

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

U.S. DISTRICT COURT
DISTRICT OF COLUMBIA
MAY -3 PM 9:17

CAMPAIGN FOR
RESPONSIBLE TRANSPLANTATION,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant,

CIRCE BIOMEDICAL, INC., et al.,

Defendant-Intervenors.

NANCY M.
MAYER-WHITTINGTON
CLERK

Civ. No. 00-2849 (RMU)

**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**

Amy R. Atwood
(D.C. Bar No. 470258)
Katherine A. Meyer
(D.C. Bar No. 244301)
Jonathan R. Lovvorn
(D.C. Bar No. 461163)

Meyer & Glitzenstein
1601 Connecticut Avenue NW
Suite 700
Washington, D.C. 20009
(202) 588-5206
Attorneys for Plaintiff

May 8, 2002

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	2
ARGUMENT	6
I. THE FDA’S LATEST DECLARATIONS FURTHER DEMONSTRATE THAT THE AGENCY HAS FAILED TO MEET ITS BURDEN OF PROOF	6
A. The FDA’s Latest Declarations Demonstrate That Its <u>Vaughn</u> Index Does Not Adequately Describe The Contents Of Withheld Records	6
B. FDA’s Declarations Demonstrate Its Exemption Claims Are Unjustified	9
1. FDA Has Not Justified Its Contention That Thousands Of Records May Be Withheld Under Exemption 4	9
2. Defendant Has Not Refuted Plaintiff’s Arguments That The Agency Has Failed To Justify The Applicability Of Exemption 5	14
3. Defendant Has Failed To Prove That Any Responsive Records Are Exempt From Disclosure Under Exemption 6	17
C. The FDA’s Latest Declarations Demonstrate That The Agency Has Not Complied With Its Duty To Disclose All Segregable, Nonexempt Information	18
D. The Agency Has Failed To Prove That It Has Conducted An Adequate Search For All Responsive Records	20
II. THE AGENCY’S LATEST DECLARATIONS DEMONSTRATE THAT RECORDS IT IS WITHHOLDING ARE “AGENCY RECORDS	23
III. PLAINTIFF IS ENTITLED TO IMMEDIATE RELIEF	25
CONCLUSION	26

TABLE OF AUTHORITIES

FEDERAL CASES

<u>Anderson v. DHHS</u> , 907 F.2d 936 (10th Cir. 1990)	11
<u>Animal Legal Defense Fund v. Department of the Air Force</u> , 44 F. Supp. 2d 295 (D.D.C. 1999), quoting <u>Coastal States v. DOE</u> , 617 F.2d 854 (D.C. Cir. 1980)	8-9
<u>Animal Legal Defense Fund v. Department of the Air Force</u> , 44 F. Supp. 2d 295 (D.D.C. 1999)	9, 10
<u>Armstrong v. Executive Office of the President</u> , 97 F.3d 575 (D.C. Cir. 1996)	19
<u>Bureau of National Affairs v. Department of Justice</u> , 742 F.2d 1484 (D.C. Cir. 1984)	24
<u>CNA Financial Corp. v. Donovan</u> , 830 F.2d 1132 (D.C. Cir. 1987)	13
<u>Center for Automobile Safety v. NHTSA</u> , 244 F.3d 144 (D.C. Cir. 2001)	11
<u>Coastal States v. DOE</u> , 617 F.2d 854 (D.C. Cir. 1980)	9
<u>Department of Justice v. Tax Analysts</u> , 492 U.S. 136 (1989)	23
<u>EPA v. Mink</u> , 410 U.S. 73 (1973)	15
<u>Getman v. NLRB</u> , 450 F.2d 670 (D.C. Cir. 1974)	11
<u>Goland v. CIA</u> , 607 F.2d 339 (D.C. Cir. 1978)	22
<u>Jackson v. Finnegan, Henderson, Farabow, Garrett & Dunnder</u> , 101 F.3d 145 (D.C. Cir. 1996)	11
<u>Kimberlin v. DOJ</u> , 139 F.3d 944 (D.C. Cir. 1998)	18, 20
<u>King v. United States Department of Justice</u> , 830 F.2d 210 (D.C. Cir. 1987)	8

<u>Mead Data Central v. Department of the Air Force,</u> 566 F.2d 242 (D.C. Cir. 1977)	16, 20
<u>Mehl v. EPA,</u> 797 F. Supp. 43 (D.D.C. 1992)	16
<u>NLRB v. Sears, Roebuck & Co.,</u> 421 U.S. at 153	16
<u>National Parks and Conservation Association v. Morton,</u> 498 F.2d 765 (D.C. Cir. 1974)	14
<u>Neugent v. Department of Interior,</u> 640 F.2d 386 (D.C. Cir. 1981)	23
<u>Ogelsby v. U.S. Department of Army,</u> 79 F.3d 1172 (D.C. 1996), quoting <u>Truitt v. Department of State,</u> 897 F.2d 540 (D.C. Cir. 1990)	21
<u>Oglesby v. U.S. Department of Army,</u> 920 F.2d 57 (D.C. Cir. 1990)	22
<u>Public Citizen Health Research Group v. FDA,</u> 185 F.3d 898 (D.C. Cir. 1999)	11, 15
<u>Public Citizen Health Research Group v. Food and Drug Administration,</u> 704 F.2d 1280 (D.C. Cir. 1983)	10, 12-13, 13
<u>Renegotiation Board v. Grumman Aircraft,</u> 421 U.S. 168 (1975)	15
<u>Schiller v. NLRB,</u> 964 F.2d 1205 (D.C. Cir. 1992)	6, 18
<u>Senate of the Cmwlth. of Puerto Rico v. DOJ,</u> 823 F.2d 574 (D.C. Cir. 1987)	9, 15
<u>Steinberg v. U.S. Department of Justice,</u> 23 F.3d 548 (D.C. Cir. 1994)	21
<u>Sterling Drug, Inc. v. Harris,</u> 488 F. Supp. 1019 (S.D.N.Y. 1980)	15
<u>Tax Analysts v. IRS,</u> 117 F.3d 607 (D.C. Cir. 1997)	9
<u>Tax Analysts v. IRS,</u> 214 F.3d 179 (D.C. Cir. 2000)	25

Union of Concerned Scientists v. NRC,
2 Med. L. Rpt. 1458 (D.D.C. 1977) 15

Vaughn v. Rosen,
484 F.2d 820 (D.C. Cir. 1973) passim

Vaughn v. Rosen,
523 F.2d 1136 (D.C. Cir. 1975) 14, 16

Weisberg v. Department of Justice,
543 F.2d 308 (D.C. Cir. 1976) 23

Wolfe v. DHHS,
839 F.2d 768 (D.C. Cir. 1988) 17

DOCKETED CASES

Jasper v. Carlton,
Civ. No. 97-2105 (D.D.C. Sept. 3, 1998) 25

FEDERAL STATUTES

21 U.S.C. § 355(b) 16

5 U.S.C. § 552 passim

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.

Civ. No. 00-2849 (RMU)

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

Pursuant to Local Rule 7.1(h), plaintiff Campaign for Responsible Transplantation ("CRT") submits this response to defendant Food and Drug Administration's ("FDA") Statement of Material Facts.

1. Not disputed.
2. Plaintiff does not dispute that the Public Health Service has defined xenotransplantation as "any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (A.) live cells, tissues, or organs from a nonhuman animal source or (B.) human body fluids, cells, tissues, or organs that have had *ex vivo* contact with live nonhuman animal cells, tissues, or organs." Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation (Jan. 19, 2001) (Plaintiff's Exhibit ("Pl. Ex.") A at 15.
3. Not disputed.

4. Not disputed.

5. Not disputed.

6. Not disputed.

7. Not disputed.

8. Not disputed.

9. Not disputed.

10. Not disputed.

11. Not disputed. However, CRT did not agree, and still does not agree, with the agency's proposal that the four categories of information – as proposed in the defendant's January 23, 2001 letter – should be “excluded” from the scope of plaintiff's Freedom of Information Act (“FOIA”) request.

12. Not disputed.

13. Not disputed. However, in its February 2, 2001 letter to the FDA, CRT stated that it “[could not] agree as to the types of records [it was] willing to exclude until [it had] a better understanding of the categories of records that are responsive to CRT's FOIA request.” See Pl. Ex. HH at 2.

