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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR)	
RESPONSIBLE TRANSPLANTATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 00-2849 (RMU/AK)
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION,)	
)	
Defendant,)	

**MEMORANDUM IN SUPPORT OF PLAINTIFF'S
MOTION FOR AN AWARD OF ATTORNEYS' FEES AND COSTS**

Introduction

Plaintiff, the Campaign for Responsible Transplantation ("CRT"), seeks an award of attorneys' fees and costs in connection with its efforts in compelling the government to release thousands of pages of records in this case under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. As demonstrated below, because plaintiff "substantially prevailed" in the litigation, 5 U.S.C. § 552(a)(4)(E), and CRT meets all of the other criteria for an award of attorneys' fees and costs, its motion should be granted.

Because the government disputes that CRT is entitled to any fees and costs in this case, the parties have agreed that they will first brief this issue, and, should plaintiff obtain a favorable ruling from the Court, the parties will attempt to negotiate an appropriate amount of reimbursement. See Plaintiff's Consent Motion For Briefing Schedule On Plaintiff's Entitlement

To Fees and Costs (December 15, 2005).¹

BACKGROUND

A. Xenotransplantation

On March 9, 2000, CRT submitted a FOIA request to defendant Food and Drug Administration (“FDA”) for “all records concerning applications for approval to conduct clinical trials in humans that involve xenotransplantation” and “all information concerning currently on-going and concluded clinical trials involving xenotransplantation.” See FOIA Request, Plaintiff’s Exhibit 13 to Plaintiff’s (First) Motion for Summary Judgment (“Pl. 1st SJ Mem.”) (January 15, 2002). In its request, CRT specified that it was not seeking “any information that would identify a patient in any way, or involve the disclosure of any personal identifying information.” Id. at 1.

CRT is a non-profit organization dedicated to informing the public about the ethical issues and public health risks associated with the transplantation of animal organs and tissue into humans – called “xenotransplantation.” CRT was formed in 1998 out of concern over the rush to commercialize animal-to-human organ, cell and tissue transplantation using genetically modified pigs, and nonhuman primates. See www/crt-online.org. CRT believes that xenotransplantation poses a grave danger to human health due to the risk of transferring deadly animal viruses to the human population. CRT also believes that there are safer and more cost-effective ways to resolve the alleged shortage of human organs for transplantation that are not being adequately

¹Plaintiff attempted to resolve this matter without the involvement of the Court. However, although the government’s counsel suggested that the amount of fees and costs requested by plaintiff may be reasonable, the government does not believe that CRT is eligible for any fees in this case, which is what has necessitated the need for a ruling on this motion.

explored. Id.

CRT is an international coalition of more than 90 public interest groups, physicians, scientists, veterinarians, lawyers, and concerned laypersons, including the Physicians Committee for Responsible Medicine, the International Center for Technology Assessment, the Jane Goodall Institute, the Earth Island Institute, and the New Mexico Center for Chronic Disorders. CRT, and its executive director, Alix Fano, are well known policy experts on this particular issue. See, e.g., New York Times, “Breakthrough in Pig Cloning Could Aid Organ Transplants” (January 4, 2002) (quoting Alix Fano as “[a] leading opponent of xenotransplantation”); The Lancet, “Pig Organ Transplantation Brought One Step Closer,” (Vol. 359) (January 12, 2002) (quoting Alix Fano); Wired (February 27, 2001) (“This Little Piggy Goes To Steve”) (quoting Ms. Fano) (all of these articles are included in Exhibit A). CRT operates a website that is completely devoted to xenotransplantation, *supra*, and it also regularly issues Press Releases concerning this subject. See, e.g., Press Releases (attached as Exhibit B).

