

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR
RESPONSIBLE TRANSPLANTATION,

Plaintiff,

v.

Civ. No. 00-2849 (RMU/AK)

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant,

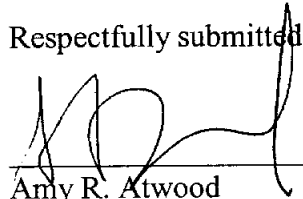
CIRCE BIOMEDICAL, INC., et al.,

Defendant-Intervenors.

PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, plaintiff Campaign for Responsible Transplantation moves the Court for summary judgment in this Freedom of Information Act case, on the grounds that there are no material facts in dispute and plaintiff is entitled to summary judgment as a matter of law. In support of this motion, plaintiff submits the accompanying memorandum of law, Exhibits 1-31, and a proposed Order.

Respectfully submitted,



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July 9, 2003

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**PLAINTIFF'S MEMORANDUM IN SUPPORT OF CROSS-MOTION FOR SUMMARY
JUDGMENT AND IN OPPOSITION TO FEDERAL DEFENDANT'S RENEWED
MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Having narrowed its request for information under the Freedom of Information Act, 5 U.S.C. § 552, *et seq.* (“FOIA”) throughout this litigation, and in response to the latest, “New Vaughn Index” produced by defendant Food and Drug Administration (“FDA”), *see* Defendant’s (“Df.”) New Vaughn Index (Df. Exhibit (“Df. Ex.”) B in Support of Renewed Motion for Summary Judgment, plaintiff Campaign for Responsible Transplantation (“CRT”) now narrows its request even further (without conceding that any such information is exempt from disclosure) to include only 34 records that FDA has withheld from disclosure pursuant to FOIA Exemptions 4 and/or 5, U.S.C. §§ 552(b)(4), (b)(5), and to exclude all information that would identify a particular sponsor of a clinical trial or the actual product to which the records at issue pertain. Plaintiff’s (“Pl.”) Index of Records Still At Issue (“Pl. Index”) (Plaintiff’s Ex. (“Ex.”) 1).

Thus, CRT no longer seeks access to information that identifies names of sponsors, diseases, products, or contractors, as well as cells used/studied, trial locations, manufacturing information, protocols, amendment reviews, quality assurance/control, preclinical studies results, or IND numbers. Nor does CRT seek records identified as “non-responsive” by FDA. Df. Memo. (Jun. 8, 2003) at 16-19. However, CRT continues to seek access to FDA-generated information concerning the public health risks posed by xenotransplantation – a biotechnology that poses a threat to human xenotransplantation patients, their close contacts, health care workers, and the public at large. As demonstrated below, defendants have failed to prove, as they must, that FDA may withhold this information under the FOIA, and, accordingly, CRT is entitled to summary judgment.¹

¹ Alternatively, as explained *infra* at 7-8, with respect to certain records that FDA has still failed to adequately describe, CRT would need to take limited discovery to further respond to FDA’s position that such records may continue to be withheld in their entirety. *See* Pl. Index at Docs. 201, 773, 775, 1088, 1357, 1364, 1863, 2093, 2280, 2390, 2610, 2713, 2783, 3006, 3016, 3098, 3591; *see also* 2d Decl. of Alix Fano Pursuant to Rule 56(f) (“2d Rule 56(f) Fano Decl.”)

BACKGROUND

A. The Public Health Threat Posed By Xenotransplantation

FDA defines 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.” PHS Guidelines On Infectious Disease Issues In Xenotransplantation (Jan. 19, 2001) (“PHS Guidelines”) (Ex. 3) at 15. Xenotransplantation includes Circe’s “HepatAssist System,” which uses live pig liver cells to mimic the blood-cleansing function of the human liver, Circe, HepatAssist System (Ex. 4), products injecting pig cells into patients’ brains to treat stroke, Parkinson’s and Huntington’s Diseases, Diacrin, Fact Sheets (Ex. 27, Attachments A, C), and genetically modified pigs cells that “trick” the immune system into recognizing the cells as “human.” 66 Fed. Reg. 4688, 4689 (Jan. 18, 2001) (Ex. 5).

As CRT has explained, Pl. 1st SJ Mem. at 6-13, xenotransplantation poses a public health threat, as studies show that xenotransplantation involving pigs threatens patients, their “close contacts,” and the public with the transmission of Porcine Endogenous Retroviruses (“PERVs”). Id. at 6. According to one expert, the “worst-case scenario” of PERV transmission is that a “new pandemic that would spread across the world, just like HIV.” Frontline: Organ Farm, Interview With Robin Weiss (2000) (“Weiss Interview”) (Ex. 6) at 9 (emphasis added). This threat has not abated

(Ex. 2) at ¶ 14. In addition, if the Court has any doubt that factual information being withheld under Exemption 5 is not exempt, CRT requests the Court to conduct an *in camera* inspection to insure that FDA has disclosed all non-exempt information in Docs. 201, 1364, 1863, 1913, 2001, 2007, 2093, 2280, 2390, 2610, 2713, 2762, 2783, 3024, 3098, 3144, 3245, 3476, 3585, 3590, and 3591.

– indeed, a recent study has revealed that PERVs replicate from infected human cells. Scheef, *et al.*, *Transcriptional Regulation of [PERVs]*, *Journal of Virology* (Dec. 2002) (Ex. 7).

Because xenotransplantation poses this health threat, experts, including FDA, have stressed that “it is vital that the public . . . be informed and educated about potential infectious disease risks.” 66 Fed. Reg. at 4695 (Ex. 5) (emphasis added); Frontline: Organ Farm, Interview with Fritz Bach (“Bach Interview”) (Ex. 8) at 1 (“[i]f we put the public at potential risk, we have to inform the public”); Trans., Biological Resp. Modifiers Adv. Cmte. (Dec. 17, 1997) (“BRMAC Transcript”) (Ex. 9) at 16, FDA Dep. Comm. Pendergast (“extensive public discussion and debate will be needed” because decisionmakers “have a duty to the public at large”).

However, despite this serious public health threat and other unanswered questions posed by xenotransplantation, FDA is allowing numerous clinical trials in humans to go forward. Thus, pursuant to its duty to regulate xenotransplantation products as “drugs,” “devices,” or “biological products” under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, the Public Health Service Act, 42 U.S.C. § 262(a), and FDA regulations, 21 C.F.R. Parts 310, 312, FDA has approved approximately 35 “investigational new drug” applications (“IND”), authorizing the IND sponsors to conduct xenotransplantation clinical trials in humans. PHS Guidelines (Ex. 3) at 4.²

² Indeed, from records disclosed to CRT during this lawsuit thus far, CRT has learned that Parkinson’s Disease patients participating in FDA-approved xenotransplantation clinical trials who had pig cells injected into their brains developed malignant cancers that had to be removed. *See* Docs. 367, 368, 473 (Ex. 10). In addition, records show that other patients experienced “adverse events” – including brain swelling, tremors, hallucinations, and body soreness. Docs. 9, 14, 159, 269, 488, 501, 592, 676 (Ex. 11). In one 1996 incident involving “an error in quality control,” a pig that might have tested positive for an infectious virus was used as a source animal for fetal neural tissue. Doc. 400 (Ex. 12).

B. Procedural History

To learn more about FDA's regulation of xenotransplantation clinical trials, on March 9, 2000, CRT – a public interest group concerned about xenotransplantation – requested “all records concerning applications for approval to conduct clinical trials in humans that involve xenotransplantation” and “all information concerning currently on-going and concluded clinical trials involving xenotransplantation.” See FOIA Request (Mar. 9, 2000) (Ex. 13). In its request, CRT specified that it was not seeking “any information that would identify a patient in any way, or involve the disclosure of any personal identifying information.” Id. at 1. To demonstrate to FDA that such information is not “confidential” commercial information within the meaning of Exemption 4 of the FOIA, CRT also attached many exhibits to its request demonstrating that companies that are conducting clinical trials have publicly disclosed numerous details about such trials, e.g., in press releases, journals, on websites, and during government advisory committee meetings. FOIA Appeal (Aug. 2, 2000) (Ex. 14). After receiving no response from FDA, CRT filed this suit on November 29, 2000. Many companies intervened to defend the alleged exempt status of records, including Circe Biomedical, Diacrin, Diacrin/Genzyme, Nextran, and Novartis; CRT narrowed its request to include only agency-generated records and moved for a Vaughn Index on May 29, 2001.

