UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant,	Civ. No. 00-2849 (RMU)
CIRCE BIOMEDICAL, INC., DIACRIN, INC., DIACRIN/GENZYME LLC, GENZYME CORP., NEXTRAN, INC., and NOVARTIS PHARMACEUTICALS CORP., Defendant-Intervenors.	

A.

B. PLAINTIFF'S MEMORANDUM IN SUPPORT OF

C. MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 et seq., as amended, involves the defendant Food and Drug Administration's ("FDA") unlawful refusal to disclose FDA-generated records that concern clinical trials involving xenotransplantation – a novel, unregulated, and extremely unsafe form of biotechnology in which live animal organs, tissues, and/or cells are implanted into humans for the experimental purpose of determining whether they have any value in treating human diseases. The FDA insists that virtually every word of each of the thousands of pages of documents at issue may be withheld in their entirety under several different exemptions to the FOIA.

However, because the Vaughn index that defendant submitted to plaintiff on September 4, 2001 fails to meet even the most elementary requirements of Vaughn v. Rosen and this Court's July 23, 2001 Order and Memorandum Opinion, plaintiff is moving for summary judgment. Thus, as explained further below, the index omits even the most basic description of the withheld records – including which agency official wrote the document, which official received it, and what it concerns. In addition, the index simply parrots statutory language to justify the agency's withholding, and the government asserts that entire documents are covered by several FOIA exemptions, without providing any specificity whatsoever. Defendant has also failed to justify its assertion that some of the records that are responsive to plaintiff's request are not even "agency records" that are subject to disclosure under the FOIA.

Furthermore, the agency has yet to disclose information that it has determined is non-exempt and thus releasable to plaintiff. Even further, although the FDA lifted its 1997 hold on xenotransplantation clinical trials, none of the records listed in the Vaughn index appear to pertain to this extremely important regulatory decision. Accordingly, plaintiff does not believe

that the FDA has even identified some of the most important records at stake in this litigation, let alone justified their withholding.

Defendant's refusal to comply with the clear, basic requirements of Vaughn is particularly problematic here, where defendant sought and obtained the Court's permission to file a "representative" Vaughn index with respect to one category of responsive records – i.e., those agency-generated records that concern each of the 35 "investigational new drug applications" ("IND") involving xenotransplantation that are currently pending at the FDA. Hence, the agency's failure to justify its withholding of the records that refer to one of those INDs – which are purportedly representative of the records that pertain to each of the other 34 INDs – likewise means that the FDA has also failed to meet its burden of proof with respect to the agency-generated records that apply to each of these additional 34 INDs.

In sum, by unlawfully continuing to withhold responsive records at this late date – i.e., almost two years after plaintiff initially requested the records at issue – the FDA is in severe violation of the FOIA's strict policy of disclosure and the agency's overarching duty to "narrowly construe" the exemptions to the Act. Dep't of the Interior and Bureau of Indian Affairs v. Klamath Water Users Protective Assn., ____ U.S. ____, 121 S.Ct. 1060, 1065 (2001). Accordingly, summary judgment should be granted for plaintiff.[1]

[1] As explained infra at 22-23, plaintiff has already substantially narrowed its original FOIA request to include only records concerning xenotransplantation that have actually been generated by or within the FDA itself. Thus, plaintiff is no longer seeking any of the records that were submitted to the FDA by the sponsors of the products. In addition, in a December 20, 2001 joint stipulation that was submitted by plaintiff, defendant, and intervenor Novartis Pharmaceuticals Corp., CRT agreed to further narrow the scope of its FOIA request, to include only information involving pigs and/or non-human primates. Joint Stipulation at 2 (Dec. 20, 2001). Finally, since this limitation should also exclude records that concern applications to conduct clinical trials involving intervenor Genzyme Corporation's Epicel product, by letter dated Jan. 9, 2002, CRT notified Genzyme by letter that it no longer seeks any of this information.

BACKGROUND

To place the defendants' unlawful withholding of records in context and demonstrate the importance of public disclosure of the records at issue, it is necessary to review the pertinent background, including the applicable statutory and regulatory scheme that applies to xenotransplantation, the public health risks associated with this process, the FDA-approved xenotransplantation clinical trials involving patients, and the procedural history of this case.

A. The Statutory And Regulatory Scheme That Applies To Xenotransplantation

As defined by the FDA, xenotransplantation is:

> 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 [outside the body] contact with live nonhuman animal cells, tissues, or organs.

Public Health Service Guideline On Infectious Disease Issues In Xenotransplantation ("PHS Guidelines") (Jan. 19, 2001) (Plaintiff's Exhibit ("Pl. Ex.") A) at 15. "Xenotransplantation products" are "live [animal] cells, tissues, or organs used in xenotransplantation," and include "transgenic animals" – i.e., source animals whose cells have been genetically modified to contain human DNA to "trick" a patient's immune system into recognizing the cells as "human." See 66 Fed. Reg. 4688, 4689 (Jan. 18, 2001) (Pl. Ex. B) ("Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation"). Unlike, for example, pig valves that are used to repair human heart valves – a product that has been FDA-approved for some time – xenotransplantation involves live animal cells, tissues, or organs. See id. (explaining that "[n]onliving biological products or materials from animals, such as porcine heart valves and porcine insulin, are not classified as xenotransplantation products . . .").

In simpler terms, many biotechnology companies, including the intervenors in this case, are developing experimental xenotransplantation products – predominantly those using pigs as source animals – that involve, for example, the use of live pig liver cells to create "bioartificial livers," or the experimental injection of live fetal pig cells into human patients' brains or spinal cords to treat diseases. However, despite years of experimentation with these products, no xenotransplantation product that involves live animal cells, tissues, or organs has yet been approved by the FDA as both safe and effective for its intended use, as required by the Food, Drug and Cosmetic Act before such products may be lawfully marketed in the United States. See 21 U.S.C. § 355(a)-(b)(1).[2]

The FDA and Center for Biologics Evaluation and Research ("CBER"), a component of the FDA, regulate xenotransplantation products as "drugs," "devices," and/or "biological products" pursuant to 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. Such products cannot be marketed in the U.S. until the FDA determines that they are both "safe and effective" for their intended use. See, e.g., 21 U.S.C. § 355(a)-(b)(1); 21 C.F.R. Part 314. To demonstrate this, the sponsor of the product must submit an "investigational new drug" application ("IND") to the FDA, which, if approved, allows the sponsor to begin a "clinical investigation" to test the product in patients. 21 U.S.C. § 355(b)(l); 21 C.F.R. Part 312.[3]

[2] However, intervenor Genzyme Corporation's Epicel product, a device that uses mouse cells in skin grafts for burn patients, has received approval by the FDA, pursuant to 21 U.S.C. § 360j(m), to be used as a humanitarian device. As such, Genzyme is not required to submit an IND for approval to the FDA for Epicel.

[3] The IND application typically includes chemistry, manufacturing, and control information, pharmacology and toxicology information, as well as the results of testing on animals. See 21 C.F.R. §§ 312.23(a)(7)-(11).

To conduct clinical trials, the sponsor must obtain the "legally effective informed consent" of the patient. 21 C.F.R. § 50.20. Once clinical trials are commenced, the FDA can terminate them if the safety of human patients is threatened. See 21 C.F.R. §312.44(b)(1)-(3); see also 21 C.F.R. § 312.44(d) (FDA must terminate an IND immediately if it "concludes that continuation of the investigation presents an immediate and substantial danger to the health of individuals"). Similarly, the FDA can put an IND on "clinical hold" if, for example, 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." 21 C.F.R. § 312.42(b)(4)(viii). If the FDA imposes a clinical hold on a product, the sponsor is prohibited from dispensing it to patients, id. at § 312.42(a), and the sponsor may only resume the clinical 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).[4]

In addition, whenever there is "[a]ny adverse experience associated with the use of the drug that is both serious and unexpected" – i.e., for which "[t]here is a reasonable possibility that the experience may have been caused" by the drug or product – a sponsor must, "as soon as possible," submit a "written IND safety report" to the CBER. 21 C.F.R. §§ 312.32(a), (c)(A)-(B). An "adverse drug experience" is "[a]ny adverse event associated with the use of" a drug or product "in humans, whether or not considered drug [or product] related," such as adverse events that occur from overdose, abuse, withdrawal, and pharmacological failure. 21 C.F.R. §§ 310.305(b), 314.80(a), 600.80(a). Adverse drug experiences may be "life-threatening," i.e., place the patient "at immediate risk of death," or "serious," i.e., result in death, pose a serious

[4] Some INDs are withdrawn by sponsors or become inactive simply because the sponsors decide not to pursue them. 21 C.F.R. § 312.45.

threat to the patient's life, or result in the patient's hospitalization, disability, incapacity, or birth defect. Id. at § 312.32(a).[5]

B. Health Risks Posed By Xenotransplantation

Although currently performed solely in the context of clinical trials, because of the unintentional transmission of animal viruses to patients, xenotransplantation poses enormous health risks to patients, their families, health care workers, and the public at large. Such cross-species viral infections already occur outside of the xenotransplantation context, and include such well-known viruses as "mad cow" disease, Ebola, Hantavirus, rabies, herpes, hepatitis B and C, influenza, and the human immunodeficiency virus ("HIV"), which probably originated in monkeys. See, e.g., FDA, Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans ("FDA Primate Guidelines") (Pl. Ex. E) at 3.

Xenotransplantation products involving pigs as source animals – the predominant type of xenotransplantation – threaten patients, their close contacts, and the public with the transmission of potentially dangerous pig viruses, i.e., porcine endogenous retroviruses ("PERV"). As the FDA and leading scientists have concluded, the threat of PERV infections from xenotransplantation is real, exacerbated by circumstances that are unique to xenotransplantation products in particular, and, most importantly, perhaps impossible to prevent or effectively treat.