Xenotransplantation is a relatively new, highly controversial experimental approach to dealing with human disease that, to date, has not been proven either safe or effective. Xenotransplantation, especially experiments involving pig cells and tissue – currently the most predominant form of such experiments – poses serious health risks to the recipients of the animal parts, to those in the health care profession who are exposed to patients receiving such parts, and to the public at large, because of the transmission of potentially dangerous porcine endogenous retroviruses, called “PERVs”. See Pl. 1st SJ Mem. at 6-13. Indeed, according to one expert, the “worst-case scenario” of PERV transmission is that it could cause a “new pandemic that would spread across the world, just like HIV.” Frontline: Organ Farm, Interview With Robin Weiss

(2000) (“Weiss Interview”) (Pl. Ex. 6 to 1st SJ Mem.) at 9 (emphasis added); see also Scheef, et al., Transcriptional Regulation of [PERVs], *Journal of Virology* (Dec. 2002) (Pl. Ex. 7) (study revealing that PERVs replicate from infected human cells).

In fact, it is precisely because xenotransplantation poses these serious health risks that experts – including the FDA – have stressed that “it is vital that the public . . . be informed and educated about potential infectious disease risks” associated with xenotransplantation. 66 Fed. Reg. 4688, 4695 (January 18, 2001) (emphasis added); see also Bach Interview (Pl. Ex. 8) at 1 (“[i]f we put the public at potential risk, we have to inform the public and take segments of the public who are well-informed to discuss [this] with us, and to help us find the conditions under which we could proceed”) (emphasis added); Statements of FDA Deputy Commissioner Mary Pendergast, Transcript, Biological Response Modifiers Advisory Committee. (Dec. 17, 1997) (“BRMAC Transcript”) (Pl. Ex. 9) at 16 (“extensive public discussion and debate will be needed” concerning xenotransplantation because public health decision makers “have a duty to the public at large”) (emphasis added).

However, despite these serious public health threats and other unanswered questions posed by xenotransplantation, the FDA has permitted many clinical trials in humans to go forward, without any public scrutiny. Thus, pursuant to its statutory and regulatory duty to regulate xenotransplantation products as “drugs,” “devices,” or “biological products” under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., the Public Health Service Act, 42 U.S.C. § 262(a), and FDA regulations, 21 C.F.R. Parts 310, 312, FDA has approved approximately 35 “investigational new drug” applications (“IND”), thereby authorizing the IND sponsors to

conduct xenotransplantation clinical trials in humans.²

B. CRT's FOIA Request and The Court's Rulings

It was against this background that CRT submitted its FOIA request almost six years ago. However, the FDA chose not to respond to the request. Therefore, on November 29, 2000, after exhausting all of its administrative remedies, CRT filed this lawsuit in an attempt to obtain access to as many of the requested records as possible. CRT consented to the intervention of several biotechnology companies that are the sponsors of the clinical trials involving xenotransplantation. However, subsequently, CRT narrowed its request to include only records that were actually generated by the FDA – i.e., it did not seek copies of any records that were submitted to the agency by the companies. See Plaintiff (Second) Summary Judgment Memorandum (July 9, 2003) at 1 .

Because the agency had never provided CRT a substantive response to its request, CRT did not know what responsive records the agency had, or on what basis any such records could be withheld by the agency. Therefore, on May 9, 2001, CRT moved for the production of a Vaughn index, so that it would have some idea of what records the agency had that were responsive to its request, and the basis upon which the agency was withholding such records from the public. See Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974).

² Indeed, CRT learned from records disclosed in this lawsuit that Parkinson's Disease patients participating in FDA-approved xenotransplantation clinical trials who had pig cells injected into their brains developed malignant cancers that had to be removed. See Doc. Nos. 367, 368, 473 (Pl. Ex. 10). In addition, records show that other patients experienced "adverse events" – including brain swelling, tremors, hallucinations, and body soreness. Doc Nos. 9, 14, 159, 269, 488, 501, 592, 676 (Pl. Ex. 11). In one 1996 incident involving "an error in quality control," a pig that might have tested positive for an infectious virus was used as a source animal for fetal neural tissue. Doc. No. 400 (Pl. Ex. 12).