On July 23, 2001, the Court ordered FDA to produce a Sample Vaughn Index to defend its withholding of records. CRT v. FDA, 180 F. Supp. 2d 29, 33 (D.D.C. 2001). Thus, for responsive records that concern individual INDs, FDA was ordered to index records contained in a “representative” IND so the Court can “extrapolate its conclusions from the representative sample to the larger group of withheld material.” Id. (quoting Fensterwald v. CIA, 443 F. Supp. 667, 669 (D.D.C. 1977)). Accordingly, plaintiff selected IND “G” – to be used for this index. Letter from

Atwood to Sonfield, Levy (Aug. 3, 2001) (Ex. 15). All other responsive records were to be addressed in the Vaughn Index. CRT v. FDA, 219 F. Supp. 2d 106, 116 (D.D.C. 2002).

FDA produced its first Sample Vaughn Index on August 31, 2001, in which the agency claimed that thousands of FDA-generated records containing information about xenotransplantation clinical trials – including records concerning trials in general as well as records specifically concerning IND G – may be lawfully withheld from disclosure. See Df. Notice of Filing (Aug. 31, 2001). After the parties briefed the adequacy of the Vaughn Index in cross-motions for summary judgment, the Court held that FDA’s first Sample Vaughn Index was inadequate, ordered FDA to produce a second Sample Vaughn Index by November 11, 2002, and ordered the parties to renew settlement discussions. CRT v. FDA, 219 F. Supp. 2d at 116. At an October 16, 2002 Hearing, the Court stated that it expected FDA “to provide an adequate Vaughn index this time,” but that, if FDA’s Second Vaughn Index was “insufficient” then “the consequences to additional litigation may be more dire than those encountered so far.” Trans., Status Hearing (Oct. 16, 2002) (Ex. 16) at 2.

The FDA produced its second Sample Vaughn Index on December 20, 2002. In the absence of any sworn declarations justifying the exemption claims, on April 28, 2003, CRT nevertheless narrowed its request to 126 records that it still wished to pursue. Letter from Atwood to Counsel (Apr. 28, 2003) (Ex. 17). FDA then filed its Renewed Mot. on June 5, 2003, and intervenor Diacrin/Genzyme LLC filed a memorandum in support of the FDA’s motion on June 8, 2003.

C. Statutory Framework

The FOIA is intended “to facilitate public access to Government documents.” Dept. of State v. Ray, 502 U.S. 164, 173 (1991); Dept. of Justice v. Reporters Comm. for Freedom of Press, 489 U.S. 749, 775 (1989). The FOIA requires each federal agency to make requested records “promptly

available to any person” within 20 working days of receipt of the request, 5 U.S.C. §§ 552(a)(3), (a)(6)(A), and vests jurisdiction in the district courts “to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld.” *Id.* at § 552(a)(4)(B). The exclusive bases for withholding records are the nine exemptions provided in the Act. 5 U.S.C. §§ 552(b)(1)-(9); Anderson v. Dept. of HHS, 907 F.2d 936, 941 (10th Cir. 1990). Moreover, the agency bears the burden to prove that withheld records lawfully fall within a claimed exemption, *id.* at § 552(a)(4)(B), and, consistent with the Act’s goal of broad disclosure, all of the exemptions “must be narrowly construed.” Dept. of Air Force v. Rose, 425 U.S. 352, 361 (1976). Furthermore, the agency “shall” provide the requester with “[a]ny reasonably segregable portion” of an otherwise exempt record, “after deletion of the portions which are [lawfully] exempt.” 5 U.S.C. § 552(b); Schiller v. NLRB, 964 F.2d 1205, 1209 (D.C. Cir. 1992).

To prove that information may be lawfully withheld, the agency may rely on an index of the information. Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974) (“Vaughn I”). A Vaughn Index must include a sworn declaration or affidavit, *id.* at 826 n. 20, and “three indispensable elements”; it must (a) “adequately describe each withheld document or deletion from a released document,” (b) demonstrate that the documents may be lawfully withheld by “stat[ing] the exemption claimed for each deletion or withheld document, and (c) explain[ing] why the exemption is relevant.” Founding Church of Scientology of Washington, D.C. v. Bell, 603 F.2d 945, 949 (D.C. Cir. 1979). Such explanations cannot assert that the withheld information is exempt, but must offer a “relatively detailed analysis,” Oglesby v. U.S. Dept. of Army, 79 F.3d 1172, 1178 (D.C. Cir. 1996), that “correlat[es] those claims with the particular part of a withheld document to which they apply.” Mead Data Central, Inc. v. U.S. Dept. of Air Force, 566 F.2d 242, 251 (D.C. Cir.

1977). If the agency fails to prove that records may be lawfully withheld, the district court “has several options, including inspecting the documents in camera” and “allowing the plaintiff discovery.” Spirko v. U.S. Postal Service, 147 F.3d 992, 997 (D.C. Cir. 1998).

ARGUMENT

I. FDA’S VAUGHN INDEX FAILS TO ADEQUATELY DESCRIBE RECORDS.

In its September 3, 2002 Opinion, the Court admonished FDA that “descriptions” of records that “only provide a vague hint at the possible contents of the documents” “do[] not give the court or [CRT] the necessary functional description of the documents at issue.” CRT v. FDA, 219 F. Supp. 2d at 112. For example, the Court observed that a document described as “Internal Memo RE: Xeno” actually “represents a bevy of documents,” id. at 114, and held that the “indices fail to provide a basic functional description of many of the documents.” Id. (citing Oglesby II, 79 F.3d at 1184).

Yet, FDA has provided another Vaughn Index that is insufficient with respect to a number of the remaining 34 records at issue. See generally New Vaughn Index (Df. Ex. B); see also Pl. Index (Ex. 1). Thus, Doc. 3590 – a 44-page, “Undated” document – is described as “General: Transcript of minutes of internal meeting; re: xeno issues: informed consent, PERV assay, responses to docket on published draft guideline.” Similarly, Doc. 3098 – a 40 page document – is described only as “IND G: Internal Email Exchange re: Species and strains for xeno databases.” FDA describes other records as containing information about “a non-hold issue” (Doc. 773), “IND G: Internal Memo re: Telecon between FDA staff and sponsors regarding a clinical hold” (Doc. 3006), and “IND G: handwritten notes of telecon between FDA and sponsor re: PERV” (Doc. 3585).