[5] In addition to the FDA's oversight of xenotransplantation through its regulation of INDs, two federal advisory committees also consider and advise federal agencies about issues posed by xenotransplantation. The first of these is the Xenotransplantation Subcommittee of the Biologics Response Modifiers Advisory Committee ("BRMAC"), which is an advisory committee to the Department of Health and Human Services ("DHHS"). See generally, Transcript, Meeting of the BRMAC Xenotransplantation Subcommittee ("BRMAC Transcript") (Dec. 17, 1997) (Pl. Ex. C). In addition, DHHS recently chartered the Secretary's Advisory Committee on Xenotransplantation ("SACX"), a federal advisory committee that specifically considers "the full range of complex scientific, medical, social, and ethical issues and the public health concerns raised by xenotransplantation . . .." See SACX Charter (Pl. Ex. D).

Xenotransplantation eliminates the usual physical barriers between humans and pigs – i.e., skin, membranes, and the gastrointestinal tract – by introducing live pig cells directly into human patients in some way, and, thus, xenotransplantation inevitably involves the introduction of PERVs into patients. See, e.g., Stoye & Coffin, The Dangers Of Xenotransplantation, Nature Medicine (Nov. 1995) ("Stoye & Coffin") (Pl. Ex. F) at 1100 (transplanting an organ carrying PERVs is "equivalent to injecting a patient with a live . . . virus") (emphasis added). As Dr. Robin Weiss, a leading virologist and researcher of PERVs, has observed, PERVs cannot be eliminated from the pig's DNA, and, thus, the risk of PERV infection in xenotransplantation using pigs simply cannot be prevented. See Frontline: Organ Farm, Interview With Robin Weiss, M.D. (Spring-Winter 2000) ("Weiss Interview") (Pl. Ex. G) at 6 ("The problem with [PERVs] is that they are sitting there in the DNA of the pig chromosomes, so it doesn't matter how clean the pigs are; the viruses are sitting there right inside them") (emphasis added).[6]

Moreover, as leading virologists and scientists have further observed, while PERVs are usually dormant in pigs, when introduced to human patients during xenotransplantation, PERVs may infect the patient because: (a) the patient is extremely immunosuppressed, (b) the patient has not developed the necessary antibodies to withstand infection from the virus, or (c) the virus may "recombine" with the patient's own viruses to create an entirely new virus. See, e.g., BRMAC Transcript (Pl. Ex. C) at 39, Statements of John Coffin, M.D., Professor of Molecular Biology, Tufts University School of Medicine ("[e]ndogenous retroviruses can recombine with infecting exogenous viruses to create new antigens . . .").[7]

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[6] Thus, PERVs are "impossible to remove using the usual methods for deriving pathogen-free animals." Stoye & Coffin (Pl. Ex. F) at 1100 (emphasis added).

[7] Either way, as the FDA itself has determined, PERV infections from xenotransplantation may infect not only patients, but also those who come into contact with them – including hospital and health care workers, family members, sexual partners, members of the

In 1997, a major study confirmed that PERVs are "capable of infection, replication, and serial transfer in a range of human cell lines." See Patience, et al., Infection of Human Cells by an Endogenous Retrovirus of Pigs, Nature Medicine (Mar. 1997) ("Nature Medicine Report") (Pl. Ex. I) at 282. As Dr. Robin Weiss, one of the authors of that report, subsequently noted, these findings showed that PERVs "had the potential to infect humans[,]" – especially given the right conditions, such as those which are clearly present in the xenotransplantation setting, where "human blood cells will be coursing through the pig organ" and "human cells that line blood vessels will begin to invade and line the blood vessels of the organ." See Weiss Interview (Pl. Ex. G) at 5.

Indeed, in light of the Nature Medicine Report's findings, not only is the risk of PERV infections from xenotransplantation plausible, but, according to Dr. John Coffin, a leading researcher on the issue, "some kind of infection" appears to be "virtually an inevitable consequence" of xenotransplantation. See BRMAC Transcript (Pl. Ex. C) at 35, statements of John Coffin, M.D. (emphasis added); see also id. at 51 ("it is virtually certain that at least some recipient cells will become infected in some significant fraction of patients") (emphasis added); Allan, Silk Purse Or Sow's Ear, Nature Medicine (Mar. 1997) (Pl. Ex. J) at 276 ("health officials should resist the transplant community's clamor for animal organs in light of these findings" since "[o]ur first priority must be to protect the public health").

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community, and, ultimately, the public at large. See, e.g., PHS Disease Guidelines (Pl. Ex. A) at 5, 9-10 (a patient's "close contacts" include his/her family members, health care professionals, and sexual contacts, and the "potential infectious disease risks posed by xenotransplantation extend beyond the individual patient to the public at large"); see also 66 Fed. Reg. 4688, 4695 (Pl. Ex. B) (the "potential risk of transmission of infectious disease extends beyond the patient receiving the treatment"); Institute of Medicine, Xenotransplantation: Science, Ethics, and Public Policy (1996) ("IOM Report") (Pl. Ex. H) at 43 (the risk of PERV infections "through human populations is real and poses a public health concern").

Thus, according to the FDA itself, the Nature Medicine Report's findings "demonstrated" the "ability" of PERVs "to infect human cell lines[,]" and gave "scientific plausibility to concerns that this retrovirus from porcine xenotransplantation products may be able to infect recipients . . .." PHS Disease Guidelines (Pl. Ex. A) at 6 (emphasis added). In addition, the FDA's own scientific studies have demonstrated that pig blood cells harbored "the type C retrovirus that infects human . . . cells," thereby corroborating the Nature Medicine Report's findings. See Wilson, et al., Type C Retrovirus Released From Porcine Primary Peripheral Blood Mononuclear Cells Infects Human Cells, Journal of Virology (Apr. 1998) (Pl. Ex. K) at 3086; see also BRMAC Transcript (Pl. Ex. C) at 65, Statements of Carolyn Wilson, M.D., CBER (the FDA study showed that stimulation of pig cells "releases a type C retrovirus which infects human cells").[8]

Moreover, the risk of PERV infections is exacerbated by several conditions that are inherent to xenotransplantation procedures. First, for any kind of transplantation to be successful, the human recipient's immune system must be severely suppressed through the use of

[8] More recent studies have further confirmed the public health threat regarding infectious diseases in xenotransplantation. See, e.g., Martin, et al., Expression Of Pig Endogenous Retrovirus By Primary Porcine Endothelial Cells And Infection Of Human Cells, The Lancet (Aug. 29, 1998) at 692 (Pl. Ex. L) (finding that cells from pig aortas, livers, lung and skin – tissues that are likely to be used in xenotransplantation – all produce PERVs); see also Van Der Laan, et al., Infection By Porcine Endogenous Retrovirus After Islet Xenotransplantation In SCID Mice, Nature (Sep. 7, 2000) (Pl. Ex. M) at 90 ("PERV is transcriptionally active and infectious cross-species in vivo after transplantation of pig tissues" – demonstrating that "a concern for PERV infection risk" in immunosuppressed xenotransplantation patients "may be justified"); Fox, Panel Refines FDA Xenotransplantation Guidelines for Protecting Blood, ASM News (2000) (Pl. Ex. N) at 129 (confirming that PERV infections could remain dormant in xenotransplantation patients for years); Griffiths, Xenotransplantation: One Trotter Forward, One Claw Back, The Lancet (Sep. 23, 2000) (Pl. Ex. O) at 1049 (study showed that, if stimulated, pig cells could be activated "into an infectious state"). Since 1992, at least 16 patients who have taken part in xenotransplantation clinical trials died soon afterward. See Declaration of Alix Fano, Executive Director, CRT ("Fano Decl.") (Pl. Ex. P) at ¶ 14.

"immunosuppressants" or anti-rejection drugs. Yet, in xenotransplantation, even more extreme and probably life-long immunosuppression is imperative, because, without it, the human body's immune system will recognize the transplanted animal cells, tissue, or organ as foreign, and try to protect itself from possible infection by destroying the xenotransplant – a violent response that is called "hyperacute rejection." See, e.g., Baxter/Nextran, Inc., Challenges of Organ Transplantation (Pl. Ex. Q) ("in pig to human xenotransplantation," the patient's immune system "surrounds, attacks and kills" what it recognizes to be "foreign matter in the body"). Therefore, xenotransplantation patients' immune systems must be suppressed to an even greater degree, and the risk of PERV infection is heightened, because the body's first line of defense against that threat is severely suppressed. See, e.g., Borie, et al., Microbiological Hazards Related to Xenotransplantation of Porcine Organs Into Man, Infection Control and Hospital Epidemiology (May 1998) (Pl. Ex. R) at 356 ("recipients of pig organs will be given an immunosuppressive regimen potentially favoring the spread of any swine pathogens transmitted with the organ") (emphasis added); see also Martin, et al., (Pl. Ex. L) at 694 ("Xenotransplant patients . . . will need long-term, intensive immunosuppression, increasing considerably the risk for viral xenozoonosis.") (emphasis added); Brown, et al., Xenotransplantation And The Risk Of Retroviral Zoonosis, Trends In Microbiology (Oct. 1998) (Pl. Ex. S) at 411 ("Immunosuppressive therapy and other manipulations" might "further facilitate the transmission of xenogeneic agents that find it difficult or impossible to infect humans under natural circumstances.") (emphasis added).

In addition, xenotransplantation IND sponsors – including intervenors Nextran and Novartis – are developing "transgenic pigs" for use as source animals in xenotransplantation. Transgenic pigs are "humanized" pigs – i.e., pigs whose DNA is genetically modified to

"express human proteins." See Weiss, Xenografts and Retroviruses, Science (Aug. 20, 1999) (Pl. Ex. T) at 1221. Thus, since the human immune system is considered to be the greatest hurdle to achieving successful xenotransplantation, the purpose of these transgenic pigs is to develop a way to "trick" the immune system into recognizing the foreign animal cells as "human." However, as Dr. Weiss has explained, like immunosuppression, the use of transgenic pigs may only further compromise the patient's first line of defense against PERV infections, since "the genetic modification of pigs" might "permit [PERVs] to become pre-adapted for human infection." See Weiss, et al., Infection Hazards of Xenotransplantation, Journal of Infection (2000) (Pl. Ex. U) at 24 (emphasis added). Thus, as Dr. Weiss and other experts have explained, "genetic modification of pigs designed to make organ xenotransplantation possible could also result in 'humanizing' [PERVs]" – i.e., make them even more transmissible to humans. Id. (emphasis added); see also Weiss, et al., Xenografts and Retroviruses (Pl. Ex. U) at 1221 ("an unfortunate byproduct of such genetically modified pigs may be that the [pig] viruses they carry may more readily infect humans") (emphasis added).