On July 23, 2001, the Court ordered FDA to produce a Sample Vaughn Index to defend its withholding of the responsive records. Campaign for Responsible Transplantation v. Food and Drug Administration, 180 F. Supp. 2d 29, 33 (D.D.C. 2001) (“CRT I”). For those responsive records that pertained to particular INDs, the FDA was ordered to produce an index of records contained in a “representative” IND so the Court could “extrapolate its conclusions from the representative sample to the larger group of withheld material.” Id. (quoting Fensterwald v. CIA, 443 F. Supp. 667, 669 (D.D.C. 1977)). Accordingly, plaintiff selected IND “G” – to be used for this representative index. Letter from Atwood to Sonfield, Levy (Aug. 3, 2001) (Pl. Ex. 15). All other responsive records – i.e., those that discuss xenotransplantation in general – were also to be addressed in the agency’s Sample Vaughn Indices. See Campaign for Responsible Transplantation v. Food and Drug Administration, 219 F. Supp.2d 106, 109 (D.D.C. 2002) (“CRT II”).

FDA produced its first Sample Vaughn Index on August 31, 2001, and contended that thousands of FDA-generated records containing information about xenotransplantation clinical trials – including records concerning trials in general, as well as records specifically concerning IND G – could lawfully be withheld from disclosure. See Federal Defendant’s Notice of Filing (Aug. 31, 2001). However, because those Indices failed to demonstrate that many of those records were actually exempt from disclosure – and hence that the agency had met its burden of proof – on January 15, 2002, plaintiff moved for summary judgment on that basis. See Pl. 1st SJ Mem. at 27-38 .

On September 3, 2002, this Court agreed with plaintiff that the FDA’s Vaughn Indices were inadequate to meet the government’s burden of proof, and granted plaintiff’s motion for

summary judgment on that basis. CRT II, 219 F. Supp.2d at 116. Finding the Sample Vaughn Indices inadequate because “[t]he description, reason for withholding, and cross-references do not provide enough information to give this court and the requester a clear indication of the justification for each exemption,” the Court ordered the FDA to submit new Vaughn indices “with proper detailed document descriptions and reasons for withholding that illuminate the contents of the documents and the reasons for nondisclosure.” Id. (emphasis added) (citation omitted).³

In December 2002, pursuant to the Court’s Order, the FDA produced its second Sample Vaughn Index, and, in connection with that exercise, on February 3, 2003, the agency released to plaintiff 1000 pages of responsive records. See Joint Status Report (January 16, 2003) at 2.

Based on that release, information in the second index, and further negotiations with the FDA and intervenors, CRT was then able to narrow its request further to 126 “representative” records that it still wished to pursue with respect to all of the INDs at issue. Letter from Atwood to Counsel (Mar. 20, 2003) (Pl Ex. 16). After the FDA disclosed additional information on April 10, 2003, plaintiff prepared a list of the remaining records and exemptions at issue. Letter from Atwood to Counsel (Apr. 28, 2003) (Pl. Ex. 17).

The FDA then filed its Renewed Motion for Summary Judgment and CRT filed a cross-motion for summary judgment and made it clear that it did not seek information that would identify a particular sponsor of a clinical trial or the actual product to which the record pertains. See Pl. 2nd SJ Mem. at 1. However, plaintiff also made clear that it was entitled to obtain all of

³The Court also granted summary judgment for the FDA on the issue of the adequacy of its search for responsive records. See 291 F. Supp.2d at 110-111.