14. Not disputed.

15. Not disputed.

16. Not disputed.

17. Not disputed.

18. Plaintiff lacks sufficient knowledge to respond to this statement.

19. Not disputed.

20. Not disputed.

21. Disputed. Not material. Plaintiff did not ultimately agree, i.e., by joint stipulation, to narrow the scope of its request on that date, since it decided that doing so might unnecessarily foreclose access to information.

22. Disputed. Not material. Plaintiff did not agree, by joint stipulation, to narrow the scope of its request on that date, since it decided that doing so might unnecessarily foreclose access to information.

23. Plaintiff is without sufficient knowledge to respond to this statement. However, this statement is not material to whether any of the records at issue in this case must be disclosed to plaintiff.

24. Disputed. Not material. This statement reflects FDA's interpretation of negotiations between the parties. Plaintiff did not agree, by joint stipulation, to narrow the scope of its request on that date, since it decided that doing so might unnecessarily foreclose access to information.

25. Disputed. Not material. This statement reflects FDA's characterization of negotiations between the parties. Plaintiff did not ultimately agree, i.e., by joint stipulation, to narrow the scope of its request on that date, since it decided that doing so might unnecessarily foreclose access to information.

26. Plaintiff disputes defendant's characterization that plaintiff drafted a stipulation that "did not accurately reflect" a prior agreement between the parties. Plaintiff does not dispute that, in the course of negotiations with the FDA, it drafted a joint stipulation for how the parties could agree to narrow the scope of the litigation.

27. Disputed. Not material. This statement reflects the FDA's characterization of negotiations between the parties.

28. Not disputed.

29. Not disputed.

30. Not disputed.

31. Not disputed.

32. Not disputed.

33. Not disputed.

34. Plaintiff is without sufficient knowledge to respond to this statement. However, plaintiff disputes that this search was adequate to locate all records that are responsive to plaintiff's request, since the agency's initial search did not locate 55 responsive records, including records containing information about the FDA's 1997 clinical hold and adverse events. For these reasons, plaintiff asserts that it needs discovery on these issues. See Rule 56(f) Declaration of Alix Fano ("Rule 56(f) Fano Decl.") (Pl. Ex. QQ) at ¶¶ 2, 12.

35. Plaintiff does not dispute that FDA sent its Sample Vaughn Index to plaintiff on August 31, 2001. However, plaintiff did not receive defendant's Sample Vaughn Index until September 4, 2001. Plaintiff does not dispute that the FDA's Sample Vaughn Index is comprised of two general sections, including one section that numbers 387 pages and lists FDA-generated records concerning xenotransplantation clinical trials in general, and a second section that numbers 228 pages and lists FDA-generated records concerning xenotransplantation that concern IND "G." However, plaintiff disputes defendant's characterization of the number of records listed in each section. There are 2,579 records listed in the section for FDA-generated records concerning xenotransplantation clinical trials in general. There are 873 records listed in the section for FDA-generated records concerning IND "G." See generally Sample Vaughn Index (Pl. Ex. RR).

36. Not disputed.

37. Plaintiff is without sufficient knowledge to respond to the reasons that FDA did not file a copy of its Sample Vaughn Index with the Court. Plaintiff filed a copy of the Sample Vaughn Index with its Reply Memoranda on May 8, 2002. See Pl. Ex. RR.

38. Plaintiff disputes the FDA's statement to the extent that it characterizes the Sample Vaughn Index, including its descriptions of records and legal justification for withholding information, as adequate. See Plaintiff's Memorandum in Support of Summary Judgment Motion ("Pl. Memo.") at 27-43; Plaintiff's Reply Memorandum ("Pl. Reply") at 6-24; Rule 56(f) Fano Decl. at ¶¶ 2-11.

39. Plaintiff does not dispute that the FDA invoked Exemptions 4, 5, 6, in whole or in part, as bases for withholding records. However, plaintiff disputes that the agency carried its burden to prove that it was justified in withholding the records on the basis of these Exemptions. See Pl. Memo. at 27-41; Pl. Reply at 10-23; Rule 56(f) Fano Decl. at ¶¶ 2, 6-11.

40. Disputed. The agency has not carried its burden to prove that records that it refers to as "personal notes" or "marginalia" are not "agency records" that are subject to the FOIA. See Pl. Memo. at 41-42; Pl. Reply at 23-24; Rule 56(f) Fano Decl. at ¶¶ 2, 13.

41. Not disputed. However, the information that the FDA released on October 15, 2001 is comprised of transcripts of advisory committee meetings that are readily accessible to the public on the agency's Internet website.

42. Not disputed.

43. Not disputed.

44. Not disputed.

45. Not disputed. However, plaintiff lacks sufficient knowledge to respond to defendant's statement that these records were "inadvertently" excluded from its original Sample Vaughn Index.

46. Not disputed.

47. Plaintiff does not dispute that the FDA redacted information and withheld information from a disclosure to plaintiff that the agency made on Dec. 14, 2001. However, plaintiff disputes that the agency carried its burden to prove that the redactions of vast amounts of information pursuant to Exemptions 4, 5, and 6 was lawful. See Pl. Memo. at 27-41; Pl. Reply at 10-23; Rule 56(f) Fano Decl. at ¶¶ 2, 6-11.

48. Not disputed.

49. Not disputed.

50. Not disputed.

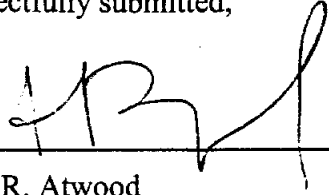
51. Not disputed.

52. Not disputed.

53. Not disputed. However, plaintiff lacks sufficient knowledge to respond to defendant's statement that these records were "inadvertently" excluded from its original Sample Vaughn Index, because two the six of the records that the agency disclosed were used as examples in plaintiff's motion for summary judgment. See Memorandum in Support of Plaintiff's Motion for Summary Judgment at 37, 43; see also Rule 56(f) Fano Decl. at ¶¶ 2, 12.

54. Disputed. Defendant has not carried its burden to prove that it has provided plaintiff with all segregable portions of nonexempt documents or that the FDA has lawfully withheld thousands of pages of records from disclosure. See Pl. Memo. at 27-45; Pl. Reply at 10-25; Rule 56(f) Fano Decl. at ¶¶ 2, 6-13.

Respectfully submitted,



Amy R. Atwood
(D.C. Bar No. 470258)
Katherine A. Meyer
(D.C. Bar No. 244301)
Jonathan R. Lovvorn
(D.C. Bar No. 461163)

Meyer & Glitzenstein
1601 Connecticut Avenue NW
Suite 700
Washington, D.C. 20009
(202) 588-5206
Attorneys for Plaintiff

May 8, 2002

INTRODUCTION

Rather than crossing the great divide still separating defendant Food and Drug Administration's ("FDA") oft-repeated, conclusory assertions that thousands of records are exempt from disclosure in their entirety, and satisfaction of the agency's burden to prove that these records may be withheld under the Freedom of Information Act ("FOIA"), the FDA has filed a Cross-Motion for Summary Judgment and two additional declarations that only further support plaintiff's major arguments in this litigation. As explained below, the agency's latest declarations only further demonstrate that its Vaughn index is woefully inadequate to support its decision to withhold thousands of records that remain at issue in this case. The FDA's latest declarations also raise new concerns regarding both the adequacy of the government's search for responsive records, and satisfaction of its duty to provide plaintiff with all "reasonably segregable" nonexempt portions of records. 5 U.S.C. § 552(b).

Since the agency has had numerous chances, yet has still failed to justify its decision to withhold information regarding a serious public health risk that is posed by xenotransplantation, summary judgment should be entered for plaintiff, and the Court should order the records to be disclosed. Alternatively, if the Court concludes that genuine issues of material fact preclude the entry of summary judgment at this time, plaintiff requests that it be allowed to take discovery concerning the records that have been withheld, the bases for the agency's exemption claims, the adequacy of the agency's search, and the agency's assertion that certain materials are not "agency records" under FOIA. See also generally Rule 56(f) Declaration of Alix Fano ("Rule 56(f) Fano Decl.") (Plaintiff's Exhibit in Support of Summary Judgment Motion ("Pl. Ex.")) (QQ).¹

¹ Plaintiff is filing a separate Reply Memorandum in response to the defendant-intervenors' joint Memorandum in Opposition to plaintiff's Motion for Summary Judgment.