Third, and even more troubling for the public at large, the potentially most harmful PERVs are those that are latent, or slower to manifest – such as HIV, herpes, and hepatitis, as opposed to "faster" viruses, such as Ebola. See Brown, et al., (Pl. Ex. S) at 411-412 (since retroviruses are "characterized by long periods of clinical latency," a virus could "transmit insidiously and become well established in a population before the clinical symptoms become apparent in individuals and signal a widespread public health problem") (emphasis added). Consequently, patients infected with PERVs as a result of otherwise clinically successful xenotransplantation trials might live longer, but could infect many others with whom they come into contact during their lives. See, e.g., Fox, Panel Refines FDA Xenotransplant Guidelines for

Protecting Blood, ASM News (2000) (Pl. Ex. N) at 129 (reporting about a Novartis study that found that pig cells persisted for eight years after Russian patients underwent xenotransplantation procedures).

To address this factor, the FDA recently issued legally nonbinding "guidelines" for xenotransplantation IND sponsors under which, as part of a patient's "informed consent," the xenotransplantation patient effectively agrees to extend his assumption of the risk of infection to his "close contacts" – including the patient's family members, health care professionals, and sexual contacts, PHS Disease Guidelines (Pl. Ex. A) at 5, 20 – inform these "close contacts" of the "uncertainty regarding the risk of xenogeneic infections" and "behaviors known to transmit infectious agents from human to human," and adhere to "methods to reduce the risk of transmission." 66 Fed. Reg. 4688, 4695 (Pl. Ex. B). Thus, the patient's "close contacts" – who will inevitably increase and change throughout the patient's lifetime – must also agree to refrain from risky behaviors, including "unprotected sex, breast feeding, intravenous drug use with shared needles, and other activities that involve potential exchange of blood or other body fluids . . .." Id.[9]

In sum, as scientists have warned, xenotransplantation "puts the larger human community at risk" by "juxtaposing animal tissue and its microbiological flora with humans in ways that bypass most or all of the normal host defense systems" and "creat[ing] intimate and prolonged contact that might facilitate the transmission of xenogeneic infections." Brown, et al. (Pl. Ex. S) at 411 (emphasis added).[10]

[9] Patients and their close contacts must also agree to report, throughout their lifetimes, "any significant unexplained illness . . . to the research coordinator at the institutions where the xenotransplantation was performed." Id.

[10] The FDA and even companies that are clinically testing xenotransplantation products have acknowledged that xenotransplantation poses a "public health concern" that could extend

Recognizing the public health implications in allowing xenotransplantation clinical trials to proceed, in 1997 the FDA placed a "clinical hold" on all xenotransplantation clinical trials involving pigs. See PHS Disease Guidelines (Pl. Ex. A) at 7 (on October 16, 1997, "[a]s the science regarding [PERVs] . . . began to emerge, the FDA placed all clinical trials using porcine xenotransplantation products on hold"); see also 21 C.F.R. § 312.44(d) (FDA must immediately place a hold on clinical trials whenever "continuation of the investigation presents an immediate and substantial danger to the health of individuals").

C. Despite The Health Risks Posed By Xenotransplantation, The FDA Has Allowed Clinical Trials To Proceed.

1. The Agency's Decision To Lift Its Hold On Xenotransplantation Clinical Trials

Despite unresolved, serious questions about the risk of PERV infection in xenotransplantation and the corresponding health threat to the public at large, sometime between 1998 and 2000, the FDA lifted its hold on pig xenotransplantation clinical trials. The agency instead required IND sponsors to simply develop "assays" for detecting and screening for PERVs in new and former xenotransplantation patients and "informed consent documents" to facilitate patients' and their close contacts' understanding of the "implications of the capacity of [PERVs] to infect human cells in vitro." See PHS Disease Guidelines (Pl. Ex. A) at 7.

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well beyond the individual patient. See 66 Fed. Reg. 46887, 4689 (Pl. Ex. B); PHS Disease Guidelines (Pl. Ex. A) at 9-10 (the "potential infectious disease risks posed by xenotransplantation extend beyond the individual patient to the public at large"); IOM Report (Pl. Ex. H) at 43; Diacrin, Inc., Annual Report to the Securities and Exchange Commission ("SEC") (Dec. 31, 2000) (Pl. Ex. V) at 32 ("Xenotransplantation poses a risk that viruses or other animal pathogens may be unintentionally transmitted to a human patient"); Circe Biomedical, Inc., Registration Statement to the SEC (June 20, 1997) (Pl. Ex. W) at 11 ("it is possible that" xenotransplantation products will "transmit viruses, infectious diseases or other contaminants from non-human species to human patients").

Moreover, FDA lifted the xenotransplantation clinical hold despite the agency's own scientific findings that PERVs can infect human cells, BRMAC Transcript (Pl. Ex. C) at 65, Statements of Dr. Carolyn Wilson, M.D., CBER (summarizing CBER's own findings that PERVs "infect[] human cells"), as well as the consensus of a BRMAC Xenotransplantation Subcommittee "focus group" that clinical trials should not proceed "until such time as animal studies or human studies provide a measure of confidence that spreading infection will not result in the recipient." Id. at 152, Statements of John Coffin, M.D. The focus group's consensus was overruled, however, on the ground that "the only way of testing the [risk of infection] is clinical trials." Id. at 158-59, Statements of BRMAC Subcommittee Chairman Hugh Auchincloss (clinical trials should proceed despite the risks) (emphasis added); see also id. at 275, Statements of Auchincloss (xenotransplantation clinical trials should proceed since there is no way of knowing whether PERV infections will result "until we have done 1000 patients or maybe even 10,000 patients" and "[w]e really just need to do patients" to know what the risk of PERV infection truly is).[11]

Thus, the FDA decided to overlook the "principle problem" that it knows "essentially nothing" about the potential for PERV infection in "normal and immunosuppressed human hosts," BRMAC Transcript (Pl. Ex. C) at 151, Statements of John Coffin, M.D., and allowed trials to proceed even though "[w]e know that these tissues have virus" – and, indeed, in spite of the fact that members of the BRMAC Xenotransplantation Subcommittee considered it "likely" that these viruses will be transmitted to human patients "sooner or later." Id. at 217, Statements

[11] In other words, despite the scientific consensus that this kind of medical experimentation poses an unknown – and potentially grave – public health risk, the FDA decided to allow xenotransplantation clinical trials to proceed on the grounds that the only way to measure the true extent of this risk is to create circumstances under which PERV infection might actually occur.

of Jay Siegel, M.D., Director, FDA Office of Therapeutics, Research and Review (emphasis added). Indeed, Dr. Weiss has stressed the alarming fact that "we don't know whether one in a thousand or one in a million people will [become infected], and what will then happen to that virus once it's adapted to grow in humans." Weiss Interview (Pl. Ex. G) at 11 (emphasis added). Thus, as expressed by perhaps the leading expert on this issue, the "worst-case scenario" in allowing xenotransplantation to proceed is that the FDA could be facilitating a "new pandemic that would spread across the world, just like HIV has done." Id. at 9 (emphasis added).

2. FDA Has Allowed 35 Xenotransplantation INDs To Proceed To Clinical Investigations.

Despite the agency's own repeated acknowledgement of the risk of cross-species infections to the general population, the FDA has nevertheless allowed at least 35 xenotransplantation clinical investigations to proceed. See Defendant's Memorandum In Support Of Motion For A Sample Vaughn Index (Jun. 12, 2001) at 2 (35 INDs "concern xenotransplantation and are therefore responsive" to plaintiff's FOIA request). Moreover, biotechnology corporations that sponsor some of these trials have publicly disclosed or acknowledged that they have submitted xenotransplantation IND applications to the FDA. Indeed, as the FDA itself has observed, "[s]ponsors of xenotransplantation IND's have publicly disclosed information regarding the scope of xenotransplantation clinical trials" during public BRMAC meetings and workshops, through publicly accessible filings to the SEC, and on Internet websites. See 66 Fed. Reg. 4688, 4691 (Pl. Ex. B). In particular, sponsors' "Internet sites often provide this information in the form of descriptive summaries of clinical trials, press releases, recruitment opportunities for patients, investment opportunities, and general awareness material" – thus, as the FDA itself has acknowledged, information concerning xenotransplantation clinical trials is "already widely disclosed." Id. (emphasis added).

Moreover, as the FDA has further acknowledged, "[t]his disclosure has not impeded commercial development of these products." Id. (emphasis added).

To provide the Court with examples of the kinds of products that are the subject of the records at issue in this case, a brief discussion of some of the experimental xenotransplantation products that are currently the subject of INDs is set forth below.

- **Circe Biomedical's Xenotransplantation IND**

Intervenor Circe Biomedical is seeking FDA approval of its first xenotransplantation product, a bioartificial liver support system, which – as Circe has described extensively in public during open advisory committee meetings, in its publicly available SEC filings, and on its Internet website – uses pig liver cells to approximate the blood-cleansing function of the human liver. See Circe Biomedical, The HepatAssist Liver Support System (Pl. Ex. X); see also Circe Memorandum in Support of Intervention at 2 (Jan. 12, 2001). According to Circe, the HepatAssist system has completed two phases of clinical trials at 10 sites throughout the United States, with the participation of at least 39 human patients. See Circe Biomedical, Clinical Trials (Pl. Ex. Y); see also BRMAC Transcript (Pl. Ex. C) at 18, statements of Achilles Demetriou, M.D. (stating that Circe has "developed a bioartificial liver which utilizes porcine hepatocytes and we have used it to treat 37 patients"); Circe SEC Registration Statement (June 20, 1997) (Pl. Ex. Y) at 5 (discussing completion of Phase I/II clinical trial and proposed protocol for a Phase II/III trial of the HepatAssist System).