In addition, for numerous records, FDA does not even know who wrote the records (author “Unknown” for Docs. 773, 2001, 2007, 2390, 2762, 3144, 3476, 3585, 3590), who received them

(recipient “Unknown” for Docs. 773, 775, 2001, 2007, 2390, 2762, 3006, 3024, 3144, 3476, 3585, 3590), or when they were generated (“Unknown” for Docs. 775, 2001, 2007, 2390, 2762, 3024, 3144, 3476, 3585, 3590). FDA also fails to identify the titles or positions of the documents’ authors and recipients. *Id.* Moreover, for Docs. 773, 775, 2762, 3006, 3098, 3476, and 3591, FDA does not explain which information is being withheld pursuant to which Exemption(s) or as “non-responsive,” thus failing to “state the exemption claimed for each deletion or withheld document, and explain why the exemption is relevant.” *Founding Church*, 603 F.2d at 949; *cf.* *CRT v. FDA*, 219 F. Supp. 2d at 115 (knowing the basis upon which a record has been withheld “is crucial” since “each category has a different legal standard”). Accordingly, and because FDA has already been given two opportunities to produce a sufficient *Vaughn* Index, the Court should order the disclosure of these records. *See Carlton v. DOI*, Civ. No. 97-2105, slip. op. at 16-17 (Sep. 3, 1998) (Kessler, J) (Ex. 31) (given its “apparent inability to prepare an adequate index” “and FOIA’s ‘general philosophy of full agency disclosure’,” agency must “produce all agency records withheld”).³

II. INFORMATION MAY NOT BE WITHHELD UNDER EXEMPTION 4.

A. The Applicable Standards

Under Exemption 4, FDA may withhold records that contain “trade secrets” or information that is (a) “commercial or financial,” (b) obtained from a person, and (c) “privileged or confidential.” 5 U.S.C. § 552(b)(4); *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 872 (D.C. Cir. 1992) (*en*

³ At minimum, for Docs. 201, 773, 775, 1088, 1357, 1364, 1863, 2093, 2280, 2390, 2610, 2713, 2783, 3006, 3098, 3585, and 3591, CRT needs discovery to obtain additional information that would allow it to further demonstrate to the Court why the records may not be withheld. *See* 2d Rule 56(f) Fano Decl. (Ex. 2) at ¶ 14.

banc) (citing Nat'l Parks & Conservation Ass'n. v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974)).

Information may be lawfully withheld as a “trade secret” only if the agency can prove that it is:

a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.

Pub. Citizen H.R.G. v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983) (“Pub. Citizen I”).

When – as here – the records are submitted to the agency mandatorily, commercial information is only “confidential” if disclosure is likely to “cause substantial harm to the competitive position of the person from whom the information was obtained.” Critical Mass, 975 F.2d at 873 (citing Nat'l Parks, 498 F.2d at 770). However, fear of “embarrass[ment]” or “unfavorable publicity” that may result from disclosure of requested information “simply do[es] not amount to ‘harm flowing from the affirmative use of proprietary information by competitors.’” CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1154 (D.C. Cir. 1987); Pub. Citizen I, 704 F.2d at 1291 n. 30 (“[c]ompetitive harm should not be taken to mean simply any injury to competitive position, as might flow from . . . the embarrassing publicity attendant upon public revelations”).

Moreover, the likelihood of “substantial competitive harm” must be proven by showing the existence of competition and that “substantial competitive injury would likely result from disclosure.” Niagara Mohawk Power Corp. v. DOE, 169 F.3d 16, 18 (D.C. Cir. 1999); see also Washington Research Project v. DHEW, 504 F.2d 238, 244 (D.C. Cir. 1974) (“the reach of” Exemption 4 “is not necessarily coextensive with the existence of competition in any form”). In addition, requested information must be disclosed if identical information is in the public domain, since such information can no longer be considered “confidential.” Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 244 F.3d 144, 150 (D.C. Cir. 2001). Thus, “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.” *Id.*; see also Pub. Citizen H.R.G. v. FDA, 185 F.3d 898, 904 (D.C. Cir. 1999) (“Pub. Citizen II”) (FOIA’s public interest is to facilitate “learn[ing] something directly about the workings of the *Government*”) (emphasis supplied).

B. FDA And Intervenors Have Failed To Prove That Substantial Competitive Harm Will Likely Result From Disclosure Of The Requested Information.

The information that FDA has withheld under Exemption 4 falls within three categories: (1) clinical hold information (Docs. 775, 3006, 3016); (2) information concerning side effects, adverse events, and the methods used to detect PERVs and reduce the likelihood of transmission of PERVs to patients – *i.e.*, “PERV assays” and “PERV testing” (Docs. 2762, 3476, 3585, 3591); and (3) factual information about clinical trials, including the importation of transgenic animals from the United Kingdom, number of patients, patients enrolled and treated, and a “Review of Sponsor Xenotransplantation Interim Regulatory Authority meeting” (Docs. 2280, 2762, 3476, 3591).

1. Clinical Hold Information

FDA may put an IND on “clinical hold” if, *e.g.*, patients “are or would be exposed to an unreasonable and significant risk of illness or injury,” 21 C.F.R. § 312.42(b)(1)(i), or if “it would not be in the public interest for the study to be conducted or continued.” *Id.* at § 312.42(b)(4)(viii). If FDA imposes a clinical hold on a product, the sponsor may no longer dispense it and may only resume the investigation if it “corrects the deficiency(cies)” or “otherwise satisfies the agency that the investigation(s) can proceed.” *Id.* at § 312.42(b)(6)(e). Here, FDA and Diacrin have failed to

prove that disclosure of records containing clinical hold information will likely result in substantial competitive harm. See Pl. Index (Ex. 1) at Docs. 775 (pp. 1-2), 3006, 3016.

To begin with, in its sworn declarations, FDA does not even contend that clinical hold information contained in Doc. 775 is “confidential commercial information.” In fact, the solitary instance where FDA does make any attempt to prove that it may withhold clinical hold information as confidential commercial information is in its New Vaughn Index, which is an unsworn document. See New Vaughn Index (Df. Ex. B), e.g., at Doc. 775. However, since one of the elementary requirements of a Vaughn Index relied upon to demonstrate that the agency has met its burden of proof is that the index must be sworn by an agency official or employee who is familiar with the contents of the records, Vaughn I, 484 F.2d at 827 n. 20, this unsworn Vaughn Index does not provide a valid basis for withholding this information. Accordingly, plaintiff is entitled to summary judgment as to the redacted clinical hold information that is contained in Doc. 775.

While Diacrin CEO Michael Egan does assert that clinical hold information in connection with IND G – the IND used for the Sample Vaughn Index – is confidential commercial information, see Supp. Declaration of Michael Egan (“Supp. Egan Decl.”) (Ex. 18) at ¶ 3, the alleged harm falls woefully short of what is required to prove that the release of such information would result in “substantial competitive harm.” See Pub. Citizen II, 185 F.3d at 906 (“[c]onclusory and generalized allegations of substantial competitive harm . . . cannot support an agency’s decision to withhold requested documents”) (quoting Pub. Citizen I, 704 F.2d at 1291).

Indeed, Mr. Egan’s assertions “professing the extent of competitive injury [Diacrin] would suffer from disclosure” of clinical hold information in IND G fall far short of the level of detail

deemed inadequate by the Court of Appeals in Pub. Citizen II, 185 F.3d at 906, where a drug IND sponsor, Schering Corporation, asserted that disclosure:

‘would reveal substantial basic research’ as well as ‘disease models . . . that have been developed by Schering at a great expense,’ and that ‘[t]oxicology data . . . have significant value beyond the compound under investigation . . . [and would be applicable] to any drug product any of whose metabolites were identical or similar to those of [the IND] . . . [and] other drugs [of] a similar chemical type.’

Id. The Court of Appeals concluded that these claims – and the “even more general” arguments in Schering’s brief, i.e., that “disclosure would reveal its ‘assessment of regulatory requirements and its experience with FDA in this area, as well as [its] judgment as to what requirements will be necessary in order to establish the drug’s safety and effectiveness,’” id. – amounted to the kind of “[c]onclusory and generalized allegations of substantial competitive harm” that “cannot support an agency’s decision to withhold requested documents.” Id. (quoting Pub. Citizen I, 704 F.2d at 1291) (emphasis added). Accordingly, the Court “that the [FDA] may not withhold the disputed documents” in Schering’s IND under Exemption 4. Id.

