenda and list of participants in the Public Health Service and Transplant Community initial "mini panel" convened January 18, 1995 to discuss the public health issues raised by xenotransplantation and possible means of addressing these issues.
- (4.) Text of FDA talk given to the National Academy of Sciences Institute of Medicine Steering Committee requesting that they: (a) include an additional day for the discussion of the science base and infectious disease implications of xenotransplantation at their planned workshop meeting on "Xenotransplantation: Ethics and Public Policy;" and (b) make the meeting open to public. [Representatives from the CDC and NIH were present for the talk and supported this proposal.]
- (5.) The committee accepted our proposal, made the meeting open to the public and began their agenda with the panel discussions of infectious disease and immunology issues as the foundation for the subsequent development of a full and balanced discussion of the risks and social concerns in xenotransplantation. The agenda and list of participant at this meeting is included.

(6.) Statement of tasks at hand and agenda for FDA Xenotransplantation working groups.

(7.) Briefing material, agenda, and participant list for the April 11-12 th, 1995 meeting of the Biologic Response Modifier Advisory Committee (BRMAC) meeting on xenotransplantation. Also included are the slides presented by the FDA and the CDC.

(8.) Agenda and list of participants at the "Federal Day" meeting. This was a meeting of all participants or their designees who participated in drafting the PHS Guideline on Xenotransplantation. The purpose of this meeting was to review the current draft of the guideline and discuss cross-agencies perspectives on unresolved issues. A secondary purpose was to highlight as a group the major features of the guideline for presentation at the up-coming BRMAC meeting in July, 1995.

(9.) Agenda, list of committee members and participants, and the slides presented at the July Meeting of BRMAC at which the DRAFT PHS "Considerations" on Xenotransplantation were presented for discussion and questions were posed for the committee.

(10.) Publication/Reprint of The New England Journal of Medicine article entitled "Xenotransplantation and Xenogeneic Infections" and co-authored by members of the FDA and CDC working groups. (*NEJM* 333 (22) 1498-1501,1995).

(11.) List of the CDC officials who have formally cleared the present draft of the PHS Guideline and the list of FDA staff to whom the document has been sent for final clearance. Dr. J. Siegel, Dr. K. Zoon, and Dr. P. Noguchi (FDA/CBER) cleared the document to enter FDA clearance review process. The NIH Director, Dr. Harold Varmus has read and concurred with an earlier version of the document and asked the directors of the various NIH institutes to individually review the draft. I have incorporated the majority of these suggestions in the current version which has cleared the CDC and is in clearance at FDA. The NIH Division of Science Policy Analysis and Development (Dr. Lana Skirboll and Dr. Sarah Carr) have been most helpful and are facilitating the signing of final clearance forms. When we have the penultimate final draft I would like to pass that back to NIH and CDC for final sign-off.

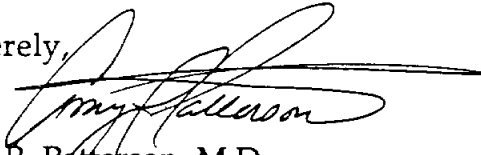
(13.) A table that lists the current clinical trials in xenotransplantation that are under FDA review. Some of these trials are actively underway with preliminary reports of marked success while others have either just been initiated or are in the "pre-IND" phase.

(14.) A sample of articles from Science and Nature and Nature Medicine as well as the lay press regarding xenotransplantation, the inherent controversies, and some commentary on the FDA as well. Also included is the FDA Talk Paper prepared for our press officers (Ms. Lenore Gelb and staff).

(15.) Copy of the clearance DRAFT PHS Guideline on Infectious Disease Issues in Xenotransplantation. I have also included for your reference a copy of the DRAFT Appendix A and the DRAFT list of references which are intended for publication in the final guideline.

Your interest in this topic is greatly appreciated and if you need any further information please let me know. Also, your thoughts regarding the meeting on February 14 th would be most helpful, as I would like to be prepared with any other information you may require at that time.

Sincerely,



Amy P. Patterson, M.D.

Staff Fellow
FDA/CBER/OTRR/DCGT and DCTDA
Building 29B, Room 2NN112
NIH Campus, HFM-530

Tel (301) 827 - 0706
FAX (301) 827 - 0449

CC: Dr. Phil Noguchi
CC: Dr. Dana Delman
CC: Dr. John Bishop
CC: Dr. Thomas Eggerman
CC: Dr. Jay Siegel

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Reply Memorandum was served, by first-class mail, postage pre-paid, this 15th day of June 2002, on the following:

Amy R. Atwood
Jonathan Russell Lovvorn
Meyer & Glitzenstein
1601 Connecticut Avenue, NW Suite 700
Washington, DC 20009

Richard Merrill
Bruce Kuhlik
Jalena Specht
Covington & Burling
1201 Pennsylvania Avenue NW
Washington, D.C. 20004-2401

Robert A. Dormer
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 200
Washington, D.C. 20005

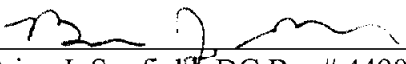
Robert M. Buchanan, Jr.
Choate, Hall & Stewart
53 State Street
Exchange Place
Boston, Massachusetts 02109

Craig A. Hoover
Jeffrey D. Pariser
555 13th Street N.W.
Washington, D.C. 20004

Roger W. Louis
Genzyme Corporation
1 Kendall Square
Building 1400
Cambridge, Massachusetts 02139

and

John M. Engel, III
Fox Kiser
750 17th Street, NW, Suite 1100
Washington, D.C. 20006



Brian J. Sonfield, DC Bar # 449098
Assistant United States Attorney
Judiciary Center Building
555 4th Street, NW
Washington, D.C. 20530
202-514-7143