Indeed, during the December 1997 BRMAC Xenotransplantation Subcommittee meeting, Circe publicly described its clinical trials at great length:

> Working with the FDA, we were able to begin a phase I clinical investigation in which we targeted severe acute-liver failure patients, end-stage with stage III or stage IV hepatic encephalopathy. We have, in this phase, treated 41 patients, 27 [with acute liver failure], three [patients with rejection of human livers, post-

> transplantation], nine chronic patients where they had an acute exacerbation of a chronic disease, and two cancer patients . . .. We have utilized three clinical sites, the fundamental one with Cedars Sinai Medical Center which we have treated now 24 patients in our clinical trial . . .. We have also involved the UCLA Medical Center with six patients . . .. All in all, we have had 96 treatments….

BRMAC Transcript (Pl. Ex. C) at 123-124, statements of Barry Solomon, M.D., Circe Biomedical; see also id. at 125-26 (describing the HepatAssist "treatment" step-by-step).

- **Nextran's Xenotransplantation IND**

Intervenor Nextran has submitted an IND "to conduct a xenotransplantation trial involving the use of transgenic porcine livers . . .." Nextran Memorandum in Support of Intervention at 2 (Jan. 16, 2001). Nextran's "researchers have genetically engineered pigs" to include human proteins on "the surface of their organs" – i.e., to "trick" the human immune system into not recognizing and rejecting the xenograft as foreign. Baxter/Nextran, Xenotransplantation: Pigs As Donors (Pl. Ex. Z); see also Baxter/Nextran, Xenotransplantation, Research Update (Pl. Ex. AA) (stating that Nextran recently "concluded a Phase I clinical trial that used transgenic pig livers" as a medical procedure "for patients with acute liver failure" and will develop and submit to the FDA a protocol "for a Phase I in vivo [inside the body] clinical trial"); BioSpace, Xenotransplantation: Insights Into The Development Of A Novel Technology (March 28, 2000) (Pl. Ex. BB) (noting that Nextran is among the companies currently pursuing the "Holy Grail" of xenotransplantation – i.e., "xenotransplantation of entire organs"); BRMAC Transcript (Pl. Ex. C) at 147-148, Statements of Marlin Levy, M.D. (describing Nextran's xenotransplantation clinical trial).

- **Diacrin's and Diacrin/Genzyme's Xenotransplantation INDs**

Intervenor Diacrin, Inc. and Diacrin/Genzyme, LLC are advancing several xenotransplantation products through various stages of clinical trials. See, e.g., Diacrin and

Diacrin/Genzyme, Memorandum In Support Of Intervention (Jan. 24, 2001) at 1-2 (disclosing that Diacrin "currently has before" the FDA "active [INDs] involving clinical trials using xenotransplantation"); see also generally BRMAC Transcript (Pl. Ex. C) at 101-107, Statements of Diacrin CEO Michael Egan (summarizing, in extensive detail, the data from Diacrin/Genzyme's clinical studies).

According to information publicly disclosed on its Internet website, Diacrin has submitted five xenotransplantation INDs to the FDA that involve the injection of pig cells into human patients. See Diacrin Product Development Programs (Pl. Ex. CC); see also Diacrin Fact Sheets (Pl. Ex. DD). Following two "adverse events" last year – including brain seizures in one patient and brain swelling in another, both which occurred after pig cells were injected into the patients' brains – the FDA placed Diacrin's investigation using fetal pig cells for stroke on clinical hold. See Press Release, Diacrin Suspends Phase 1 Clinical Trial For Stroke (Apr. 17, 2000) (Pl. Ex. EE); see also Diacrin Stroke Fact Sheet (Pl. Ex. DD) ("In April 2000, we put this Phase I clinical trial on hold while we investigate the cause of two adverse events").

In addition, intervenor Diacrin/Genzyme, LLC is sponsoring two xenotransplantation INDs that involve the injection of fetal pig cells into human patients' brains. See Diacrin, Inc., SEC Annual Report (2000) (Pl. Ex. V) at 2-3 (disclosing that Diacrin/Genzyme is developing NeuroCell-PD and NeuroCell-HD). Diacrin/Genzyme had its "first meetings with the FDA in April of '94 and then . . . approximately a year later . . . treated [its] first Parkinson's disease patient." BRMAC Transcript (Pl. Ex. C) at 102, Statements of Diacrin CEO Michael Egan; see also id. at 103 (stating that "24 patients that have now been treated" for Parkinson's disease and Huntington's disease); id. at 112-113, Statements of Steven Fink, M.D. (describing the

Parkinson's Phase I clinical trial, involving 12 patients and resulting in 232 adverse events, including the death of one patient).

D. Procedural History Of This Case

1. Administrative Proceedings

CRT is a non-profit, public interest organization that was founded in 1998 "to promote a ban on xenotransplantation" because of the "public health risks" and "scientific, medical, social, regulatory, economic, animal welfare, and environmental concerns" that are currently associated with this procedure. See Fano Decl. (Pl. Ex. P) at ¶ 3. Now an international coalition of physicians, scientists, nurses, and public interest groups that represents over 3 million people, CRT is "dedicated to ensuring that the public is fully informed about the many issues that are posed by xenotransplantation." Id.

By letter to the FDA dated March 9, 2000, CRT requested access to "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 Letter (Mar. 9, 2000) ("FOIA Request") (Pl. Ex. FF) at 1. CRT requested this information "so it could ascertain whether the FDA is adequately monitoring xenotransplantation clinical trials in light of the significant public health risks that are implicated." See Fano Decl. (Pl. Ex. P) at ¶ 14. In addition, CRT requested the information to shed light on the agency's 1997 decision to halt clinical trials due to the risk of PERV infection, and the factors behind the FDA's subsequent decision to lift the ban and to allow clinical trials to resume. See Fano Decl. at ¶ 13 (the FDA "never adequately explained to the public why it lifted its hold on clinical trials despite the public health risks that are posed by xenotransplantation").

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 . . .." FOIA Request at 1 (Pl. Ex. FF). Accordingly, plaintiff expressly requested that any such personal identifying information "be deleted from the requested material where necessary to protect the personal privacy of an individual." Id.

When five months went by and the agency still had not provided any substantive response to CRT's request, nor any indication as to when FDA would so respond, CRT appealed the denial of its FOIA request by letter dated August 2, 2000. See Letter (Aug. 2, 2000) ("FOIA Appeal") (Pl. Ex. GG). When the agency failed to provide any response to CRT's appeal CRT filed its Complaint in this case. Complaint (Nov. 27, 2000).

2. Litigation To Date

After the suit was filed, the FDA notified sponsors of INDs that records concerning their INDs fell within the scope of plaintiff's FOIA request. As a result, with the consent of plaintiff, six biotechnology companies and sponsors of xenotransplantation INDs intervened as defendants. See Orders Granting Intervention (Mar. 1, 2001)

Meanwhile, on January 18, 2001, the FDA published a proposed rule in the Federal Register, which would make available for public disclosure "information necessary to ensure a continued mechanism for public education and input" about xenotransplantation. 66 Fed. Reg. 4688, 4691 (Jan. 18, 2001) (Pl. Ex. B). Specifically, the rule would require xenotransplantation IND sponsors to submit versions of INDs with all confidential commercial information redacted which would then be made available for public disclosure. Id. The preamble to the proposed rule stressed that "it is vital that the public . . . be informed and educated about potential infectious disease risks" that are associated with xenotransplantation, precisely because of the

scientific, medical, and regulatory communities' near-unanimous concern about this major public health risk. Id. at 4695 (Pl. Ex. B) (emphasis added). Indeed, the FDA also insisted that, because clinical investigations of xenotransplantation products "raise serious ethical and scientific issues, the [FDA's] decisionmaking process should be as transparent and fully informed as possible." Id. at 4692 (emphasis added).[12]

By letter dated February 2, 2001, CRT suggested that the FDA prepare a comprehensive "list of the types of records that are responsive to CRT's request" to enable plaintiff to further narrow its request. See Letter (Feb. 2, 2001) (Pl. Ex. HH) at 2. By letter dated February 15, 2001, defendant agreed to produce a "rough index of documents," and, on March 23, 2001, defendant informed plaintiff that there were 35 xenotransplantation IND applications. See Letters (Feb. 15, 2001) (Pl. Ex. II) and (Mar. 23, 2001) (Pl. Ex. JJ) (without indices). In addition, the FDA asserted, that all agency-generated information that is responsive to plaintiff's request is "exempt from disclosure" in its entirety. Letter (Mar. 23, 2001) (Pl. Ex. JJ) at 1.

Without conceding that any of the information that had been submitted by the IND sponsors is exempt from disclosure, on May 29, 2001, CRT further narrowed the scope of its request to include only those responsive records and information that had been actually generated by or within the FDA itself, and it moved for a Vaughn index of all such records so that it could have a meaningful basis for evaluating the agency's position that all such records are exempt from disclosure under the FOIA. Motion Requesting A Vaughn Index (May 29, 2001). In response, defendant requested that – rather than having to index all such responsive, agency-generated records – it instead be allowed to prepare a "sample" Vaughn index that would index

[12] This proposal, which was published by the prior Administration, has not been finalized by the agency to date.

only those agency-generated records that concern one IND that is "representative" of all 35 INDs at issue. See Cross-Motion To Permit A Sample Vaughn Index (Jun. 12, 2001) at 2. Defendant assured the Court and the plaintiff that the "types of documents contained in each xenotransplantation IND are essentially uniform" and that a "representative Vaughn index would set forth the specific types of documents included in all of the xenotransplantation INDs" and "allow Plaintiff the opportunity to contest the bases for any exemptions asserted by Defendant." Memorandum at 2 (Jun. 12, 2001) (emphasis added).