Yet, even the “conclusory and generalized allegations of substantial competitive harm” in that case provide far more detailed evidence of competitive harm than that found in Diacrin’s declaration concerning clinical hold information in this case. Compare Declaration of Ronald J. Garutti, M.D., Pub. Citizen II (Ex. 19) with Supp. Egan Decl. (Ex. 18). Thus, other than stating that this information “is trade secret or confidential commercial information exempt from disclosure,” Supp. Egan Decl. at ¶ 3, Mr. Egan notes that two clinical hold letters contain information about “animal handling, animal husbandry, and the animal models used in preclinical testing” and that another record contains “proprietary details related to the results of preclinical testing” and “business strategies” – information which CRT no longer seeks. Id. at ¶¶ 3(a)-(c). These sweeping assertions

do not come anywhere close to the kind of evidence of competitive harm that was flatly rejected in Pub. Citizen II. Accordingly, plaintiff is entitled to summary judgment as to the clinical hold information in Docs. 775, 3006, and 3016.⁴

2. Side Effects, Adverse Events, And PERVs

FDA and intervenors also assert that information about side effects, adverse events, and PERVs is confidential commercial information that may lawfully be withheld from CRT under Exemption 4. See 2d Brockner Ryan Decl. (Ex.) at ¶ 12(a); Aff. of Michael Egan (“Egan Aff.”) (Ex. 21) at ¶ 29; Declaration Regarding Privilege Determination (Ex. 22) at ¶ 4(e); Decl. of John Logan (“Logan Decl.”) (Ex. 23) at ¶¶ 13, 17; Decl. of Elizabeth Chen (“Chen Decl.”) (Ex. 24) at ¶ 4. However, like Diacrin’s attempt to withhold clinical hold information, FDA and Diacrin provide only “conclusory assertions” of any such harm.

For instance, the FDA declarant states that release of information about PERV assays:

if released to the public . . . could be detrimental to the sponsor’s competitive position by enabling competitor sponsors to reduce research costs in their own clinical trials and to develop their clinical trials at a lower cost by avoiding difficulties the initial sponsor spent time and money to overcome.

2d Brockner Ryan Decl. at ¶ 12(a). Again, this is the kind of “generalized” allegation that the Court of Appeals rejected in Pub. Citizen II. 185 F.3d at 906. In addition, for records in this category

⁴ Mr. Egan also contends that some records are “trade secrets” under Exemption 4, but fails to provide any evidence that any of the information is a “secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort, as required by Pub. Citizen I, 704 F.2d at 1288. In addition, in failing to distinguish whether clinical hold information is “trade secret” or “confidential commercial information,” Mr. Egan also ignored this Court’s admonition that the difference between “trade secret” and “confidential commercial information” is “crucial, since each category has a different legal standard.” CRT v. FDA, 219 F. Supp. 2d at 115 (emphasis added).

unrelated to IND G (Docs. 2762, 3591), the agency would be hard pressed to demonstrate how disclosure of information about side effects, adverse events, survival rates in patients, PERV assays, and PERV testing will cause “substantial competitive harm,” since CRT no longer seeks records revealing the names of sponsors, diseases, or products, making it extremely difficult to correlate the information to any particular sponsor. See supra at 1; see also, e.g., McDonnell Douglas Corp. v. U.S. Dept. of Air Force, 215 F. Supp. 2d. 200, 208 (D.D.C. 2002) (there is “serious doubt o[f] the likelihood that any of the disputed information would be likely to cause substantial harm” where too many “variables” are needed to deduce sensitive information); Pub. Citizen H.R.G. v. FDA, 539 F. Supp. 1320, 1327 (D.D.C. 1982) (it is “hard to conceive of how substantial competitive injury would result” from release of commercial information “void of specific information on particular companies”). Similarly, rather than explaining whether the information constitutes “trade secrets” or “confidential commercial information,” or explaining why disclosure would result in substantial competitive harm, Mr. Egan merely claims that disclosure of “details of” side effects and PERV assays concerning records in IND G is “strictly confidential to Diacrin and include[s] trade secrets.” Egan Aff. (Ex. 21) at ¶ 29.

Unfortunately, these examples are not unique, but, rather, are illustrative of the entire sum of evidence of “substantial competitive harm” that has been generated by the defendants as to this information. See also, e.g., Chen Decl. (Ex. 24) at ¶¶ 4, 11 (disclosure of information about adverse events “would competitively harm Circe because” it “would allow competitors to free-ride on the work that Circe has already done”); Logan Decl. (Ex. 23) at ¶¶ 13, 18 (disclosure of information about the “development of assays” “would allow a competitor to develop those specifications without investing either time or money” and “stifle the development of promising therapies to treat

organ failure and impair access of patients to novel biotechnologies”). Yet, despite FDA’s and intervenors’ apparent view that information is “trade secret or confidential commercial information” merely because they assert that it is, see, e.g., Egan Aff. (Ex. 21) at ¶ 4, much more is required to carry the government’s burden of proof. See CRT v. FDA, 219 F. Supp. 2d at 115 (the difference between “trade secret” and “confidential commercial information” is “crucial, since each category has a different legal standard”); Pub. Citizen I, 704 F.2d at 1290 (“not every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4”). Therefore, because the FDA has failed to meet its burden of proof – for the second time – plaintiff is entitled to summary judgment as to information about side effects, adverse events, PERV assays, and PERV testing in Docs. 2762, 3476, 3585, and 3591.

3. Factual Information Concerning Xenotransplantation INDs

FDA and intervenors contend that disclosure of factual information, i.e., “the importation of transgenic animals from UK [for] breeding facilities” (Doc. 2280), “number[s] of patients” (Doc. 2762), “patients enrolled/treated” (Doc. 3476), and a “Review of Sponsor Xenotransplantation Interim Regulatory Authority meeting” (Doc. 3591) will cause substantial competitive harm.

For instance, according to FDA’s most recent Vaughn Index and memorandum, Doc. 2762 contains redacted information about the “number of patients” for unidentified INDs. See Pl. Index (Ex. 1 at Doc. 2762); Doc. 2762 (Ex. 25). Yet, FDA never articulates any discernible rationale for its assertion that the number of xenotransplantation patients involved in a particular IND would likely cause substantial competitive injury, other than the conclusory assertion that the disclosure of such information would give a “rival sponsor a competitive advantage” by revealing “study designs and protocols,” the development of assays, or information regarding the production of certain cells.

See 2d Brockner Ryan Decl. (Ex. 20) at ¶¶ 11-12. Thus, since FDA fails to justify its withholding of this information, CRT is entitled to summary judgment.⁵

C. FDA May Not Withhold Information Based On Sponsors' Fear Of Criticism.

Diacrin's Mr. Egan and Nextran's Mr. Logan also contend that they will suffer substantial competitive harm if records withheld under Exemption 4 are disclosed because of how the information might be used. Thus, Mr. Egan claims that "Diacrin's rivals would have a chance to pull information out of context." Egan Aff. (Ex. 21) at ¶ 35. In addition, perhaps alluding to the heart of the matter, Mr. Logan argues that if adverse event information were disclosed, then "[c]learly, . . . opponents of xenotransplantation" – such as CRT – "could use that information to inaccurately depict the risks associated with clinical trials." Logan Decl. (Ex. 23) at ¶ 17.

However, as explained supra at 9, the law in this Circuit is crystal clear that such "complaints" of "unfavorable publicity" "simply do not amount to 'harm flowing from the affirmative use of proprietary information by competitors.'" CNA Fin. Corp., 830 F.2d at 1154 (emphasis added); see also id. ("complaints" of "unfavorable publicity are "unrelated to the policy behind Exemption 4 of protecting submitters from external injury"); Pub. Citizen I, 704 F.2d at 1291 n. 30 ("[c]ompetitive harm should not be taken to mean simply any injury to competitive position,

⁵ Moreover, FDA's regulations governing INDs include only one provision that alludes to the "number of patients" that participate in clinical trials. 21 C.F.R. § 312.21 (prescribing the phases of INDs, including the number of patients that must participate in each phase of clinical trials). Thus, Phase I trials involve 20-80 patients, Phase II trials involve several hundred patients, and Phase III trials involve up to several thousand patients Id. at §§ 312.21(a)(1), (b), (c). These figures are not limited to any particular time frame, so information revealing how many patients participated in an IND in any given year, or how many participated by September, 1998, will not somehow "giv[e] a rival sponsor a competitive advantage," let alone cause the submitter "substantial competitive harm." See 2d Brockner Ryan Decl. (Ex. 20) at ¶ 11.

as might flow from . . . the embarrassing publicity attendant upon public revelations”). Thus, this simply is not a legitimate basis to withhold information from CRT.