BACKGROUND

A. The Records At Issue In This Case

Over two years ago, plaintiff Campaign for Responsible Transplantation (“CRT”) filed a FOIA request for “all records concerning applications for approval to conduct clinical trials in humans that involve xenotransplantation,” including records that concern the risk of porcine endogenous retrovirus (“PERV”) infection and other “adverse events” in xenotransplantation patients. See FOIA Request (Pl. Ex. FF). Since filing its Complaint, CRT has substantially narrowed the scope of its request to include only records that were FDA-generated and concern applications for approval to conduct xenotransplantation clinical trials involving the cells, tissues, and/or organs of pigs and/or nonhuman primates. See Joint Stip. (Dec. 20, 2001).

On September 4, 2001, FDA provided CRT with a “Sample Vaughn index” of responsive records, and a declaration prepared by Lesia M. Banks, the Chief of the Access Litigation and Freedom of Information Branch (“ALFOI”) of FDA’s Center for Biologics Evaluation and Research (“CBER”). Sample Vaughn Index (Pl. Ex. RR); Notice of Filing, Second Declaration of Lesia M. Banks (“Banks Decl.”) (Aug. 31, 2001). On December 20, 2001, FDA disclosed records and provided CRT with an Addendum to its Sample Vaughn index, which includes “documents that were not included in the original sample Vaughn index.” See Letter from Michael M. Levy, Jr. to Amy R. Atwood (Dec. 14, 2001) (Exhibit N in Support of Def. Cross-Motion for Summary Judgment (“Df. Ex.”)); Addendum to Sample Vaughn Index (Pl. Ex. SS).²

On January 15, 2002, CRT moved for summary judgment on the grounds that the FDA’s Vaughn index does not satisfy the agency’s burden of proof that virtually every word of thousands of records may be withheld in their entirety under several different exemptions to the

² Defendant did not file a copy of its Sample Vaughn index with the Court. Plaintiff is now filing a complete copy for the Court’s review. See Sample Vaughn Index (Pl. Ex. RR).

FOIA, and that certain records are not even “agency records” that are subject to FOIA. See Memorandum in Support of Plaintiff’s Summary Judgment Motion (“Pl. Memo.”) (Jan. 15, 2002). In support of its arguments, plaintiff referred to several examples of records that were inadequately described in the agency’s index – e.g., where the agency had not even said what the document was about or even identified the authors or recipients of the documents. See Pl. Memo. at 28-9; Pl. Ex. LL at § 1. In addition, CRT argued that FDA had failed to conduct an adequate search for records that were clearly covered by CRT’s request but did not appear to be listed in the Vaughn index, including information about FDA’s decision to place xenotransplantation trials on “hold,” and information about “adverse events” that have occurred during these trials. Id. at 43-5. Plaintiff also demonstrated that the agency had failed to disclose other information that it had already determined was exempt from disclosure. Id. at 43.

In response, on March 15, 2002, the FDA identified 55 additional records that it “discovered” during another search, including records that contain information about the agency’s decision to place a hold on all xenotransplantation clinical trials involving pigs, “the resumption of those clinical trials, the development of assays, and any adverse events connected with the clinical trials.” See Third Banks Decl. (Mar. 13, 2002) at ¶¶ 4-5; see also Second Addendum to Sample Vaughn Index (Pl. Ex. TT). Of the 55 records, the agency released 17 records, withheld all or portions of the remaining 38, and filed yet another Addendum to its Vaughn index with respect to those records. See id.³

³ Plaintiff and defendant have disagreed about the number of records that are at issue in this case. Plaintiff has again counted the records that the agency originally indexed, and it identifies 2,579 records that concern xenotransplantation in general and 873 records that concern IND “G.” See Pl. Ex. RR (Sample Vaughn index). Thus, assuming there are the same number of FDA-generated records for each of the 19 INDs that remain at issue, see Df. Resp. to Pl. Mat. Facts at 89, then there are approximately 16,587 records that concern the 19 pig xenotransplantation INDs. When these 16,587 records are added to the 2,579 FDA-generated documents that concern xenotransplantation in general, plus the 328 records that the agency indexed in two subsequent

On March 29, 2002, the FDA filed a Cross-Motion for Summary Judgment and two additional declarations in which the agency revealed new information about the contents of only those records which plaintiff had used as examples to demonstrate the inadequacy of the entire Sample Vaughn index. See Memorandum in Support of Defendant’s Summary Judgment Cross-Motion (“Df. Memo.”) at 12-4, 16-7, 23-5, 28-9, 32-3, 37; Fourth Banks Decl. at ¶¶ 7, 9, 11, 12, 14, 20, 22, 31, 32; see also generally Second Decl. of Joyce Frey-Vasconcells (“Frey-Vasconcells Decl.”). Thus, in response to plaintiff’s concern that the agency had not seemed to locate any records concerning either its decision to place xenotransplantation trials on hold or “adverse events” that have occurred during these trials, the FDA revealed that certain records – e.g., described only as “Clinical Trial Outline” or “Letter to: Sponsor from: CBER” – actually contain information “pertaining to FDA’s 1997 decision to place all xenotransplantation clinical trials on hold, the resumption of the trials, the development of assays, and adverse events in connection with the trials.” Fourth Banks Dec. at ¶ 7 (describing Doc. Nos. 156, 345); see also Side-by-Side Comparison of FDA’s Original and More Recent Records Descriptions (“Chart”) (Pl. Ex. UU). Specifically, FDA revealed, for the first time, that 10 records in the agency’s Vaughn index contain information about “adverse events” in patients, including four records that concern the representative IND “G.” Fourth Banks Decl. at ¶ 7. FDA provided additional information about the contents of several other records that plaintiff used as examples in its opening brief. See id. at ¶¶ 11, 14, 20, 22, 31; see also Chart (Pl. Ex. UU).⁴

Addendums to its Sample Vaughn index, there are approximately 19,494 responsive records still at issue in this case.

⁴ Thus, for example, the agency revealed that Doc. No. 30 – originally described only as “IND G: personal notes in margin of document submitted by IND sponsor” – actually contains many kinds of information, including “personal notes about the length of the clinical study, masking cells, and initiation of cultures.” See Comparison Chart (Pl. Ex.UU) at Doc. No. 30. Similarly, the agency has now revealed that Doc. No. 338 – which the agency originally described only as “IND G:

However, the agency still refuses to disclose basic information about the records at issue, including, but not limited to, which agency official wrote the records and who received them, asserting that it is “entirely unnecessary” for plaintiff and the Court to know this information in order to “ascertain[] whether Exemptions 4 or 5 apply in this case.” See Df. Memo. at 19-20; Fourth Banks Decl. at ¶ 23.

As to its contention that thousands of FDA-generated records may be withheld in their entirety under Exemption 4, the agency still refuses to state whether the withheld information is “trade secrets” or “confidential commercial information” within the meaning of the Exemption. Most glaringly, FDA did not even respond to plaintiff’s principle argument – i.e., that the sponsors of xenotransplantation INDs have already widely disclosed vast amounts of information about their products to the public – and, hence, to their competitors – via the Internet, scientific journals, and Securities and Exchange Commission filings. Indeed, although plaintiff had attached to its Summary Judgment Motion voluminous Exhibits demonstrating that much of this information was already in the public domain, see Pl. Ex. V-EE, the FDA provided no indication whatsoever that it had made any effort to ascertain whether any of the information it is withholding has already been disseminated by the companies. See Pl. Memo. at 15-19.

As to the government’s other major arguments – that thousands of records may be withheld under Exemption 5 because they pertain to a predecisional and deliberative process – the agency asserted that the records either pertain to the agency scientists’ decision as to whether to approve a particular xenotransplantation IND as “safe and effective,” or “may” be used at

8/14/00 Letter to: sponsor from: CBER” – contains the following information: “name of the sponsor; number and title of the IND; clinical development plan; statistical analysis of the clinical study; clinical trial; monitoring of safety during clinical trial; analytical plan; number of subjects per site; and testing of samples for (PERV).” Id. at Doc. No. 338.

some point in the future for the formulation of some unidentified “policies,” “rules,” or “guidances” about xenotransplantation in general.