On July 23, 2001, the Court ordered defendant to prepare a Vaughn index within 30 days that included (1) all of the "FDA-generated documents" that are contained in one "representative IND" and (2) all of the "FDA-generated documents concerning xenotransplantation clinical trials in general . . .." Order (Jul. 23, 2001). The Court further required that the "representative" IND be "typical of broader classes of documents within the pool." Memorandum (Jul. 23, 2001) at 8. On August 3, 2001, plaintiff chose IND "G" from defendant's March 23, 2001 list as the IND to be used for the portion of the Vaughn index that is "representative" of all of the FDA-generated records that pertain to each of the 35 INDs at issue. See Letter (Aug. 3, 2001) (Pl. Ex. KK).

On September 4, 2001, defendant provided its Vaughn index to plaintiff. [13] The index consists of two sections – a 387-page section that indexed 2569 "FDA-Generated Documents Concerning Xenotransplantation Clinical Trials In General" and a 228-page section that indexed 692 "FDA-Generated Documents Contained in the IND 'G' File or Relating to IND 'G.'" Thus, assuming there are the same number of FDA-generated records for each of the 35 INDs at issue, this means that there are approximately 24,220 such documents (i.e., 35 x 692). Thus, together

[13] Defendant has not filed a copy of the Vaughn index with the Court. See Notice of Filing at 2 (Aug. 31, 2001). However, plaintiff has submitted portions of the index as an Exhibit here. See generally Vaughn Excerpts (Pl. Ex. LL).

with the 2569 FDA-generated documents that concern xenotransplantation in general, according to the FDA, there are approximately 26,789 responsive documents at issue in this case. However, despite the fact that the information about these clinical investigations has already been publicly disclosed by the sponsors and the agency's responsibility to construe all exemptions narrowly and disclose all segregable, non-exempt information, the FDA has withheld virtually every single word of these documents on the grounds that all of this information is exempt from disclosure under one or more exemptions to the FOIA.[14]

On October 15, 2001, several weeks after plaintiff informed the government that it planned to move for summary judgment in this case, the FDA provided plaintiff with approximately 762 pages of responsive records, including transcripts from three 1995 open meetings of the BRMAC Xenotransplantation Subcommittee and several Internet website addresses where more such transcripts were located. See Letter (Oct. 15, 2001) (Pl. Ex. MM). On December 14, 2001, the agency disclosed hundreds of pages of additional information, and an addendum to its Vaughn index that listed 38 additional responsive documents. See Letter to Amy R. Atwood from Michael M. Levy, Jr. (Dec. 14, 2001) (Pl. Ex. NN). However, the agency continues to withhold the vast majority of information at issue in this case.

[14] Moreover, although many of the documents are between one and 20 pages in length, a substantial number of the documents are extremely voluminous. Thus, for example, about 58 of the documents are between 50 and 100 pages long, and another 14 records are over 100 pages long. See, e.g., Vaughn Excerpts (Pl. Ex. LL) at § 1 (Doc. Nos. 446, 450, 1504, 2262, 2280). Nevertheless, the agency has withheld every single page of those documents.

ARGUMENT

A. Federal Agencies Have A Statutory Duty To Disclose Records Requested Under The Freedom of Information Act.

The FOIA is a disclosure statute that was intended "to facilitate public access to Government documents." U.S. Dep't of State v. Ray, 502 U.S. 164, 173 (1991). Congress intended the FOIA "to pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny." Dep't of Air Force v. Rose, 425 U.S. 352, 361 (1976). Thus, as the Supreme Court has made clear, the "core purpose of the FOIA [is to] 'contribut[e] significantly to public understanding of the operations or activities of the government.'" Dep't of Justice v. Reporters Committee for Freedom of the Press, 489 U.S. 749, 775 (1989) (other citations omitted); 5 U.S.C. § 552(a)(4)(A)(iii).

The FOIA requires each federal agency to make non-exempt records "promptly available to any person" upon request and 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). Moreover, an agency's search for responsive records must be "reasonably calculated to uncover all relevant documents." Truitt v. Dep't of State, 897 F.2d 540, 542 (D.C. Cir. 1990).

The only bases for withholding responsive records are the nine exemptions that are provided in the statute itself. 5 U.S.C. §§ 552(b)(1)-(9). Moreover, the agency bears the burden to prove that withheld records lawfully fall within a claimed exemption, id. at § 552(a)(4)(B); Reporters Committee, 489 U.S. at 755, and, consistent with the Act's goal of broad disclosure, the exemptions to the Act "must be narrowly construed." Rose, 425 U.S. at 361. Furthermore, the agency has a duty to 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).

B. The Purpose of The Vaughn Index

Because the agency alone knows the contents of any responsive records, "the FOIA requester and the court both must rely upon [the agency's] representations for an understanding of the material sought to be protected." King v. Dep't of Justice, 830 F.2d 210, 218 (D.C. Cir. 1987). As the D.C. Circuit long ago explained in Vaughn, "[t]his lack of knowledge by the party seeking disclosure seriously distorts the traditional adversarial nature of our legal system's form of dispute resolution," and deprives the reviewing court of the "controverting illumination" that would assist it in making its de novo determination of whether the exemptions asserted by the agency actually apply. Vaughn v. Rosen, 484 F.2d 820, 825 (D.C. Cir. 1973). Thus, the purpose of a Vaughn index is "to permit adequate adversary testing of the agency's claimed right to an exemption." King, 830 F.2d at 218 (emphasis added).

As the D.C. Circuit has explained, there are several "indispensable elements" of a Vaughn index. Founding Church of Scientology of Washington, D.C. v. Bell, 603 F.2d 945, 949 (D.C. Cir. 1979). Among these is that the index must "adequately describe each withheld document or deletion from a released document." Id. at 940 (emphasis added). Thus, to facilitate an understanding of the documents, the index must include "basic information" such as "the author, date, and adequate descriptions of withheld records." See Carlton v. Department of Interior, Civ. No. 97-2105, slip op. at 11 (Sept. 3, 1998) (Kessler, J.) (emphasis added) (Pl. Ex. OO). Hence, it is axiomatic that, where entries call for the requester and the Court "to guess" about the "subject of th[e] withheld document . . .," the Vaughn index simply cannot serve its functions. Id. at 11-12.

Furthermore, since "[s]pecificity is the defining requirement of the Vaughn index," King, 830 F.2d at 219, the agency must not only describe the withheld documents or portions of documents, but must also demonstrate why the documents may be lawfully withheld. Thus, a Vaughn index "must state the exemption claimed for each deletion or withheld document, and explain why the exemption is relevant." Founding Church, 603 F.2d at 949. Moreover, such explanations cannot be conclusory – i.e., they cannot simply state the agency's opinion that the withheld information is exempt, but must offer "a relatively detailed analysis . . .." Oglesby v. U.S. Dep't of Army, 79 F.3d 1172, 1178 (D.C. Cir. 1996); see also id., Vaughn, 484 F.2d at 826 (the court must not "'accept conclusory and generalized allegations of [FOIA] exemptions'"). A Vaughn affidavit is "conclusory" when it fails to "illuminate or reveal the contents of the information sought" and "set[s] forth in conclusory terms the [agency's] opinion that the [records] were not subject to disclosure under the FOIA." Vaughn, 484 F.2d at 823 (emphasis added).

Furthermore, when an agency blankets entire documents – and, particularly, large documents such as those at issue here – with multiple exemptions, it is highly unlikely that the entire documents may be lawfully withheld under the standards for each exemption, and more likely that the agency's assertions are conclusory. Indeed, if "isolated portions" of the requested records may qualify as lawfully exempt under more than one FOIA exemption, it is "preposterous to contend that all of the information is equally exempt under all of the alleged exemptions." Vaughn, 484 F.2d at 827-28 (emphasis added).

Even further, the Vaughn index must "specifically identif[y] the reasons why a particular exemption is relevant, and correlat[e] those claims with the particular part of a withheld document to which they apply." Mead Data Central, Inc. v. U.S. Dep't of the Air Force, 566

F.2d 242, 251 (D.C. Cir. 1977) (emphasis added); King, 830 F.2d at 219 ("specificity is the defining requirement of the Vaughn index") (emphasis added). Indeed, particularly when large records are at issue, "it is vital that the agency specify in detail which portions of the document are disclosable and which are allegedly exempt." Vaughn, 484 F.2d at 827 (emphasis added). Thus, the agency must "itemize each document and explain the connection between the information withheld and the exemption claimed . . .." Oglesby, 79 F.3d at 1180. This "segregability" requirement "applies to all . . . documents and all exemptions in the FOIA." Schiller v. NLRB, 964 F.2d 1205, 1209 (D.C. Cir. 1992).

Finally, a "representative" Vaughn index – like the one permitted in this case with respect to one category of information at issue in this case – must not only justify the agency's decision to withhold the records that are actually indexed, but must also allow the requester and the Court to "extrapolate its conclusions from the representative sample to the larger group of withheld material." Bonner v. Dep't of State, 928 F.2d 1148, 1151 (D.C. Cir. 1991).

As demonstrated below, the agency's Vaughn index in this case violates all of these well-established tenets of FOIA law. Accordingly, plaintiff is entitled to summary judgment.

I. DEFENDANT HAS FAILED TO CARRY ITS BURDEN TO PROVE THAT RECORDS RESPONSIVE TO PLAINTIFF'S REQUEST MAY BE LAWFULLY WITHHELD UNDER THE FOIA.

Defendant has failed to meet the most elementary requirements of Vaughn v. Rosen. The agency has failed to justify its withholding of thousands of records under Exemptions 4, 5, and 6. Defendant has also failed to establish that additional responsive records are not "agency records" that must also be disclosed to plaintiff unless they are exempt from disclosure.