Moreover, a public debate over the “benefits and risks” attendant to xenotransplantation is precisely what experts have stressed is absolutely necessary. See, e.g., Bach Interview (Ex. 8) at 3. Yet, since FDA and xenotransplantation IND sponsors alone have all of the facts at their disposal, any attempt by CRT – or the public at large – to engage in a meaningful public debate about the benefits and risks of xenotransplantation, including the FDA’s role in regulating this highly controversial biotechnology, is severely crippled, if not impossible – a result that is completely at odds with the core purpose of the FOIA. Pub. Citizen II, 185 F.3d at 904 (FOIA serves public interest by exposing the “workings of the Government”); see also Bach Interview at 4 (“we need a discussion with select informed groups” “who will . . . cross-examine the experts”).

D. FDA May Not Withhold Information That Has Been Publicly Disclosed.

Furthermore, sponsors of xenotransplantation INDs have willingly shared large amounts of information about their products, including information concerning clinical holds, side effects, adverse events, PERV testing, and PERV assays – thus, their claims about substantial competitive injury ring hollow. See 2d Rule 56(f) Fano Decl. (Ex. 2) at ¶ 9 (noting that “[a]nyone who follows the issue of xenotransplantation clinical trials knows about the companies’ disclosures of information about their products”). Indeed, as CRT demonstrated in its first summary judgment memorandum at 13-19, and according to the FDA itself, see 66 Fed. Reg. at 4691 (Ex. 5), sponsors of xenotransplantation INDs have disclosed vast amounts of information about their products on

websites, during open BRMAC sessions and Public Health Service workshops, and in filings with the SEC, disclosure which has been done in an effort to promote “investment opportunities.” *Id.*⁶

For example, Diacrin claims that clinical hold and adverse event information – including, *e.g.*, Doc. 3016, which contains clinical hold information – “is trade secret or confidential information” that is “exempt from disclosure.” Supp. Egan Decl. (Ex. 18) at ¶¶ 3(a), (b). Yet, this assertion is completely undermined by the company’s own disclosure of the same kinds of allegedly “proprietary” information. *See, e.g.*, Diacrin Press Release (Apr. 17, 2000) (Ex. 29) (reporting that Diacrin “put on hold a Phase I clinical trial using porcine fetal neural cells in stroke patients” due to the need to “investigate[] the cause of two adverse events”).

Indeed, when Diacrin advertised its xenotransplantation products and solicited investments from the public, it revealed many details about a clinical hold for its product for stroke treatment, *i.e.*, that “[a]t the time the trial was suspended [Diacrin] had treated 5 patients,” Diacrin, Porcine Neural Cells for Stroke (Ex. 27, Attachment (“Att.”) D), that “[b]oth patients who suffered adverse events have recovered,” and that, after reviewing “the scientific and clinical information relating to these adverse events,” Diacrin “concluded that they were most likely associated with the surgical procedure used to implant the cells.” Diacrin Press Release (Ex. 29) at 2; *see also* Diacrin Product Development Programs (Ex. 27, Att. I) (numbers of potential patients for each product).

Thus, it could not be clearer that, in this lawsuit, Diacrin, Diacrin/Genzyme, and Nextran have set forth unsubstantiated claims that information about clinical holds and adverse events is confidential commercial information, while simultaneously “cherry-picking the details to be made

⁶ For the Court’s convenience, CRT has created exhibits of public disclosures of information by intervenors. *See* Publicly Disclosed Information: Circe Biomedical (Ex. 26), Diacrin and Diacrin/Genzyme (Ex. 27), and Nextran (Ex. 28).

public” – based on their own, undecipherable rationale – a result that the “FOIA was designed to preclude.” Army Times Pub. Co. v. Dept. of Air Force, 998 F.2d 1067, 1072 (D.C. Cir. 1993). Moreover, since the overwhelming abundance of evidence in this record demonstrates that sponsors of xenotransplantation INDs have not themselves regarded such information to be “confidential,” their convenient assertions of confidentiality here are completely unavailing. Anderson, 907 F.2d at 952 (citing CNA Fin. Corp., 830 F.2d at 1154) (“Because materials such as these appear to be in the public domain, no meritorious claim of confidentiality can be made.”) (emphasis added). Indeed, because the FDA has never undertaken any analysis of whether information that has been withheld from CRT has already been publicly disclosed by the sponsors of these clinical trials, it cannot demonstrate that such information is “confidential.” See id.⁷

E. The Public Interest Weighs Heavily In Favor Of Disclosure.

Even if the companies had proven that they would likely suffer substantial competitive harm if the Court orders the disclosure of information concerning clinical holds, side effects, adverse events, PERV testing, PERV assays, and other factual information, the overwhelming public interest in disclosure still precludes FDA from withholding these records. Pub. Citizen H.R.G. v. NIH, 209 F. Supp. 2d 37, 45 (D.D.C. 2002) (noting the “central role a rough balancing must play between the

⁷ When CRT made this point in its first summary judgment brief, FDA responded in a declaration that stated that “[i]nformation in the IND that has been publicly disclosed was released to Plaintiff.” See Fourth Banks Decl. at ¶ 24. But in its brief, FDA provided a modified version of this assertion by stating that “[i]nformation in the IND that FDA is aware is public has been produced to Plaintiff.” Df. 1st Memo. at 20 (emphasis added). However, when plaintiff questioned this inconsistency, and pointed out that the FDA had conspicuously failed to state whether it included all of the information submitted by CRT as Exhibits to its FOIA request, see Pl. 1st Reply Memo. to FDA at 14, FDA failed to respond further. See Df. 1st Reply Memo. at 4-5. In its most recent summary judgment brief, FDA does not rely on the Fourth Banks Declaration, nor address this extremely salient point at all.

private and public interests when considering a withholding under exemption 4”) (citing Pub. Citizen II, 185 F.3d at 904). Indeed, where xenotransplantation experiments undeniably pose a significant threat to the general public, the issue of whether – and, if so, to what extent – the FDA is monitoring xenotransplantation experiments in humans is of vital interest to the public. As Nextran itself has noted, “public awareness and understanding of xenotransplantation are vital because the infectious disease risks posed by xenotransplantation could extend beyond the individual patient to the public at large.” Logan Decl. (Ex. 23) at ¶ 18. Thus, since the public needs to know whether the government is adequately protecting it against the “worst-case scenario” that FDA could be facilitating a “new pandemic that would spread across the world, just like HIV has done,” see Weiss Interview (Ex. 6) at 9 (emphasis added), the balance weighs heavily in favor of disclosure, especially in light of defendants’ failure to prove substantial competitive harm.

Accordingly, for these reasons, CRT is entitled to summary judgment as to the information withheld under Exemption 4 in Docs. 775, 2280, 2762, 3006, 3016, 3476, 3585, and 3591.⁸

II. FDA HAS FAILED TO DEMONSTRATE THAT THE AGENCY MAY LAWFULLY WITHHOLD INFORMATION UNDER EXEMPTION 5.

FDA is withholding 25 records in their entirety pursuant to Exemption 5’s deliberative process privilege, see Pl. Index (Ex. 1), including: (1) eight records reflecting decisions already made by the agency (id. at Docs. 775, 1088, 1357, 2001, 2007, 2093, 3144, 3245); and (2) 21 records

⁸ Since IND G is purportedly representative of the other INDs still at issue, plaintiff is also entitled to disclosure of information about clinical holds, side effects, adverse events, PERV testing, and PERV assays contained in each of the other INDs. CRT v. FDA, 180 F. Supp. 2d at 33 (purpose of the sample Vaughn Index is to allow the Court to “extrapolate its conclusions from the representative sample to the larger group of withheld material”).

consisting of purely factual information (*id.* at Docs. 201, 1357, 1364, 1863, 1913, 2001, 2007, 2093, 2280, 2390, 2610, 2713, 2762, 2783, 3024, 3098, 3144, 3476, 3585, 3590, 3591).