ARGUMENT

I. THE FDA’S LATEST DECLARATIONS FURTHER DEMONSTRATE THAT THE AGENCY HAS FAILED TO MEET ITS BURDEN OF PROOF.

A. The FDA’s Latest Declarations Demonstrate That Its Vaughn Index Does Not Adequately Describe The Contents Of Withheld Records.

In its opening brief, CRT randomly chose 11 documents from FDA’s Vaughn index to illustrate that the agency’s descriptions do not facilitate plaintiff’s – or the Court’s – basic understanding of the nature of the records at issue to permit any adversarial testing of the agency’s exemption claims. See Pl. Memo. at 28-9. Thus, the agency’s Vaughn index does not serve its basic purpose – to restore “the traditional adversarial nature of our legal system’s form of dispute resolution,” and to provide the Court with the requisite “controverting illumination” that would assist the Court in making a de novo determination of whether the exemptions asserted actually apply. See Pl. Memo. at 25, quoting Vaughn v. Rosen, 484 F.2d 820, 825 (D.C. Cir. 1973) (“Vaughn I”); see also Schiller v. NLRB, 964 F.2d 1205, 1209 (D.C. Cir. 1992). Obviously recognizing the deficiencies in its original declarations and Vaughn index, defendant has now prepared new declarations – however, only with respect to those records used as examples in CRT’s brief – merely highlighting plaintiff’s argument on this point by demonstrating that, in fact, much more information can readily be provided concerning the nature of each record that has been withheld. See Fourth Banks Decl. at ¶ 31; see also Comparison Chart (Pl. Ex. UU).

For example, for documents that the agency originally described only as “Internal Memo RE: Xeno,” the FDA has now explained that these records actually contain many different kinds

of information, including, e.g., “scientific information” regarding the use of non-human primates in xenotransplantation and “patient experiments.” See Comparison Chart (Pl. Ex. UU) at Doc. Nos. 200, 935. In addition, FDA has now revealed that Doc. No. 3044, which was originally described simply as “Undated/Unsigned Handwritten Notes, re: Cells” contains extensive scientific information, including information about “testing for viruses.” Id. at Doc. No. 3044.⁵

Among the noteworthy examples of the agency’s attempt to cure its categorical failure to describe the contents of withheld records is Doc. No. 31. Originally described only as “personal notes in margin of document submitted by IND sponsor,” the agency has now revealed that this record actually contains information about “testing for PERV.” Id. at Doc. No. 31. The agency has similarly disclosed that Doc. No. 33 – also originally described in the same way as Doc. No. 31 – contains, among other things, information regarding an undefined “PERV development program.” Id. at Doc. No. 33. Doc. No. 53, originally described only as a “CBER Amendment Review,” contains information about adverse events – as do several other records – extremely salient information that simply could not be discerned from the agency’s original descriptions of these records. See, e.g., Comparison Chart (Pl. Ex. UU) at Doc. Nos. 55, 61, 65, 68, 70, 77, 89, 90, and 159. Likewise, the agency has now revealed that Doc. No. 55, which the FDA originally described as a “Xenotransplantation Action Plan, CBER (draft),” contains information about the agency’s “plan” for responding “to adverse public health events that occur in

⁵ In this connection, the agency’s use of subject headings and titles to describe the contents of records is patently insufficient to serve that purpose. See, e.g., id. at Doc. Nos. 923 (“General: 10/13/99, Internal Emails, RE: Really final revised petition response”); 1414 (“General: 3/26/99, E-mail, RE: MTG”). Again, one of the basic purposes of a Vaughn index is to allow the requester “to argue for the release of redacted or withheld documents with ‘desirable legal precision’ because ‘the party seeking disclosure cannot know the precise contents of the documents sought.’” See Order (July 23, 2001) at 5. Defendant’s contrary position – i.e., that cutting and pasting the headings or titles of documents into the agency’s Vaughn index satisfies this purpose, see Fourth Banks Decl. at ¶ 22 – is demonstrably wrong. See id., quoting King v. United States Dep’t of Justice,

xenotransplantation.” *Id.*, Doc. No. 55 (four page record withheld in its entirety pursuant to Exemption 5’s deliberative process privilege). Similarly, the agency has now disclosed that several records contain information about the agency’s 1997 clinical hold and resumption of clinical trials, although this fact could not possibly be ascertained from the agency’s original descriptions. *See* Pl. Ex. UU, Doc. Nos. 25, 156, 181, 323, 345, 346, 353, 393, 763.

It is important to stress that FDA has only provided this supplemental information with respect to the 64 documents that CRT used as examples in its opening brief. Accordingly, there is every reason to believe that FDA can simply provide at least such information with respect to the thousands of additional records at issue in this case. However, even as to those few records for which FDA has now supplied additional descriptions, it is still impossible to discern which agency officials wrote the records and which agency officials received them, or, in many cases, what the records actually concern. Indeed, FDA has taken the position that “the names of the author and recipients of the documents” is “entirely unnecessary” for the Court to know. *Id.* at ¶ 23. However, crucially, FDA has not asserted, let alone proven, that such information may be withheld under any Exemption. Furthermore, this information is “necessary” for plaintiff – and the Court – to assess whether the claimed Exemption applies.

For example, FDA has withheld thousands of records under Exemption 5, without disclosing the identities or even official positions of the authors and recipients of these records. However, “[t]he need to describe” the contents of “each withheld document when Exemption 5 is at issue is particularly acute because ‘the deliberative process privilege is so dependent upon the individual document and the role it plays in the administrative process.’” Animal Legal Defense Fund v. Dep’t of the Air Force, 44 F. Supp. 2d 295, 299 (D.D.C. 1999), quoting Coastal

830 F.2d 210, 218 (D.C.Cir.1987) (“[t]he Vaughn index . . . should provide the requester with ‘a meaningful opportunity’ to argue for the release of withheld documents”) (emphasis added).

States v. DOE, 617 F.2d 854, 897 (D.C. Cir. 1980) (emphasis added). Thus, it is well-established that, for an agency to withhold requested information pursuant to Exemption 5's deliberative process privilege, it must demonstrate that the information is both predecisional and deliberative. Tax Analysts v. IRS, 117 F.3d 607, 616 (D.C. Cir. 1997). Thus, "[t]he identity of the parties . . . is important" because "a document from a subordinate to a superior official is more likely to be predecisional, while a document moving in the opposite direction is more likely to contain instructions to staff explaining the reasons for a decision already made." Coastal States, 617 F.2d at 868.

Here, however, since the FDA's declaration and Vaughn index do not "indicate[] the titles and positions of the documents' authors and recipients," see ALDF, 44 F. Supp. 2d at 300-01, it is impossible for plaintiff, or the Court, to determine whether in fact the records are deliberative or predecisional within the meaning of Exemption 5. See also Senate of the Cmwth. of Puerto Rico v. DOJ, 823 F.2d 574, 586 (D.C. Cir. 1987) (without knowing the "nature of the decisionmaking authority vested in the officer or person issuing the disputed document," and "the relative positions in the agency's 'chain of command' occupied by the document's author and recipient," there is absolutely no way for CRT to evaluate the defendant's claims that Exemption 5 applies to thousands of records) (additional citation omitted).

Accordingly, since the agency has not provided basic information about the contents of records that it is withholding, plaintiff needs to take discovery on this information – including who authored the documents, who received them, and for what purpose. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2-3, 5.

B. FDA's Declarations Demonstrate Its Exemption Claims Are Unjustified.

1. FDA Has Not Justified Its Contention That Thousands Of Records May Be Withheld Under Exemption 4.

FDA's latest declarations also call into further doubt the agency's reliance on Exemption 4 to withhold thousands of pages of records. First, FDA has not even responded to CRT's argument that FDA failed even to distinguish whether the information is being withheld because it qualifies as "trade secret" or "confidential commercial information." Pl. Memo. at 32-3; see also generally Sample Vaughn Index (Pl. Ex. RR); Second Banks Decl. at ¶ 9. However, as CRT explained, see Pl. Memo. at 32-3, this is a crucial distinction, since each category involves an entirely separate legal analysis. Indeed, since "agencies . . . [have a] burden [to] prov[e] that all essential elements of the exemption exist," ALDE, 44 F. Supp. 2d at 303, merely asserting in conclusory terms that "[t]he types of trade secret and/or confidential commercial information contained in these documents include, but are not limited to" several categories of information – as the agency has done here, see Df. Memo. at 27 – is simply not enough to meet that burden. See Vaughn I, 484 F.2d at 826 (the Court must not "accept conclusory and generalized allegations of [FOIA] exemptions"); Public Citizen Health Research Group v. Food and Drug Administration, 704 F.2d 1280, 1291 (D.C. Cir. 1983) (Public Citizen I) ("[c]onclusory and generalized allegations of substantial competitive harm, of course, are unacceptable and cannot support an agency's decision to withhold requested documents") (emphasis added).