A. Defendant's Vaughn Index Does Not Adequately Describe Withheld Records.

Defendant's descriptions of the records that it is refusing to disclose are far from even minimally adequate under the D.C. Circuit's requirement that the agency provide "a functional description of the documents . . .." Oglesby, 79 F.3d at 1184. Indeed, defendant's index fails to provide basic information about the records at issue, including the types of records, the authors and recipients of the records, and any information about the nature of the contents of the records that it has withheld. Oglesby, 79 F.3d at 1184; see also Carlton v. DOI, slip op. at 11 (Pl. Ex. OO) (basic information that would allow the Court to "make a rational decision whether the withheld material must be produced" includes "the author, date, and adequate descriptions of withheld records"). In fact, as a rendition of just a few of defendant's descriptions demonstrates, the agency's Vaughn index requires plaintiff and the Court to guess about the contents of the withheld documents.

For example, many documents are described only as "Internal Memo RE: Xeno." See Vaughn Excerpts (Pl. Ex. LL) at § 1 (Doc. Nos. 200, 935, 1065, 1179). However, there is no information about who prepared the memoranda, who received them, or the purpose for which they were prepared. Id. Indeed, based on this extremely cursory description, the only thing that is known about these documents is that they are memoranda that contain some kind of information about xenotransplantation. However, as demonstrated above, "xenotransplantation" encompasses many issues, including the regulatory issues, patient protection, public health concerns, informed consent, in vivo versus ex vivo xenotransplantation, clinical holds, etc. Thus, simply describing the records as "Memo RE: Xeno" falls far short of the agency's obligation to describe the contents of these records, as required by Vaughn and its progeny.

Similarly, the agency has described document number 923 only as "Internal Emails, RE: Really final revised petition response," but this description does not identify who created these emails, how many of them exist, or the emails' recipients. Id. at Doc. No. 923. Nor does the description provide any elucidation of what is meant by a "really final revised petition response," or to what petition these emails even pertain. By the same token, document number 47, a 52-page document withheld in its entirety, is described only as "Draft FDA Points to Consider on Xenotransplantation," but this description does not identify who created these "Points to Consider," for whom they were created, or what about xenotransplantation was under consideration. Id. at Doc. No. 47.

These examples are by no means aberrant. On the contrary, they are typical of all of the descriptions that are contained in defendant's Vaughn index. See generally, e.g., Vaughn Excerpts (Pl. Ex. LL) at § 1 (Doc. No. 201 ("Internal Memo RE: Xeno analysis"); Doc. No. 2257 ("Undated Draft Lecture Notes"); Doc. No. 2991 ("undated, Review, RE: Master File"); Doc. No. 2995 ("2/16/99, E-mail, RE: TSE"); Doc. No. 3043 ("3/28/96 Internal Memo, re: Screening Draft"); Doc. No. 3044 ("Undated/Unsigned Handwritten Notes, re: Cells"). Like all of the descriptions of documents that defendant has listed in its Vaughn index, these descriptions wholly fail to provide the most basic information about the contents of the records.

Accordingly, there simply is no basis upon which defendant can possibly bear its burden to demonstrate to this Court that each of these records may be withheld in their entirety. See, e.g., Kimberlin v Dep't of Justice, 139 F.3d 944, 950 (D.C. Cir. 1998) (agency's description of a 37-page document as "material collected by the United States Attorney's Office" did not meet the requirements of Vaughn).

B. Defendant's Vaughn Index Does Not Justify Its Decision To Withhold Responsive Records.

In addition to simply failing to adequately describe the documents at issue, defendant has also violated the requirements of Vaughn by attempting to justify its refusal to disclose responsive documents with "[c]onclusory and generalized allegations . . .." Public Citizen Health Research Group v. FDA, 185 F.3d 898, 906 (D.C. Cir. 1999), quoting Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1291 (D.C. Cir. 1983) (affidavits that contain "conclusory assertions" cannot carry the government's burden to prove that the requested information may be lawfully withheld). Indeed, to justify the agency's refusal to disclose documents by asserting that they fall within the various exemptions claimed, defendant simply parrots the statutory language. Yet, to prove that withheld records are actually exempt, an agency must make well substantiated showings under each exemption, and, especially where an agency claims that entire documents are exempt from disclosure, the agency must show that there are no non-exempt, segregable portions. Here, however, the FDA has failed to do so with respect to each of the exemptions that it has asserted.

1. Defendant Has Failed To Prove That Records Are Exempt From Disclosure Under Exemption 4.

The FDA appears to claim that approximately 26,738 records are exempt from disclosure – most in their entirety – under Exemption 4 of the FOIA, which pertains to "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). This includes 278 documents that concern xenotransplantation clinical trials in general and 756 records that pertain to IND "G" – thus, if the records that pertain to IND "G" are truly representative of those that exist for each of the 35 xenotransplantation INDs, the FDA

has withheld approximately 24,460 such additional records (i.e., 35 x 756 = 24,460 + 278 = 26,738).

Under well-established D.C. Circuit FOIA jurisprudence, Exemption 4 exempts (1) trade secrets and (2) information which 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 banc). Information can be lawfully withheld from disclosure 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.

Public Citizen Health Research Group, 704 F.2d at 1288.

Accordingly, to withhold "confidential commercial information" under this Exemption, the agency must prove that the withheld information is "commercial or financial," that it was "obtained from a person," and that it is "privileged or confidential." 5 U.S.C. § 552(b)(4). Information is "confidential" if disclosure is likely either to "impair the Government's ability to obtain necessary information in the future" or "cause substantial harm to the competitive position of the person from whom the information was obtained." Critical Mass, 975 F.2d at 873, citing National Parks and Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974).

Here, in asserting that Exemption 4 applies to thousands of agency-generated documents in their entirety, defendant merely repeats Exemption 4's language – i.e., by stating that the documents "[c]ontain[] confidential commercial information and/or trade secret information, the release of which could cause substantial harm to the competitive position of the IND sponsor because a competitor could unfairly appropriate the information for use in the preparation of its own IND(s)." See, e.g., Vaughn Excerpts (Pl. Ex. LL) at § 2 (Doc. Nos. 338, 394, 407, 490).

However, such an attempt to "justify" withholding thousands of pages of responsive information simply does not satisfy the FOIA's disclosure mandate, the requirements for a Vaughn index, or the requirements of Exemption 4.

Indeed, the FDA does not even specify whether it is claiming that the withheld information is a "trade secret" or "confidential commercial information," or make any of the demonstrations that must attend each such separate – and distinct – assertion. For example, the agency does not make any attempt whatsoever to so much as assert – let alone prove – that any of these agency-generated records contain "trade secrets" – i.e., a secret, plan, formula, process, or device. Center for Auto Safety, 244 F.3d 144, 150-51 (D.C. Cir. 2001).[15]

Similarly, the FDA does not even come close to establishing that any of these records constitute "confidential commercial information" that was "obtained from a person." Center for Auto Safety v. NHTSA, 244 F.3d 144, 147 (D.C. Cir. 2001); Public Citizen Health Research Group, 185 F.3d at 901. While CRT acknowledges that some of the information referred to in the withheld records here may have originally been obtained from the sponsors of these clinical trials – and, hence, is probably also "commercial" in nature – surely not every single word of the thousands of agency-generated documents at issue in this case that have been withheld under Exemption 4 meets these requirements. This is especially true when plaintiff long ago deliberately narrowed its request to seek only information generated by the FDA itself. See, e.g., Philadelphia Newspapers v. HHS, 69 F. Supp. 2d 63, 66-67 (D.D.C. 2000), citing Grumman

[15] The D.C. Circuit has rejected affidavits with much greater detail than the FDA's Vaughn index in this case. See, e.g., Public Citizen Health Research Group, 185 F.3d at 906 (affidavit that stated that the disclosure "would reveal substantial basic research" and "disease models . . . that have been developed" by the sponsor "at great expense" was insufficient to carry the burden to prove Exemption 4 status); see also Kimberlin, 139 F.3d at 950 (a 37-page document, which was described only as "material collected by the United States Attorney's Office" did "not even qualify as a 'Vaughn index'").

Aircraft Engineering Corp. v. Renegotiation Board, 425 F.2d 578, 582 (D.C. Cir. 1970) (since government generated charts were "prepared by the government," they were not "obtained from a person," and, thus, could "not be withheld under Exemption 4").

Moreover, even assuming that some of the records that are being withheld contain information that was obtained from outside the government, the agency must nevertheless also show that this information is "confidential." However, since the information which the agency apparently considers to be "commercial" was required to be submitted under the agency's IND regulations, 21 C.F.R. Part 312, the agency certainly may not legitimately contend that the information is "confidential" because it will "impair the Government's ability to obtain necessary information in the future." See Critical Mass, 975 F.2d at 878 (disclosure of information supplied by mandatory obligation will not impair an agency's ability to obtain similar information in the future).

Nor can the agency demonstrate that all of this information is "confidential" because it will "cause substantial competitive harm" to the sponsors of these products, since, as demonstrated supra at 16-20, vast amounts of information concerning these same xenotransplantation clinical trials is, in the words of the FDA itself, "already widely disclosed" by the sponsors of these products, and, as the agency has also conceded, "[t]his disclosure has not impeded commercial development of these products" within the meaning of Exemption 4. See 66 Fed. Reg. 4688, 4691 (Pl. Ex. B) (FDA explaining that sponsors of xenotransplantation INDs have "publicly disclosed information regarding the scope of xenotransplantation clinical trials"). Indeed, the FDA's own regulations provide that the agency will not keep confidential the existence of an IND if that information has already "previously been publicly disclosed or acknowledged." 21 C.F.R. §§ 312.430, 601.51; see also Niagara Mohawk Power Corp. v. U.S.

Dep't of Energy, 169 F.3d 16, 19 (D.C. Cir. 1999) ("materials normally immunized from disclosure under FOIA lose their protective cloak once disclosed and preserved in a permanent public record").[16]

Therefore, because the FDA has not made even the most rudimentary showing that any of the withheld information satisfies the criteria of Exemption 4, let alone that thousands of agency-generated records may be withheld in their entirety under this exemption, plaintiff is entitled to summary judgment on this point. See Vaughn Excerpts (Pl. Ex. LL) at § 2; Public Health Citizen Research Group, 185 F.3d at 904 ("In litigation seeking the release of information under the FOIA, 'the agency has the burden of showing that requested information comes within a FOIA exemption'").