Exemption 5 excludes “inter-agency or intra-agency memorandums or letters which would not be available by law to a party . . . in litigation with the agency,” 5 U.S.C. § 552(b)(5), including “documents protected by the . . . ‘deliberative process’ privilege.” Petroleum Info. Corp. v. DOI, 976 F.2d 1429, 1433 (D.C. Cir. 1992) (citing NLRB v. Sears, Roebuck, & Co., 421 U.S. 132, 150-53 (1975)). Exemption 5’s “deliberative process privilege” “shields only government ‘materials which are both predecisional and deliberative.’” Tax Analysts v. IRS, 117 F.3d 607, 616 (D.C. Cir. 1997) (citation omitted). Information is “predecisional” if it was ‘prepared in order to assist an agency decisionmaker in arriving at his decision,’ rather than to support a decision already made.” Petroleum, 976 F.2d at 1434 (emphasis added). Information is “deliberative” “if it ‘reflects the give-and-take of the consultative process.’” NAHB v. Norton, 309 F.3d 26, 39 (D.C. Cir. 2002) (quoting Petroleum, 976 F.2d at 1434).

To prove that materials are deliberative, FDA must show that they “bear on the formulation or exercise of agency policy-oriented *judgment*.” Petroleum, 976 F.2d at 1435 (emphasis supplied). Thus, the court “must be able to pinpoint an agency decision or policy to which the document contributed.” Senate of the Cmwlth of Puerto Rico v. DOJ, 823 F.2d 574, 585 (D.C. Cir. 1987) (emphasis added) (quoting Paisley v. CIA, 712 F.2d 686, 698 (D.C. Cir. 1983)). In addition, the privilege does not protect decisional documents or materials that support agency decisions already made. Sears, 421 U.S. at 151-53, 155-59. Finally, except in rare cases, an agency may not withhold factual information under the privilege, but must segregate it from the exempt material and disclose it to the requester. Petroleum, 976 F.2d at 1434 (citing EPA v. Mink, 410 U.S. 73, 87-91 (1973)).

A. FDA Must Disclose Decisional Documents And Records That Explain An Agency Decision Already Made.

FDA is withholding eight records that either are themselves decisional documents or explain decisions already made by the agency or its employees. Thus, FDA is withholding the “reasons why [an] IND was placed on hold,” (Doc. 775), information concerning the “[l]ife long xenotransplantation requirements” that apply “if [a] sponsor withdraws” its IND (Doc. 1088), records of “adverse events to be reported” to the National Xenotransplantation Database (“NXD”) and “NXD Patient Adverse Event” (Doc. 2001; see also Doc. 3144), a chart “showing the NXD Reportable Adverse Events, separating events that need to be reported” from “events that do not” (Doc. 2007), “steps to inactivate a virus” (Doc. 2093), and a “brief description of steps being taken to deal with the issue of potential spread of infectious agents by xenotransplantation” (Doc. 3245). See also Doc. 1357 (“IND G: memo re: Holds For Lack of Assays, addresses a numbered regulation in relation to a clinical hold”).⁹

Because all of these records are either themselves decisional documents, Sears, 421 U.S. at 151-53, or “support a decision already made,” they are not “predecisional” to any agency policy judgment. Petroleum, 976 F.2d at 1434. Thus, CRT is entitled to summary judgment as to Docs. 775, 1088, 1357, 2001, 2007, 2093, 3144, and 3245.

B. FDA Is Withholding Factual Information As Deliberative.

FDA is also withholding as “deliberative” 21 records that, according to the agency’s own descriptions, contain factual material. Thus, the agency is claiming that factual information about,

⁹ Moreover, to the extent that any of this information has been shared with any of the sponsors, it simply may not be withheld under Exemption 5. Mead Data, 566 F.2d at 365 (materials are not “deliberative” when exchanged between agency and “outside party”).

e.g., the “Effects of Xenotransplantation in Humans” (Doc. 201), a “list of competing xenotransplantation products” (Doc. 1489), and information about “steps to inactivate a virus” (Doc. 2093) may be withheld as deliberative. Indeed, FDA claims that records containing data (Doc. 2713), or an “interpretation of data” (Doc. 1364) are deliberative, which, under well-established FOIA jurisprudence, simply is not the case. See Petroleum, 976 F.2d at 1436-37; see also Vaughn v. Rosen, 523 F.2d 1136, 1145 (D.C. Cir. 1975) (agency may not withhold “the raw data upon which decisions can be made” since “they are not themselves a part of the decisional process); Playboy Enterprises v. DOJ, 677 F.2d 931, 935 (D.C. Cir. 1982) (fact report not within privilege because compilers’ mission was simply “to investigate the facts”); Carter v. Dept. of Commerce, 307 F.3d 1084, 1085 (9th Cir. 2002) (agency may not withhold “statistically adjusted data” as deliberative).

Thus, these are “materials relating to routine computations or measurements over which the agency has no significant discretion” – i.e., the kind of “materials that do not embody agency judgments” that may be withheld as deliberative. Petroleum, 976 F.2d at 1436; see also Sterling Drug v. Harris, 488 F. Supp. 1019, 1028-29 (S.D.N.Y. 1980) (objective medical analyses of drug test may not be withheld as “deliberative”); Union of Concerned Scientists v. NRC, 2 Med. L. Rpt. 1458 (D.D.C. 1977) (expert scientific opinions not exempt under Exemption 5). Nor are they the kind of facts that reflect “political concerns,” the “interpretation of ‘complex and controversial events,’ ” id., or “summaries of facts,” the disclosure of which would reveal the agency’s deliberations – i.e., the only bases upon which Court of Appeals has held that an agency may attempt to establish that factual information is nevertheless deliberative. See id. (citing Quarles v. Dept. of Navy, 893 F.2d 390, 393 (D.C. Cir. 1990) (quotation omitted); Montrose Chemical v. Train, 491 F.2d 63 (D.C. Cir. 1974). Accordingly, CRT is entitled to summary judgment as to the factual information in Docs. 201, 1357,

1364, 1863, 1913, 2001, 2007, 2093, 2280, 2390, 2610, 2713, 2762, 2783, 3024, 3098, 3144, 3476, 3585, 3590, and 3591.

C. The FDA Has Failed To Identify Any Agency Policy Judgment To Which The Records Relate.

Moreover, for all of the records that FDA claims are “predecisional and deliberative,” the agency has failed to “pinpoint an agency decision or policy to which the document contributed.” See Senate of the Cmwltth of Puerto Rico, 823 F.2d at 585. Thus, the agency’s declarants ambiguously and variously assert that records are “one step in the process FDA utilizes to review and approve INDs,” 2d Brockner Ryan Decl. (Ex. 20) at ¶15(a), “part of the give-and-take of FDA’s decision-making process,” id. at ¶15(b), id. at ¶15(c), or predecisional and deliberative to “the development of FDA policies about xenotransplantation policies in general.” Second Decl. of Joyce Frey-Vasconcells (Ex. 30) at ¶ 12 (emphasis added). Yet, this is a severely overbroad application of Exemption 5, since “a continuing process of agency self-examination” is not enough to render a document predecisional, Maricopa Audubon Soc’y v. USFS, 108 F.3d 1089, 1094 (9th Cir. 1997), and under FDA’s construction, an agency could rely on such shifting agency “policy” decisions to withhold virtually every record it generates. Petroleum Information, 976 F.2d at 1436 n. 8 (“[e]ven the most mundane material could be said to reflect the exercise of agency discretion in some sense”).¹⁰

¹⁰ FDA asserts that “[t]he existence of the privilege does not depend on the agency’s ability to identify a specific decision to which the records relate,” see Df. Memo. at 12 (citing Sears, 421 U.S. at 151 n. 18), but FDA’s reliance on footnote 18 in Sears is seriously misplaced. The Court of Appeals has made clear that “if documents are not a part of a clear ‘process’ leading to a final decision on the issue, as they were in both the Sears and Grumman cases, they are less likely to be properly characterized as predecisional; in such a case there is an additional burden on the agency to substantiate its claim of privilege.” Coastal States Gas Corp. v. DOE, 617 F.2d 854, 868 (D.C. Cir. 1980).