Second, defendant has failed to address plaintiff's other main substantive argument that, in an effort to gain public support and financial investors for their inherently risky xenotransplantation products, sponsors of xenotransplantation INDs – including intervenors in this litigation – have already disclosed much of this information on their Internet websites, during public meetings, and in SEC filings, and, therefore, this information simply cannot

qualify as either a trade “secret” or “confidential” within the meaning of Exemption 4. See Pl. Memo. at 16-9, 33-4. Indeed, as FDA itself has publicly acknowledged, “information . . . concerning clinical trials on . . . xenotransplantation is already widely disclosed.” 66 Fed. Reg. 4688, 4691 (Pl. Ex. B) (emphasis added); see also Anderson v. DHHS, 907 F.2d 936, 952 (10th Cir. 1990) (“[b]ecause materials such as these appear to be in the public domain, no meritorious claim of confidentiality can be made”).⁶

In response, the FDA asserts in its brief, that “[i]nformation in the IND that FDA is aware is public has been produced to Plaintiff.” See Df. Memo. at 20 (emphasis added). However, in a declaration, the agency provides a modified version of this assertion by stating that “[i]nformation in the IND that has been publicly disclosed was released to Plaintiff.” See Fourth Banks Decl. at ¶ 24. Moreover, neither statement is accompanied by any detail as to what information the agency is referring to, and there is absolutely no indication in the record that the FDA has made any attempt whatsoever to determine whether any of the information it is withholding under Exemption 4 has in fact been disclosed by the companies in the many public

⁶ Defendant and intervenors have objected to CRT’s emphasis on the public health risk associated with xenotransplantation, on the grounds that this information is not “material” to this case. See Defendant’s Response to Plaintiff’s Material Facts at 1; Defendant-Intervenors (“Int.”) Resp. to Pl. Mat. Facts pp. 1-2. However, the public interest in this information is extremely relevant to the agency’s Exemptions 6 and 4 claims. See, e.g., Getman v. NLRB, 450 F.2d 670, 674 (D.C. Cir. 1974); Public Citizen Health Research Group v. FDA, 185 F.3d 898, 908 (D.C. Cir. 1999) (“Public Citizen II”) (Garland, J., concurring) (other citations omitted) (“Exemption 4 requires a balance of the interest in nondisclosure ‘against the public interest in disclosure’”); accord Center for Auto Safety v. NHTSA, 244 F.3d 144, 150 (D.C. Cir. 2001) (“applications of Exemption 4 attempt to balance private interests in protection from disclosure, governmental interests in access to data, and public interest in transparent governmental decisionmaking”). Moreover, because the FDA failed to dispute any of these material facts, they should be deemed admitted. See Jackson v. Finnegan, Henderson, Farabow, Garrett & Dunnder, 101 F.3d 145, 154 (D.C. Cir. 1996) (“the district court is to deem as admitted the moving party’s facts that are uncontroverted by the nonmoving party’s [] statement” of facts).

forums that plaintiff provided to the agency both with its original FOIA request and its voluminous Exhibits on this point. See Pl. Memo. at 15-9; Pl. Ex. V-EE.⁷

Indeed, to understand the true breadth of FDA's contention that vast amounts of records may be withheld in their entirety under Exemption 4, the Court need look no further than what FDA, in its own "timeline," describes as a form letter that was mailed to all sponsors of xenotransplantation INDs in October, 1997, when the agency placed a "hold" on all xenotransplantation clinical trials, but which the agency is withholding in its entirety under Exemption 4. See "PERV Administrative Timeline" (Pl. Ex. VV); Sample Vaughn Index (Pl. Ex. RR) at Doc. Nos. 345, 784, 1701, 1744. However, since, according to FDA itself, this "[c]ommunication" was "formatted as a single letter to all sponsors affected (customized letters dropped)," FDA cannot possibly prove that these records are exempt because their disclosure would reveal a "trade secret" or cause "substantial competitive" harm to sponsors, since all of their competitors got the same letter. See "PERV Timeline" (Pl. Ex. VV) (emphasis in original). On the other hand, FDA's explanation to the xenotransplantation industry as to why it had decided to place all such clinical trials on hold is of extreme importance to CRT and the public debate on this extremely controversial biotechnology. See Pl. Memo. at 6-15.

Similarly, the FDA has withheld a two-page record described as "IND G: 8/23/96 Telecon re Adverse Event Report" on the grounds that it is also exempt in its entirety under Exemption 4. See Sample Vaughn Index (Pl. Ex. RR) at Doc. No. 676. However, because it is well settled that information that bears on the safety of a product is not a "trade secret," Public

⁷ For that matter, the FDA has yet to even acknowledge that IND "G" concerns Diacrin, or to disclose any information from the thousands of pages of IND "G" records that would reveal this fact, even though Diacrin's own Chief Operating Officer has now acknowledged that this is so. See Affidavit of E. Michael Egan, Chief Operating Officer, Diacrin ("Egan Aff.") (Exhibit in Support of Defendant-Intervenors' Opposition Memorandum) at ¶ 7.

Citizen I, 704 F.2d at 1286-90, the agency certainly cannot meet its burden of proof with respect to that particular prong of Exemption 4. And, even if the agency were able to prove that some of the information somehow nevertheless qualifies for protection as “confidential commercial information” – a demonstration that has yet to be made in this case – this would certainly not justify the agency’s withholding of all of this information. For example, if the record states that a particular (unidentified) patient “died as a result of the adverse event he experienced during the course of this clinical trial,” such information could not possibly provide a “substantial competitive” benefit to a competitor of that particular IND sponsor, especially if the agency does not identify the sponsor or particular product to which this information pertains. On the other hand, such information is extremely relevant to the public controversy surrounding the safety of xenotransplantation and whether the FDA is fulfilling its statutory duty to protect the public – including clinical patients and their contacts – from the risk of transmission of animal viruses.

However, it is well established that, while Exemption 4 is designed to protect submitters from substantial “competitive” harm, it may not be used to shield information from the public simply because it may be publicly embarrassing. See, e.g., CNA Financial Corp. v. Donovan, 830 F.2d 1132, 1154 (D.C. Cir. 1987) (concerns about “unfavorable publicity” are “unrelated to the policy behind Exemption 4”). Thus, the Court of Appeals has “emphasize[d] that the important point for competitive harm in the FOIA context . . . is that it be limited to harm flowing from the affirmative use of proprietary information by competitors.” Public Citizen I, 704 F.2d at 1291, n. 30 (emphasis in original) (additional citations omitted). Here, however, revealing that unidentified patients have suffered health problems or even died as a result of xenotransplantation trials, without providing details about the precise product or circumstances under which this occurred, could not possibly cause any “competitive” harm to the sponsors of

those products, let alone “substantial” competitive harm, as the FDA is required to prove. Nat’l Parks and Conservation Ass’n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974).⁸

In any event, because the record is devoid of certain basic information concerning the agency’s Exemption 4 claims, and yet also demonstrates that the agency has asserted this Exemption for records that plainly are not exempt, plaintiff wishes to take discovery on these matters as well. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2, 6-7.

2. Defendant Has Not Refuted Plaintiff’s Arguments That The Agency Has Failed To Justify The Applicability Of Exemption 5.