2. Defendant Has Failed To Justify Its Decision To Withhold Responsive Records Pursuant To Exemption 5.

The FDA's Vaughn index suffers the same inadequacies with regard to records that the agency has withheld under Exemption 5 of the FOIA, which applies to "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency . . .." 5 U.S.C. § 552(b)(5). The FDA appears to claim that approximately 8,777 records are exempt from disclosure – most in their entirety – under this Exemption. This includes 2,477 records that concern xenotransplantation clinical trials in general and approximately 6,300 that concern one of the individual INDs.[17]

It is well-established that Exemption 5's "deliberative process privilege" – relied on by the FDA here – "shields only government 'materials which are both predecisional and

[16] Nor has the agency made findings of segregability as to these documents, blanketing thousands of documents with conclusory statutory language.

[17] Thus, the agency has listed 180 records that pertain to the "representative IND "G" fall within this Exemption (180 x 35 = 6,300).

deliberative.'" Tax Analysts v. IRS, 117 F.3d at 616 (emphasis added) (citation omitted). Here, however, with respect to every one of these documents, like a broken record, defendant's Vaughn index merely repeats the same, conclusory language, i.e., that the record "[c]ontains material that is protected under the deliberative process privilege because it is pre-decisional and deliberative." See Vaughn Excerpts (Pl. Ex. LL) at § 3. Defendant's declarant provides no additional illumination, beyond the statement that these records, which make up 70 percent of all of the withheld documents that concern xenotransplantation clinical trials in general, are:

> confidential internal letters, e-mails, memoranda, and drafts of CBER guidances and rules, which reflect FDA's internal deliberative decision-making processes concerning the testing and approval of new biologics products.

See Second Banks Decl. at ¶ 10. Simply parroting D.C. Circuit case law interpreting Exemption 5, defendant's declarant merely states repeatedly that "[t]he documents contain pre-decisional opinions and/or recommendations of FDA personnel, and disclosure of the withheld documents would discourage the frank exchange of opinions and recommendations among such individuals" and "therefore, [disclosure] would be harmful to the deliberative process within FDA." Id.

Yet, to carry its burden to prove that documents may be withheld in their entirety under the deliberative process privilege, the agency must prove that the material is both predecisional and deliberative. Tax Analysts, 117 F.3d at 616. Here, the FDA does not explain why each document is "deliberative" – e.g., by identifying which agency personnel and/or officials authored the document and for what purpose or at what stage of any particular decisionmaking process. See Renegotiation Bd. v. Brumman Aircraft, 421 U.S. 168, 184 (1975) (a document is "predecisional" only if the agency can show that is was "prepared in order to assist an agency decisionmaker in arriving at his decision"); see also Senate of the Cmwlth of Puerto Rico v.

DOJ, 823 F.2d 574, 585 (D.C. Cir. 1987) (a court "must be able to pinpoint an agency decision or policy to which the document contributed" in order to approve an exemption of a document as predecisional). Nor does the agency explain why each document is also "predecisional" – e.g., by showing, with any particularity whatsoever, to what decision it relates and the status of any such decision at the time that the document was generated. See Wolfe, 839 F.2d at 774, citing Coastal States, 617 F.2d at 866 (to show that material is "deliberative," the agency must prove that it "reflects the give-and-take of the consultative process").

For example, defendant withheld, in its entirety, document number 1414 – which is described only as "General: 3/26/99, E-mail, RE: MTG" – and provided, as the reason for withholding the document, only the rote statement that the record "[c]ontains material that is protected under the deliberative process privilege because it is pre-decisional and deliberative." See Vaughn Excerpts (Pl. Ex. LL) at § 3 (Doc. No. 1414). Similarly, defendant withheld document number 1512, entitled "Undated draft of a letter" using precisely the same language. See id. (Doc. No. 1512).

However, to carry its burden of proof that this material is exempt under the deliberative process privilege, the agency "must establish" the deliberative process that is involved and the "role played by the documents in issue in the course of that process." See Senate of the Cmwlth of Puerto Rico, 823 F.2d at 585-86, quoting Coastal States, 617 F.2d at 868 (emphasis added); ALDF v. Dep't of the Air Force, 44 F. Supp. 2d 295, 299 (D.D.C. 1999) (the agency must actually "specify the role played by each withheld document in the course of developing that policy" when invoking the deliberative process privilege) (emphasis added). Indeed, as this Court has recognized, "the need to describe 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.'" Id., quoting Coastal States, 617 F.2d at 867.

Here, it is impossible to determine what role the withheld documents played in the course of developing any agency policy, when neither the "role" nor the "policy" is even identified, beyond the agency's nebulous statement that the records would reveal "decision-making processes concerning the testing and approval of new biologics products." See Second Banks Decl. at ¶ 10. However, "specificity is the defining requirement of the Vaughn index," King, 830 F.2d at 219, and merely inserting the words "draft" or "internal" into a document description does not, in itself, make records deliberative. See Vaughn Excerpts (Pl. Ex. LL) at § 3 (Doc. Nos. 23, 25, 46, 47, 48, 49, 55, 58). Therefore, by not providing any meaningful explanation beyond its naked assertion the documents are "pre-decisional and deliberative," defendant attempts to execute an end-run around the FOIA's requirement that it demonstrate why the withheld records are "pre-decisional and deliberative."[18]

Because the FDA has failed to meet any of the requirements for withholding records under Exemption 5, its contention that it may withhold some 8,777 records under this Exemption must also fail.

[18] In addition, as is true with virtually all of the records at issue in this case, defendant has failed to make any findings of segregability. For example, it is well established that "factual material" that is contained in otherwise deliberative records must nevertheless be disclosed. EPA v. Mink, 410 U.S. 73, 87-88 (1973). Here, however, rather than comply with the segregability requirement, defendant has blanketed entire documents – some of which are hundreds of pages long and inevitably contain vast amounts of factual and scientific data – with the rote statement that every single word of the document "contains material that is protected under the deliberative process privilege because it is pre-decisional and deliberative." See Vaughn Excerpts (Pl. Ex. LL) at § 3 (FDA withholding Doc. Nos. 446, 450, 872, each numbering over 100 pages in length, in their entirety under Exemption 5).

3. Defendant Has Not Proven That Records May Be Lawfully Withheld Under Exemption 6.

Defendant has also claimed that approximately 186 records responsive to plaintiff's request may be lawfully withheld under Exemption 6 of the FOIA, which pertains to "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy," 5 U.S.C. § 552(a)(6); Vaughn Excerpts (Pl. Ex. LL) at § 4 (Doc. Nos. 336, 2322), 17 that concern xenotransplantation clinical trials in general, and 140 that pertain to the 35 IND applications.[19]

To withhold records under Exemption 6, the agency must first show that the records are "personnel and medical and similar files" concerning the intimate details of a person's life. 5 U.S.C. § 552(b)(6). In addition, the agency must prove that that disclosure of such information would constitute a "clearly unwarranted invasion of personal privacy." Id. This requires "a balancing of the individual's right of privacy against the preservation of the basic purpose" of the FOIA "to open agency action to the light of public scrutiny." Rose, 425 U.S. at 361. Moreover, because the agency must demonstrate that disclosure would constitute a "clearly" unwarranted invasion of personal privacy, it is well established that the agency – and the reviewing Court – must "tilt . . . [the balance] in favor of disclosure." Getman v. NLRB, 450 F.2d 670, 674 (D.C. Cir. 1974).

Here, however, as with the other exemptions cited by the FDA, defendant has failed to carry its burden of proof that any of these records may be lawfully withheld from plaintiff under Exemption 6. Indeed, defendant's position that information may be withheld under Exemption 6 is particularly perplexing in light of the fact that CRT specifically excluded from its request any information that would reveal the personal identities of patients in any way. See FOIA Request

at 1 (Pl. Ex. FF). Thus, if in fact the information at issue concerns the identities of individuals who are the subjects of xenotransplantation clinical experiments, it is not clear why the agency considers such information to remain at issue in this case. If, however, the information involves some other category of information, the FDA has not explained this in any coherent fashion.

Rather, refusing to break from tradition, the agency again simply restates the relevant FOIA language to justify its assertion that these records fall within Exemption 6, by asserting that the records "[c]ontain[] information about individuals involved in clinical trials, the disclosure of which would constitute an unwarranted [invasion] of privacy." See Vaughn Excerpts (Pl. Ex. LL) at § 4. Again, however, since plaintiff's FOIA request specified that it did not seek the names of patients or any information that would reveal patients' identities, plaintiff does not know why defendant appears to consider such information to remain within the scope of the request. Assuming, however, that the FDA is withholding information that has not been excluded from plaintiff's request, defendant has not come close to meeting its burden to prove that such information falls within Exemption 6.[20]

First, the FDA has not identified any privacy interest at stake here, other than that of the patients – which, again, should not be at issue here. FOIA Request at 1 (Pl. Ex. FF). Therefore, it is difficult to discern what privacy interest should be weighed here against the public interest in disclosure. Meanwhile, as discussed supra at 8-21, there is a tremendous public interest in disclosure of the requested information, as scientists, physicians, ethicists – and the FDA itself – have all acknowledged on many occasions. As the FDA itself most recently acknowledged, because of the "public health risks" posed by xenotransplantation, there is a need for "public education on, and discussion and consideration on, public health and safety issues." 66 Fed.

[19] Thus, the FDA has listed about four such records with respect to IND G (4 x 35 = 140).