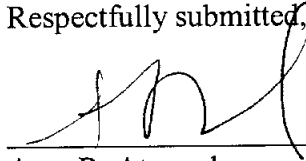
Indeed, for 10 records, the agency concedes that it does not even know who wrote the records (author “Unknown” for Docs. 773, 2001, 2007, 2390, 2762, 3144, 3476, 3585, 3590), who received them (recipient “Unknown” for Docs. 773, 775, 2001, 2007, 2390, 2762, 3006, 3024, 3144, 3476, 3585, 3590), or when they were generated (“Undated” or date “Unknown” for Docs. 775, 2001, 2007, 2390, 2762, 3024, 3144, 3476, 3585, 3590). Also, for all of the records, FDA does not identify the “titles and positions of the documents’ authors and recipients.” ALDF v. Dept. of Air Force, 44 F. Supp. 2d 295, 300-01 (D.D.C. 1999) (where agency failed to “provide[] dates or indicate[] the titles and positions of the documents’ authors and recipients,” it could not “explain how they factored into the deliberative process”). In the absence of such crucial information, it is impossible to understand how FDA can claim that these records are nonetheless predecisional and deliberative, when it cannot even explain when the record was generated, let alone how the document was “prepared in order to assist an agency decisionmaker in arriving at his decision.” Grumman, 421 U.S. at 184. Thus, CRT is entitled to summary judgment as to these records.¹¹

CONCLUSION

For all of the foregoing reasons, summary judgment should be entered in favor of CRT, and FDA should be ordered to disclose the documents for which the agency has repeatedly failed to carry its burden to prove they are exempt. See Carlton, slip. op. at 16-17 (Ex. 31) (given the agency’s “apparent inability to prepare an adequate index” “and FOIA’s ‘general philosophy of full agency disclosure’,” agency must “produce all agency records withheld”).

¹¹ Moreover, for one of these records, the FDA claims that the record was generated by a “Sponsor,” id. at Doc. 3024 (emphasis added), which, if true, obviously means that it absolutely cannot be withheld under Exemption 5. Mead Data, 566 F.2d at 365 (materials are not “deliberative” when exchanged between agency and “outside party”). Thus, this record must be immediately disclosed.

Respectfully submitted,



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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/AK)

PLAINTIFF'S STATEMENT OF MATERIAL FACTS

Pursuant to Local Rule 7.1(h), plaintiff Campaign for Responsible Transplantation ("CRT") submits this statement of material facts:

1. Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, et seq. ("FOIA"), on March 9, 2000, CRT – a public interest group concerned about the risks and issues associated with xenotransplantation – requested from the Food and Drug Administration ("FDA") "all records concerning applications for approval to conduct clinical trials in humans that involve xenotransplantation" and "all information concerning currently on-going and concluded clinical trials involving xenotransplantation." See FOIA Request (Mar. 9, 2000) (Plaintiff's Exhibit ("Ex.") 13).

2. Xenotransplantation poses a public health threat, as studies show that xenotransplantation involving pigs threatens patients, their "close contacts," and the public with the transmission of Porcine Endogenous Retroviruses ("PERVs"). According to one expert, the "worst-

case scenario” of PERV transmission is that a “new pandemic that would spread across the world, just like HIV.” Frontline: Organ Farm, Interview With Robin Weiss (2000) (“Weiss Interview”) (Ex. 6) at 9. A recent study found that PERVs replicate from infected human cells. Scheef, et al., Transcriptional Regulation of Porcine Endogenous Retroviruses, Journal of Virology (Dec. 2002) (Ex. 7).

3. Because xenotransplantation poses this health threat, experts, including FDA, have stressed that “it is vital that the public . . . be informed and educated about potential infectious disease risks.” 66 Fed. Reg. at 4695 (Ex. 5); Frontline: Organ Farm, Interview with Fritz Bach (“Bach Interview”) (Ex. 8) at 1 (“[i]f we put the public at potential risk, we have to inform the public”); Trans., Biological Resp. Modifiers Adv. Cmte. (Dec. 17, 1997) (“BRMAC Transcript”) (Ex. 9) at 16, FDA Dep. Comm. Pendergast (“extensive public discussion and debate will be needed” because decisionmakers “have a duty to the public at large”).

4. FDA has approved approximately 35 investigational new drug applications (“IND”), thereby allowing xenotransplantation clinical trials in humans to go forward, pursuant to its duty to regulate xenotransplantation products as “drugs,” “devices,” or “biological products” under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., the Public Health Service Act, 42 U.S.C. § 262(a), and FDA regulations, 21 C.F.R. Parts 310, 312. PHS Guidelines (Ex. 3) at 4.

5. According to records released to CRT during this litigation, Parkinson’s Disease patients participating in FDA-approved xenotransplantation clinical trials, who had pig cells injected into their brains, developed malignant cancers that had to be removed. See Docs. 367, 368, 473 (Ex. 10). In addition, records show that other patients experienced “adverse events” – including brain swelling, tremors, hallucinations, and body soreness. Docs. 9, 14, 159, 269, 488, 501, 592, 676 (Ex.

11). In one 1996 incident involving “an error in quality control,” a pig that might have tested positive for an infectious virus was used as a source animal for fetal neural tissue. Doc. 400 (Ex. 12).

6. To demonstrate to FDA that the requested information is not “confidential” commercial information within the meaning of Exemption 4 of the FOIA, CRT attached many exhibits to its FOIA request demonstrating that companies that are conducting clinical trials have publicly disclosed numerous details about such trials, e.g., in press releases, journals, on websites, and during government advisory committee meetings. See FOIA Request (Ex. 13).

7. When Diacrin advertised its xenotransplantation products and solicited investments from the public, it revealed many details about a clinical hold for its product for stroke treatment, i.e., that “[a]t the time the trial was suspended [Diacrin] had treated 5 patients” with the product, Diacrin, Porcine Neural Cells for Stroke (Ex. 27, Attachment (“Att.”) D), that “[b]oth patients who suffered adverse events have recovered,” and that, after reviewing “the scientific and clinical information relating to these adverse events,” Diacrin “concluded that they were most likely associated with the surgical procedure used to implant the cells.” Diacrin Press Release (Ex. 29) at 2; see also Diacrin Product Development Programs (Ex. 27, Att. I) (reflecting the status of numerous products and highlighting the numbers of potential patients for each product). Yet, there is no evidence that FDA has gone through plaintiff’s Exhibits of previously disclosed information, see FOIA Request (Ex. 13), to determine whether information contained in those publicly disseminated records is nevertheless being withheld from CRT by FDA.

8. CRT has narrowed the scope of its FOIA request throughout this litigation, Second Declaration of Alix Fano Pursuant To Rule 56(f) (“2d Rule 56(f) Fano Decl.”) at ¶¶ 11-12, and has

now narrowed its request even further to include only 34 records that the Food and Drug Administration (“FDA”) has withheld from disclosure pursuant to FOIA Exemptions 4 and/or 5. 5 U.S.C. §§ 552(b)(4), (b)(5); see Plaintiff’s Index of Records Still At Issue (“Pl. Index”) (Ex. ___). Thus, CRT no longer seeks access to information that identifies sponsor names, product names, cells used/studied, disease names, locations of clinical trials, manufacturing information, clinical protocols, amendment reviews, quality assurance, quality control, results from preclinical studies, IND numbers, and names of contractors. See 2d Rule 56(f) Fano Decl. at ¶ 2. Nor does CRT seek records identified as “non-responsive” by the FDA. See FDA Memo. (Jun. 8, 2003) at 16-19.