Similarly, the agency has unlawfully applied Exemption 5’s deliberative process privilege to withhold thousands of pages of records in their entirety. Indeed, the agency has failed to point to any discrete agency policy decision to which any of these records apply. Instead, the agency asserts that the deliberative process at stake is “whether [an] IND should go into effect.” See Df. Memo. at 21. Yet, as the agency’s own declarations reflect, the records that the agency seeks to withhold reflect purely scientific findings – i.e., the development of assays, testing for PERV, and other factual findings by CBER “reviewers” and “managers,” all of whom appear to be scientists charged with the duty of determining whether these products are “safe and effective” within the meaning of the Food, Drug, and Cosmetic Act. See 21 U.S.C. § 355(b); 21 C.F.R. § 312.22; see also Second Frey-Vasconcells Decl. at ¶¶ 5-10; id. at ¶ 8 (“a reviewer considers the safety and scientific issues concerning the IND”). However, these deliberations are simply not the kinds of policy deliberations that Exemption 5 is designed to protect. See, e.g., Vaughn v. Rosen, 523 F.2d 1136, 1144 (D.C. Cir. 1975) (“Vaughn II”) (to qualify for Exemption

⁸ Thus, this case is a far cry from Public Citizen II, where the Court held that detailed information in a new drug application concerning the deficiencies of a particular drug qualified as “confidential commercial information” since it would allow a competitor “to eliminate much of the time and effort that would otherwise be required to bring to market a [competitive] product.” 185 F.3d at 905.

5, “the document must be a direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters”) (emphasis added).

Moreover, to the extent the agency could prove that the IND approval process is somehow policy related, it would still have to segregate and disclose all “factual” or “investigative” material that did not reveal that process. EPA v. Mink, 410 U.S. 73, 89 (1973); see also, e.g., Sterling Drug, Inc. v. Harris, 488 F. Supp. 1019, 1028-29 (S.D.N.Y. 1980) (objective medical analyses of drug tests are not exempt under Exemption 5); Union of Concerned Scientists v. NRC, 2 Med. L. Rpt. 1458 (D.D.C. 1977) (expert scientific opinion may not be withheld under the deliberative process privilege).

Obviously realizing that the IND review process is not the kind of “deliberative” process that is implicated by Exemption 5, FDA alternatively asserts that “[b]ecause xenotransplantation is a new procedure,” any documents “generated during the IND review reflect “the development of FDA policies about xenotransplantation in general,” not just FDA thoughts about a particular xenotransplantation product.” See Df. Memo. at 33-4; see also Fourth Banks Decl. at ¶¶ 16, 29 (explaining that during the agency’s review of particular INDs, in response to the surfacing of issues that “may arise,” the agency “may develop guidances, rules, and policies concerning xenotransplantation in general”) (emphasis added). However, because, conspicuously, the FDA does not identify a single such “guidance,” “rule,” or “policy” to which any of the withheld records actually relate, it simply may not lawfully withhold such vast amounts of material on this basis. See, e.g., Senate of the Cmwlth. Of Puerto Rico, 823 F.2d at 585 (agency must identify, with particularity, a discrete “agency decision or policy to which the document contributed”); Renegotiation Bd. v. Grumman Aircraft, 421 U.S. 168, 184 (1975) (agency must demonstrate that each record was “prepared in order to assist an agency decisionmaker in arriving at his

decision”); Wolfe v. DHHS, 839 F.2d 768, 774 (D.C. Cir. 1988) (en banc) (agency must prove that each record “reflects the give-and-take of the consultative process”).

Indeed, under the FDA’s construction, any record generated at any time by any agency could be exempt from disclosure under the theory that it “may,” at some point in time, be used by the agency in the course of generating agency policy. However, as the Court of Appeals long ago observed, “[t]here is a huge quantity of amorphous . . . activity in every agency which would be protected by an equivalent rationale.” Vaughn II, 523 F.2d at 1146. Indeed, as the Court further observed, an agency’s affidavits fail to carry the government’s burden of proof when they fail to “define, explain, or limit the ‘deliberative process’ which the Government seeks to protect.” Id. (emphasis added); see also id. (“[i]f we construed Exemption 5 as broadly as the Government seeks to do here, we would go a long way toward undercutting the entire [FOIA]”).⁹

Finally, it appears that FDA may be withholding many documents under Exemption 5 that contain information that FDA has shared with the sponsors of INDs, since intervenors have stated that “[c]omments and questions generated from internal FDA meetings about individual INDs are communicated to IND sponsors by telephone, fax, electronic mail, and U.S. mail.” Intervenors’ Memo. (“Int. Memo.”) at 12 (emphasis added). However, it is absolutely clear that “[i]f the information has been or is later shared with third parties,” Exemption 5 simply does not apply. Mead Data Central v. Dep’t of the Air Force, 566 F.2d 242, 253 & n. 24 (D.C. Cir. 1977); see also Mehl v. EPA, 797 F. Supp. 43, 47 (D.D.C. 1992) (“[v]oluntary disclosure of information may waive an otherwise valid FOIA exemption”).

⁹ Moreover, to the extent the FDA seeks to shield records that reflect any “established policies and decisions” about xenotransplantation, such “secret law” certainly may not be withheld under the Exemption. See NLRB v. Sears, Roebuck & Co., 421 U.S. at 153 (Exemption 5 should not apply to “statements of policy and interpretations which have been adopted by the agency”).

Accordingly, although CRT believes that it has amply demonstrated that the agency has failed to meet its burden of proof with respect to Exemption 5, to further address this point, CRT would need discovery to ascertain the precise agency decision to which the agency asserts each record pertains, and to discern the role played by each such record in that process. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2, 5-10.

3. Defendant Has Failed To Prove That Any Responsive Records Are Exempt From Disclosure Under Exemption 6.

Although defendant now asserts that the only information it has withheld under Exemption 6 would reveal “the names of individual patients participating in the xenotransplantation clinical trials and other patient-identifying information,” Fourth Banks Decl. at ¶ 18, the record is still not clear on this point.

For example, FDA has withheld, in its entirety, Doc. No. 676, a two-page record that is described as “IND G: 8/23/96 Telecon re Adverse Event Report,” see Sample Vaughn Index (Pl. Ex. QQ) at Doc. No. 676, and has claimed Exemption 4 for all of the document, and Exemption 6 with respect to all of the information in paragraph one. Id. However, FDA has not demonstrated that all of this information would reveal patients’ identities. If, for example, the sentence “John Doe died following the adverse event he experienced during this clinical trial” appears in this paragraph, the only information that would reveal the identity of a patient is his name. The rest of this information could not lawfully be withheld under Exemption 6.¹⁰

¹⁰ Similarly, the agency is withholding Doc. No. 69 from disclosure in its entirety – a one page record described as “General: Undated/Unsigned Printout With Marginalia, re: Subject in Controlled Study.” See Sample Vaughn Index (Pl. Ex. RR) at Doc. No. 69. However, it is not clear that this entire record consists of patient-identifying information. The same ambiguity applies with respect to several other records: Doc. Nos. 48 (“General: 2/24/98 CBER letter (draft) re: Pt. Notification Plan”); 336 (“General: Undated Handwritten notes regarding trials subjects”); 676 (“IND G: 8/23/96 Telecon re Adverse Event Report”); 742 (“IND G: 9/7/94 personal notes in margin of document submitted by IND sponsor”); 746 (“IND G: 10/12/94 Memo of Telecon”); 1218 (“General: 5/20/95, Internal Memo, RE: xenotransplantation update”); 1776 (“General: 4/14/95 Interoffice communication”); 2025 (“General:

Accordingly, plaintiff would need to take discovery to determine which portions of records the agency is contending fall within Exemption 6, and whether such information would, in fact, reveal only patients' identities. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2, 11.

C. The FDA's Latest Declarations Demonstrate That The Agency Has Not Complied With Its Duty To Disclose All Segregable, Nonexempt Information.

The agency's latest declarations also clearly demonstrate that the FDA has not complied with its statutory duty to disclose all segregable, nonexempt information. 5 U.S.C. § 552(b); Kimberlin v. DOJ, 139 F.3d 944, 949 (D.C. Cir. 1998). For example, in response to plaintiff's complaint that the agency's index does not provide basic information about the authors and recipients of numerous documents, the FDA does not even assert – let alone prove – that such information is exempt from disclosure, nor does it contend that such information cannot readily be segregated from the rest of the record. Rather, the FDA simply refuses to disclose this information, asserting that it is “unnecessary” for plaintiff and the Court to have such information to ascertain that the rest of the document is exempt from disclosure. See id. While, as plaintiff demonstrates supra at 9-10, such information is, in fact, extremely relevant to determining whether the agency's claimed Exemptions are lawful, FDA's excuse for failing to disclose this information is fundamentally at odds with its clear statutory duty to disclose all non-exempt information. See also Schiller, 964 F.2d at 1210 (“it is error for a district court to simply approve the withholding of an entire document without entering a finding on segregability”).