Reg. 4688 (Pl. Ex. B). Thus, as the agency has also publicly pronounced, "there is great benefit in having . . . xenotransplantation products scrutinized, as they are being developed, by individuals with a wide variety of perspectives, including scientists from different disciplines, biomedical ethicists, patient advocacy organizations, and the general public, because of the unique blend of proposed benefit as well as potential risk to society that these products possess." Id. at 4692 (emphasis added); see also Frontline: Organ Farm, Interview With Fritz Bach, M.D. ("Bach Interview") (Pl. Ex. PP) at 1 ("[i]f we put the public at potential risk, we have to inform the public") (emphasis added); see also BRMAC Transcript (Pl. Ex. C) at 16, Statements of FDA Deputy Commissioner Pendergast ("extensive public discussion and debate will be needed" over xenotransplantation because public health decisionmakers "have a duty to the public at large") (emphasis added).

Indeed, for example, at least one of the documents that is listed in defendant's Vaughn index clearly concerns an "adverse experience." See Vaughn Excerpts (Pl. Ex. LL) at § 4 (Doc. No. 269, entitled "8/23/96 Telecon to the file from re: Adverse Event Report"). As explained supra at 7, an "adverse experience" is "[a]ny adverse event associated with the use of . . . [the] product in humans . . .." 21 C.F.R. § 600.80(a). In addition, since 1992, at least 16 patients have died during or after xenotransplantation clinical trials, according to published reports. See Fano Decl. (Pl. Ex. I) at ¶ 14.[21] Moreover, as of December 17, 1997, intervenor Diacrin had documented 232 adverse events that were associated with clinical testing – in only 12 patients – of NeuroCell-PD, Diacrin's xenotransplantation product for Parkinson's disease that involves the

[20] Nor has defendant made requisite findings of segregability. 5 U.S.C. § 552(b).

[21] Thus, "CRT seeks to ascertain the true number of deaths and side effects that have occurred during and after xenotransplantation clinical trials and determine whether these deaths and side effects were attributable to xenotransplants or other causes." See Fano Decl. (Pl. Ex. P).

injection of fetal pig cells into patients' brains. See BRMAC Transcript (Pl. Ex. C) at 112-118, Statements of Steven Fink, M.D. However, none of this information has been disclosed.

Accordingly, even assuming that there is some unidentified privacy interest that is truly at stake here, clearly the public interest "tilt[s] . . . in favor of disclosure" under the balancing test that must be conducted under Exemption 6, particularly when plaintiff long ago informed the agency that it can delete all identifying information. Getman, 450 F.2d at 674. Therefore, because the FDA has completely failed to meet its burden of proof under this Exemption or show that there is no reasonably segregable non-exempt information that may be disclosed, plaintiff is also entitled to summary judgment with respect to each of these records.

II. DEFENDANT MAY NOT WITHHOLD RESPONSIVE RECORDS ON THE GROUNDS THAT THEY ARE NOT "AGENCY RECORDS."

Defendant baldly asserts that certain handwritten notes by agency personnel who are apparently responsible for reviewing the sponsors' INDs are not even "agency records" that are subject to the FOIA. See Vaughn Excerpts (Pl. Ex. LL) at § 5 (Doc. Nos. 30, 31, 32, 33); see also Second Banks Decl. at ¶¶ 6, 8. Thus, defendant has refused to disclose approximately 822 records on the grounds that it does not consider them to be "agency records," see Second Banks Decl. at ¶¶ 6, 8 – including 10 that concern xenotransplantation clinical trials in general and 2,135 which concern the 35 separate INDs.[22]

However, it is well settled that a record is an "agency record" subject to the disclosure requirements of the FOIA if it was 'either created or obtained' by the agency, and the agency was "in control of the requested materials at the time the FOIA request" was made. See Dep't of

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at ¶ 14; see also supra at 7-14 (describing the serious public health risk posed by xenotransplantation).

[22] Thus, defendant has withheld 61 records that concern IND "G" on this basis (61 x 35 = 2,135).

Justice v. Tax Analysts, 492 U.S. 136, 144-45 (1989). Moreover, an agency has sufficient "control" over the record if the materials came "into the agency's possession in the legitimate conduct of its official duties." Id. at 145 (emphasis added).

Nevertheless, to support its conclusion that these records are not "agency records," defendant states simply that they are "personal notes" that IND reviewers "scribble" in the "margins of sponsor submissions in IND files[,]" see Second Banks Decl. at ¶ 8, and that some "are not work-related." Id. However, if, presumably, such records are not work-related – e.g., they are personal reminders to agency employees to attend a doctor's appointment or to pick up children from school, then it is peculiar that defendant considers them to be responsive to plaintiff's FOIA request at all – which most definitely sought documents concerning "work-related" information. See FOIA Request (Pl. Ex. FF) (requesting all records that "concern xenotransplantation clinical trials").

However, defendant's own declarant also admits that some of these records are "work-related," but, as to these documents, the agency asserts that they are nevertheless not "agency records" because they "were intended only for personal convenience, not for distribution to other agency employees." See Second Banks Decl. at ¶ 8. Thus, because these records came into the possession of the agency "in the legitimate conduct of its official duties" – here, reviewing the safety and efficacy of xenotransplantation products – certainly these records are "agency records" that are covered by the disclosure mandate of the FOIA. Tax Analysts, 492 U.S. at 144-45. Accordingly, plaintiff is also entitled to summary judgment with respect to all of these records, unless the agency can demonstrate that they are exempt from disclosure under of the nine exemptions to the FOIA.

III. DEFENDANT HAS FAILED TO DISCLOSE INFORMATION THAT IT ACKNOWLEDGES IS NON-EXEMPT.

Defendant's Vaughn index acknowledges that certain portions of withheld documents are not exempt under any of the claimed exemptions. See, e.g., Vaughn Excerpts (Pl. Ex. LL) at § 6 (for example, for documents 324, 449, 465, 467, the agency states that it is withholding only portions of records under one or more FOIA exemptions). Indeed, defendant's own declarant states that "[a]ny information in a document that is not covered by the page and paragraph range is releasable" and that "[a]ll reasonably segregable, non-exempt FDA-generated agency records will be disclosed to Plaintiff." Second Banks Decl. at ¶ 7 (emphasis added). Thus, for example, with regard to document number 1375 – a 6-page document described only as "Internal email, re: bulleted format of proposed rule RE: gene therapy and xenotransplantation" – defendant apparently considers some portions to be "releasable." See Vaughn Excerpts (Pl. Ex. LL) at § 6 (withholding some sections of Doc. No. 821 as deliberative and stating that paragraphs 2/4 on page 9 are "releasable"). Nevertheless, defendant has yet to disclose much of this "releasable" information to plaintiff. See, e.g., Vaughn Excerpts (Pl. Ex. LL) at § 6 (Doc. Nos. 329, 386, 449, 465, 467, 853). Accordingly, the FDA should be ordered to disclose immediately all information that it itself has identified as releasable.

IV. DEFENDANT HAS NOT CONDUCTED AN ADEQUATE SEARCH FOR RESPONSIVE RECORDS.

It also appears that defendant has failed to conduct an adequate search for responsive records. See Truitt, 897 F.2d at 542 (an agency's search for responsive records must be "reasonably calculated to uncover all relevant documents"). To meet its burden in this regard, an agency's affidavit must be "relatively detailed" and "nonconclusory" as to the scope of the search that was conducted. See Weisberg v. U.S. Department of Justice, 705 F.2d 1344, 1350-51

(D.C. Cir. 1983) ("the agency must show" that "it has conducted a search reasonably calculated to uncover all relevant documents").

However, for example, nothing in defendant's Vaughn index or the accompanying declaration appears to describe records that pertain to the FDA's decision to place a clinical hold on all xenotransplantation clinical trials in October 1997. See PHS Disease Guidelines (Pl. Ex. A) at 7 (on October 16, 1997, "[a]s the science regarding" PERVs "began to emerge, the FDA placed all clinical trials using [pig] xenotransplantation products on hold"). In addition, there also appears to be nothing in defendant's Vaughn index that pertains to the agency's subsequent decision, sometime in 1998, to allow xenotransplantation clinical trials to resume. See, e.g., Fano Decl. (Pl. Ex. P) at ¶ 13 (The FDA "never adequately explained to the public why it lifted its hold on clinical trials despite the public health risks that are posed by xenotransplantation"). Indeed, although the agency has stated that it placed these trials on hold "pending development by sponsors of sensitive and specific assays" for minimizing the risk of PERV infections, nothing in defendant's Vaughn index appears to describe any documents that concern the development of such assays, and, for that matter, why the FDA apparently considered any such assays to be sufficient to alleviate the public health risk of PERV infection that is posed by xenotransplantation. Finally, although by December 1997, intervenor Diacrin had already documented 232 adverse events in connection with clinical testing of its NeuroCell-PD product alone, defendant's Vaughn index does not appear to address any of these events.

The omission of such clearly responsive records means either that the FDA simply failed to include these records in its Vaughn index, or that the records are so poorly described that this inclusion cannot be discerned. In any event, because these records certainly have not been clearly identified in the agency's Vaughn index, plaintiff must conclude that the agency's search

for records was simply not "reasonably calculated to uncover all relevant documents." See Truitt, 897 F.2d at 542; Weisberg v. U.S. Department of Justice, 705 F.2d at 1350-51. Accordingly, plaintiff respectfully requests the Court to order the FDA to conduct an adequate search for records and to disclose them to plaintiff unless the agency can meet its burden of proof that these records are exempt from disclosure.

CONCLUSION

Because the agency has completely failed to satisfy even the most rudimentary requirements of Vaughn v. Rosen and continues to withhold vast amounts of responsive information concerning an extremely serious public health risk, even when much of this same information has already been publicly disclosed by the companies themselves, the Court should grant summary judgment for plaintiff. Indeed, because the agency has demonstrated nothing but intransigence in this case for almost two years now, the Court should order the FDA to disclose all of the requested information, as other Courts have done under similar circumstances. See, e.g., Carlton, supra, slip op. at 16-17 (Pl. Ex. OO) (given the agency's "apparent inability to prepare an adequate index, and given FOIA's 'general philosophy of full agency disclosure'," the government must "produce all agency records withheld as exempt . . . .").

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