9. Plaintiff continues to seek access to records generated by the FDA concerning the public health risks associated with xenotransplantation – a biotechnology that poses a health threat to human xenotransplantation patients, their close contacts, health care workers, and the public at large. See generally Pl. Index (Ex. 1).

10. FDA is withholding eight records that either are themselves decisional documents or explain decisions already made by the agency or its employees. Thus, FDA is withholding the “reasons why [an] IND was placed on hold,” (Doc. 775), information concerning the “[I]f long xenotransplantation requirements” that apply “if [a] sponsor withdraws” its IND (Doc. 1088), records of “adverse events to be reported” to the National Xenotransplantation Database (“NXD”) and “NXD Patient Adverse Event” (Doc. 2001; see also Doc. 3144), a chart “showing the NXD Reportable Adverse Events, separating events that need to be reported” from “events that do not” (Doc. 2007), “steps to inactivate a virus” (Doc. 2093), and a “brief description of steps being taken to deal with the issue of potential spread of infectious agents by xenotransplantation” (Doc. 3245). See also Doc. 1357 (“IND G: memo re: Holds For Lack of Assays, addresses a numbered regulation

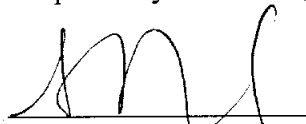
in relation to a clinical hold”).

11. FDA is withholding factual information from CRT. See Df. New Vaughn Index (Df. Ex. B in Supp. of Renewed SJ Mot.) at Doc. Nos. 201 (factual information concerning the “Effects of Xenotransplantation in Humans”), 1364 (“list of competing xenotransplantation products”), 1863 (“what Regulations and Laws apply to xenotransplantation”), 1913 (“comments on” the “detection of eperythrozoon”), 2001 (“list of adverse events to be reported to the National Xenotransplantation Database (NXD) and NXD Patient Adverse Event Report Instructions”), 2007 (“chart showing National Xenotransplantation Database Reportable Adverse Events” that “separates events that need to reported and events that do not need to be reported”), 2093 (“steps to inactivate a virus”), 2280 (“USDA contact for xenotransplantation issues” and discussion of “the importation of transgenic animals from UK to set up breeding facilities”), 2390 (information “discussing the potential threat to both human and welfare from zoonotic or animal pathogens”), 2610 (“Exchange re: Laws applying to the use of animals in xenotransplantation”), 2713 (information concerning “PERV infected animals and related data”), 2762 (“numbers of patients; types of side effects; survival rates of patients”), 2783 (“Discussion of Xenotransplantation recipients in the U.S.”), 3024 (information about “Xenogeneic cells for implantation in patients”), 3098 (“Species and strains for xeno database”), 3144 (“summary of adverse events to be reported to the National Xenotransplantation Database (NXD), a NXD Patient Adverse Event Report Instructions, and a summary of a meeting held at a xenotransplantation meeting” including information about “PERV Update, FDA Xenotransplantation Policy Development, Xenotransplantation Preclinical/Clinical Issues”), 3245 (“steps being taken to deal with the issues of potential spread of infectious adventitious agents by xenotransplantation”), 3476 (“patients enrolled/treated, adverse events attributed to xenotransport”),

3585 (“PERV testing”), 3590 (“informed consent” and “PERV assay” information), and 3591 (“PERV testing” and “PER[V] assay” information”).

12. For 10 of the records FDA is withholding under Exemption 5’s deliberative process privilege, the agency does not know who wrote the records (author “Unknown” for Doc. Nos. 773, 2001, 2007, 2390, 2762, 3144, 3476, 3585, 3590), who received them (recipient “Unknown” for Doc. Nos. 773, 775, 2001, 2007, 2390, 2762, 3006, 3024, 3144, 3476, 3585, 3590), or when they were generated (“Undated” or date “Unknown” for Doc. Nos. 775, 2001, 2007, 2390, 2762, 3024, 3144, 3476, 3585, 3590). In addition, for all of the records in its New Vaughn Index, the FDA does not identify the titles and positions of the documents’ authors and recipients.

Respectfully submitted,



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July 9, 2003

Attorneys for Plaintiff

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/AK)

**PLAINTIFF'S RESPONSE TO DEFENDANT'S SUPPLEMENTAL 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 as to which there is no genuine dispute¹:

1. Not disputed.
2. Not disputed, although CRT notes that FDA did not provide the titles and positions of the authors and recipients of the withheld records. See generally Defendant's ("Df.") New Vaughn Index (Df. Exhibit ("Df. Ex.") B in Supp. of Df. Renewed Mot.). In addition, CRT

¹ Although FDA labeled its Statement of Material Facts "Supplemental," it did not re-file the statement it submitted in support of its original Motion for Summary Judgment, nor did it incorporate that statement by reference. Nevertheless, to the extent FDA is relying on their previously filed Statement of Material Facts, plaintiff hereby incorporates by reference its original response to that statement. See Plaintiff's Response To Defendant's Statement Of Material Facts (May 8, 2002).

notes that FDA does not know the identities of the authors and recipients for many of the records, or when they were generated. See Plaintiff's ("Pl.") Index of Records Still At Issue (Ex. __ in Supp. of Pl. Cross-Mot.) at Docs. 773, 775, 2001, 2007, 2390, 2762, 3006, 3024, 3144, 3476, 3585, 3590). Moreover, to the extent that FDA contends that its New Vaughn Index is adequate to carry the agency's burden of proof that withheld records are lawfully exempt under the FOIA, plaintiff disputes that FDA's descriptions of the contents of withheld records are adequate. See Pl. Index (Ex. 1) at Docs. 201, 773, 775, 1088, 1357,1364, 1863, 2093, 2280, 2390, 2610, 2713, 2783, 3006, 3016, 3098, 3591; Second Declaration of Alix Fano Pursuant To Rule 56(f) (2d Rule 56(f) Fano Decl.") (Ex. 2) at ¶ 13.

3. Not disputed.

4. Not disputed.

5. Not disputed.

6. Not disputed.

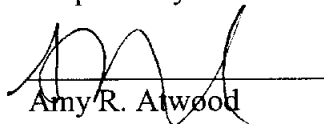
7. Not disputed.

8. Not disputed.

9. Plaintiff is without sufficient knowledge to respond to FDA's assertion that in response to plaintiff's April 28, 2003 letter, FDA conducted another review of the documents requested therein. However, plaintiff disputes that FDA has provided CRT with all reasonably segregable, non-exempt records and portions of non-exempt records, since FDA has failed to provide a detailed justification for withholding factual information. See Second Declaration of Beth Brockner Ryan (Ex. 20) at ¶ 5 (asserting that "FDA has provided Plaintiff with all reasonably segregable, non-exempt documents or parts of document responsive to Plaintiff's

modified FOIA request”); Johnson v. Executive Office for U.S. Attorneys, 310 F.3d 771, 776 (D.C. Cir. 2002) (quoting Mead Data Cent., Inc. v. U.S. Customs Service, 177 F.3d 1022, 1028 (D.C. Cir. 1999) (a “supplemental affidavit” specifically addressing segregability, including a “line-by-line review of each document withheld in full,” deemed sufficient to satisfy the segregability requirement).

Respectfully submitted,



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CAMPAIGN FOR
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Plaintiff,

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Civ. No. 00-2849 (RMU/AK)

ORDER

Upon consideration of plaintiff Campaign for Responsible Transplantation's Cross-Motion for Summary Judgment and Opposition To Federal Defendant's Renewed Motion for Summary Judgment, and the entire record in this case, it is this ____ day of _____, 2003

ORDERED that plaintiff's Cross-Motion for Summary Judgment is GRANTED, and it is further

ORDERED that defendant's Renewed Motion for Summary Judgment is DENIED.

SO ORDERED.

Ricardo M. Urbina
United States District Court Judge

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