The FDA's failure to abide by the segregability requirement permeates its entire Vaughn index. Thus, in violation of its disclosure obligations, the agency repeatedly “assert[s] only that entire documents are exempt from disclosure.” Kimberlin, 139 F.3d at 950; see also generally

2/6/97 Internal memo re Patient call”); 2054 (“General: 11/1799 Letter RE: nomination to represent FDA Xenosubcommittee”); 2131 (“General: Undated Transplant trial acceptance form”); 2322 (“IND G:

Sample Vaughn Index (Pl. Ex. RR); Pl. Ex. ZZ at § 1. But, as the D.C. Circuit admonished in Kimberlin, “the Government should know by now” that “[t]he focus in the FOIA is information, not documents, and an agency cannot justify withholding an entire document simply by” trying to show “that it contains some exempt material.” Id., quoting Mead Data, 566 F.2d at 260.

Moreover, as plaintiff demonstrated in its opening brief, the agency has also blanketed entire documents with more than one Exemption, see Pl. Memo. at 26-7, and has failed to comply with the requirement that it “correlate claimed exemptions with particular passages [within each document].” Armstrong v. Executive Office of the President, 97 F.3d 575, 578 (D.C. Cir. 1996). For example, for Doc. No. 1482, an 11 page record described as “General: Undated, Draft, Memorandum of an Interview,” the agency withheld the entire record under Exemptions 4 and 5, and, in so doing, stated only that “this is a (b)(5) doc, containing (b)(4) info,” but provided absolutely no further information on what in the document is protected by Exemption 5 and why, and what information is covered by Exemption 4 and why. See Comparison Chart (Pl. Ex. UU) at Doc. No. 1482. The same problem occurs with respect to Doc. No. 1501, and several other records. Id. at Doc. No. 1501; Pl. Ex. ZZ at § 1 (listing all records blanketed with more than Exemption). These examples are the rule, not the exception. Thus, should defendant attempt to cure the inadequacies in these examples – as it attempted to do the last time plaintiff used examples – this will not cure the agency’s categorical failure to comply with its duty to explain in detail which exemptions apply to which material, and why. See also Vaughn I, 484 F.2d at 827-28 (it is “preposterous to contend that all of the information is equally exempt under all of the alleged exemptions”).

8/14/95 Consult request”); 3288 (“IND G: 8/23/96 Telecon between Sponsor and CBER, re: Adverse Event Report”); 3506 (“General: Undated Slides re Evolving FDA” perspectives).

Accordingly, plaintiff needs to take discovery to determine which Exemptions the agency is claiming with respect to which records and portions of records, and to determine whether the FDA has complied with its duty to disclose all segregable, nonexempt information. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2, 4.

D. The Agency Has Failed To Prove That It Has Conducted An Adequate Search For All Responsive Records.

In its opening brief, CRT demonstrated that the FDA had failed to produce or identify important information that is covered by its request, including, for example, records that pertain to the agency's October 17, 1997 decision to place a clinical "hold" on all clinical trials involving xenotransplantation because of safety concerns, and the agency's subsequent decision to lift that "hold" and allow such trials to proceed. Pl. Memo. at 44. Plaintiff also showed that, similarly, the agency had failed to produce or identify any records that refer to "adverse events" – i.e., those involving health and safety concerns – that have occurred during xenotransplantation trials, although plaintiff is aware that, by 1997, one company alone – Diacrin – had experienced at least 232 such events with respect to one of its products and two serious adverse events with respect to another product in 2000, and that, in view of the agency's decision to put all such trials on hold at one point, it is likely that the other companies also experienced such "adverse events" with respect to their products. Id. Accordingly, plaintiff asserted that either the FDA had failed to locate these extremely pertinent records, or it had failed to identify them in enough detail in its Sample Vaughn index to permit the plaintiff – or the Court – to ascertain that they had in fact been located, but were being withheld.

In response, on March 15, 2002, FDA revealed that it had found 55 additional documents that were not included in its Sample Vaughn index, and has withheld all or portions of 38 of those records. According to FDA, "most" of the newly found documents "pertain to the FDA's

decision to place all porcine xenotransplantation clinical trials on hold, the resumption of those clinical trials, the development of assays, and any adverse events connected with the clinical trials” – the very information that CRT complained was missing from the agency’s initial Vaughn index and which is of paramount interest to plaintiff. See Df. Notice of Filing (Mar. 15, 2002), Third Banks Decl. at ¶ 5. However, despite the fact that such information is squarely covered by CRT’s request, goes to the heart of CRT’s concerns about the safety of these products, and yet was not even “located” until after CRT moved for summary judgment on the adequacy of FDA’s search, remarkably, FDA has failed to provide any information whatsoever as to how these records were overlooked when it prepared its initial Vaughn index.

In light of these developments, the Court cannot possibly determine de novo that the agency has conducted an adequate search for records. See Steinberg v. U.S. Dep’t of Justice, 23 F.3d 548, 551 (D.C. Cir. 1994) (court’s review of the adequacy of the search is de novo). Indeed, as the Court of Appeals has observed, “the discovery of additional documents is more probative that the search was not thorough than if no other documents were found to exist.” Goland v. CIA, 607 F.2d 339, 370 (D.C. Cir. 1978); see also Ogelsby v. U.S. Dep’t of Army, 79 F.3d 1172, 1185 (D.C. 1996) (where record shows that the agency’s original search “failed to locate . . . important documents,” and the agency fails to explain how this happened, the court “could not properly conclude” that the search was “reasonably calculated to uncover all relevant documents”), quoting Truitt v. Dep’t of State, 897 F.2d 540, 542 (D.C. Cir. 1990).

Compounding these glaring evidentiary gaps concerning how FDA could have “overlooked” 55 documents that fall squarely within the scope of CRT’s request, there also is no basis in the record to determine whether FDA has yet searched all record repositories that are likely to contain responsive information. In fact, the only information provided by the

government as to the scope of its search is that FDA stated only that it searched all 21 divisions of the Center for Biologics Evaluation and Research (“CBER”). See Fourth Banks Decl. at ¶ 5.¹¹

However, FDA has not explained why it limited its search to only this particular component of the FDA – particularly when plaintiff’s request was sent to the entire agency, and when the FDA has not ever asserted that CBER is the only place within the FDA where responsive records would likely be found. Oglesby v. U.S. Dep’t of Army, 920 F.2d 57, 68 (D.C. Cir. 1990) (“[a] reasonably detailed affidavit . . . averring that all files likely to contain responsive materials . . . were searched is necessary to afford a FOIA requester an opportunity to challenge the adequacy of the search and to allow the district court to determine if the search was adequate”) (emphasis added).

Moreover, in light of the significance of the agency’s decision to place a regulatory “hold” on all xenotransplantation clinical trials involving pigs for some period of time, plaintiff questions whether such a decision – and the subsequent decision to lift that hold – could be made by the CBER alone, without the involvement of the Commissioner’s Office, the Office of the Chief Counsel, the Office of Regulatory Affairs, or some other office within the FDA that deals with such seemingly high-level legal and regulatory matters. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 12. Indeed, in support of its argument that many of the records at issue in this case may be withheld under Exemption 5, the agency asserts that the records relate to some – as yet unidentified – “policies,” “rules,” and “guidances” concerning xenotransplantation. See, e.g., Df. Memo. at 31, 33; Fourth Banks Decl. at ¶¶ 16, 29; Frey-Vasconcells Decl. at ¶¶ 11-12. Yet, if this is true, then surely such deliberations would have to include more than just the scientists that work for the CBER. Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2, 12.

¹¹ The agency states that it also contacted the staff of one of its Advisory Committees. Id.

In addition, there are strong reasons to believe that the agency still has not identified all of the records that concern “adverse events.” First, it is counterintuitive to accept – as defendant asserts in its latest declarations – that there are a total of only 10 records concerning such events, see Fourth Banks Decl. at ¶ 7, particularly when concerns about the risk of PERV infection led the FDA to place a hold on all xenotransplantation clinical trials in 1997, and when, by that year, Diacrin had already observed at least 232 adverse events in 12 patients in one clinical trial alone. See Transcript of the Biologics Response Modifiers Advisory Committee at 112-3 (Statements of Steven Fink, M.D.) (Pl. Ex. C). Second, the agency’s assertion that only six records concerning IND “G” – the portion of the Sample Vaughn index that is supposed to be “representative” of records pertaining to all 19 INDs – contain information about adverse events, Fourth Banks Decl. at ¶ 7, is directly contradicted by the agency’s earlier representation that at least 12 records contain information about adverse events concerning IND “G.” See Letter from Levy to Lovvorn (Mar. 23, 2001) (Pl. Ex. JJ); see also Rough Index (Pl. Ex. WW).

For all of these reasons, plaintiff wishes to take discovery to obtain additional information concerning the scope and manner of the agency’s search. See Rule 56(f) Fano Decl. ¶¶ 2, 12; see also e.g., Neugent v. Dep’t of Interior, 640 F.2d 386, 390-91 (D.C. Cir. 1981); Weisberg v. Dep’t of Justice, 543 F.2d 308 (D.C. Cir. 1976).

II. THE AGENCY’S LATEST DECLARATIONS DEMONSTRATE THAT RECORDS IT IS WITHHOLDING ARE “AGENCY RECORDS.”

The FDA’s assertion that “personal notes containing substantive information” – or, what the agency calls “marginalia,” see Fourth Banks Decl. at § E – are not “agency records” and, thus, are not within the scope of plaintiff’s FOIA request, is also contradicted by the agency’s latest declarations, which demonstrate that the records fall squarely within the Supreme Court’s well-established definition of “agency records,” as set forth in Dep’t of Justice v. Tax Analysts,

492 U.S. 136, 144-45 (1989) – a case that was conspicuously ignored by the government. As plaintiff demonstrated in its opening brief, at 41-42, the Supreme Court held that a record is an “agency record” if it was “either created or obtained” by the agency and the agency is “in control of the requested materials,” i.e., the records came “into the agency’s possession in the legitimate conduct of its official duties.” Id. at 144-45.

Here, the records at issue were clearly created by CBER scientists “in the legitimate conduct of [the FDA’s] official duties” – i.e., in the course of reviewing the INDs. See Second Frey-Vasconcells Decl. at ¶¶ 5-10; id. at ¶ 8 (“a reviewer considers the safety and scientific issues concerning the IND”). Thus, the records fall squarely within the Tax Analysts definition, and, accordingly, are subject to disclosure under the FOIA. Indeed, according to defendant’s most recent declarations, these records contain information about “the length of the clinical study, masking cells,” “initiation of cultures,” “testing for PERV,” “pathogen screening, testing of cells, clinical manufacturing, qualification of pig suppliers, PERV development program, sample testing, development of assays, and lot release of cells,” Fourth Banks Decl. at ¶ 20 – all of which clearly constitute “agency records” under Tax Analysts.¹²

Yet, to further demonstrate that these records are “agency records,” plaintiff would need discovery concerning their use. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶¶ 2, 13.¹³

¹² Ignoring the Tax Analysts test, the FDA instead relies on the “totality of the circumstances” test set forth in Bureau of Nat’l Affairs v. Dep’t of Justice, 742 F.2d 1484 (D.C. Cir. 1984), a case decided five years before Tax Analysts. Df. Memo. at 36 (emphasis added). However, in Bureau of National Affairs, the D.C. Circuit held that appointment materials, such as desk calendars and telephone logs that contain a “mix of personal and business entries” – a far cry from the records at issue here – are not ‘agency records’ under FOIA. Id. at 1486 (emphasis added).

¹³ To the extent that the government argues that, even if these records are “agency records,” they are nonetheless exempt under Exemptions 4 and 5, this argument fails for the same reasons that it fails with respect to the other records at issue in this case. See supra at 10-17.

III. PLAINTIFF IS ENTITLED TO IMMEDIATE RELIEF.

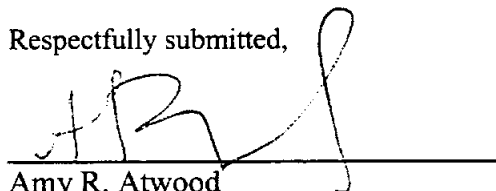
CRT is entitled to immediate relief in this case. First, the FDA still has not released all portions of records that, according to its own Sample Vaughn index, it has determined are not exempt. See Pl. Ex. ZZ at § 3. Second, more than two years after it first requested these records under the FOIA, CRT is still waiting to receive vast amounts of the requested information. As demonstrated in its opening brief and above, FDA is unlawfully withholding thousands of records by asserting that they are covered by several FOIA Exemptions – in their entirety – or are not even “agency records” under the Act, or because FDA has simply failed to conduct a search to locate all responsive records. Indeed, FDA’s conduct with regard to CRT’s FOIA request demonstrates a level of intransigence that should not be rewarded with any more delay in complying with the FOIA’s disclosure mandate. See 5 U.S.C. § 552(a); Jasper v. Carlton, Civ. No. 97-2105, slip. op. at 16-17 (D.D.C. Sept. 3, 1998) (Pl. Ex. OO) (given agency’s “apparent inability to prepare an inadequate index, and given FOIA’s ‘general philosophy of full agency disclosure,’” the government must “produce all agency records withheld as exempt”); see also Vaughn II, 523 F.2d at 1147 (where requester’s “case has been pending in administrative channels and before the courts for over three years,” the Court “grant[ed] plaintiff most of the records he requested of the [agency]”). Accordingly, under the circumstances of this case, CRT is entitled to all of the information that has been withheld.

However, if the Court agrees with CRT that FDA has not proven that all of these records may be lawfully withheld, but that summary judgment for CRT is not appropriate at this time, CRT requests that it be allowed to take discovery to obtain additional information to make its case. See Rule 56(f) Fano Decl. (Pl. Ex. QQ) at ¶ 2; see also e.g., Tax Analysts v. IRS, 214 F.3d 179, 185 (D.C. Cir. 2000) (discovery necessary to develop factual record).

CONCLUSION

For all of the foregoing reasons, as well as those set forth in plaintiff's memorandum in support of its motion for summary judgment, plaintiff's motion should be granted.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'AR', is written over a solid horizontal line.

Amy R. Atwood
(D.C. Bar No. 470258)
Katherine A. Meyer
(D.C. Bar No. 244301)
Jonathan R. Lovvorn
(D.C. Bar No. 461163)

Meyer & Glitzenstein
1601 Connecticut Avenue NW
Suite 700
Washington, D.C. 20009
(202) 588-5206
Attorneys for Plaintiff

May 8, 2002

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.

Civ. No. 00-2849 (RMU)

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Plaintiff's Reply Memorandum In Support of Motion for Summary Judgment and in Opposition to Defendant's Cross-Motion for Summary Judgment, Plaintiff's Response to Defendant's Statement of Material Facts, and Exhibits QQ-YY, were served, in the manner indicated below, this 8th day of May, 2002, on the following:

Brian Sonfield (via first class mail)
United States Attorney's Office
Judiciary Center Building
555 Fourth Street, NW
Washington, D.C. 20001

Candace Ambrose (via first class mail)
Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, Room 6B-12
Rockville, Maryland 20857
Richard Merrill (via first class mail)
Bruce N. Kuhlik

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

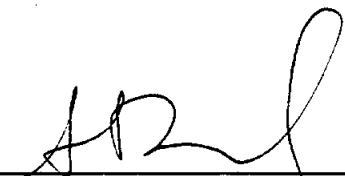
Robert A. Dormer (via first class mail)
Hyman, Phelps & McNamara, P.C.
700 13th Street NW, Suite 200
Washington, D.C. 20005

Robert M. Buchanan, Jr. (via first class mail)
Choate, Hall & Stewart
53 State Street
Exchange Place
Boston, MA 02109

Craig A. Hoover (via first class mail)
Jeffrey D. Pariser
Jeremy T. Monthly
Hogan & Hartson
555 13th Street NW
Washington, D.C. 20004

Roger W. Louis (via first class mail)
Genzyme Corporation
1 Kendall Square
Building 1400
Cambridge, MA 02139

John M. Engel, III (via first class mail)
Fox Kiser
750 17th Street NW, Suite 1100
Washington, D.C. 20006



Amy R. Atwood