the non-exempt records that pertained to all of the other INDs, which the agency had yet to provide to CRT. See Pl. 2nd SJ Mem. at 20, n. 8 (“[s]ince IND G is purportedly representative of the other INDs still at issue, plaintiff is also entitled to disclosure of information about clinical holds, side effects, adverse events, PERV testing, and PERV assays contained in each of the other INDs”), citing CRT I, 180 F. Supp. 2d at 33 (purpose of the sample Vaughn Index is to allow the Court to “extrapolate its conclusions from the representative sample to the larger group of withheld material”)); see also Plaintiff’s Opposition to Defendant’s Motion For Leave To File Sur-Reply (September 24, 2003) (“[i]t is plaintiff’s position that, with respect to any records that pertain to IND G, the agency has now disclosed in the course of the litigation, the FDA should necessarily be required to release all records that pertain to the other 18 INDs that are similar in nature, since, according to the agency’s own consistent representations, those records should not be lawfully withholdable – because the IND G records that have been disclosed are ‘representative’ of records pertaining to the other INDs”).

In response to plaintiff’s motion, on July 24, 2003 the FDA released additional records to CRT and it filed yet another Sample Vaughn Index that provided the agency’s justification for withholding the remaining information pertaining to IND G. However, the FDA continued to refuse to release to CRT thousands of pages of non-exempt material concerning the other INDs at issue in this case, on the ground that this would not be administratively efficient until the entire case was finally resolved by the Court. See, e.g., Defendant’s Sur-Reply In Further Support Of Renewed Motion for Summary Judgment (September 9, 2003) at 2 (explaining its position that it should not have to release any of the non-exempt records because this is a “massive undertaking that could take over a year”).

By Order dated December 2, 2003, this Court struck both parties' motions for summary judgment on the grounds that it was not clear from those papers precisely how many and which records remained at issue. See Order (Dec. 2, 2003). Accordingly, the Court directed the parties to file new motions for summary judgment that would make clear which IND G records remained at issue. The parties subsequently conferred on that matter, reached an agreement as to which IND G records remained at issue, and then filed renewed cross-motions for summary judgment with respect to those records.

In its briefs, plaintiff again pointed out that, although the whole point of the Court's acceptance of a Sample Vaughn Index for IND G was that those records were "representative" of the responsive records for all of the other INDs, and that all such records were "essentially uniform" in kind, see CRT I, 180 F. Supp. 2d at 34-35, the agency had nevertheless failed to release any of the non-exempt records with respect to any of the other 18 INDs that it was withholding, although it had released hundreds of such non-exempt records for IND G. See, e.g., Plaintiff's Renewed Summary Judgment Memorandum (January 5, 2004) at 3 ("now that the FDA has released hundreds of pages of responsive IND G records because the agency cannot meet its burden to prove that such information is exempt from disclosure, it must likewise be required to release all of the 'essentially uniform' records that pertain to all of the other 18 INDs at this point"). Accordingly, plaintiff requested an order from the Court compelling the FDA to release all such records. Id.

On September 24, 2004, the Court issued its Memorandum and Order. Although it upheld the agency's exemption claims with respect to the remaining IND G documents at issue, it also specifically ordered "that the FDA shall disclose all FDA generated records that pertain to

the other 18 INDs that are similar in kind to the IND G records that the FDA has already released.” Order (September 24, 2004) (emphasis added).

However, by April 1, 2005 – six months after the Court’s Order – the FDA still had not released any of the remaining non-exempt records. Accordingly, plaintiff filed a Motion to Enforce This Court’s September 24, 2004 Order (April 1, 2005), which immediately prompted the agency to begin releasing documents. See Plaintiff’s Reply In Support Of Its Expedited Motion To Enforce (April 18, 2005) at note 1 (noting that the government finally delivered the first set of additional documents on April 15, 2005). And, although the Court denied the motion to enforce, it nonetheless ordered the parties to agree by May 24, 2005 to a schedule for the release of the remainder of the records that were covered by the Court’s September 24, 2004 Order. See Order (May 3, 2005).

Pursuant to the Court’s September 24, 2004 Order, the FDA has now released over seven thousand more pages of documents that are responsive to plaintiff’s original March 9, 2000 FOIA request. Therefore, as permitted by the plain language of FOIA, CRT now seeks an award of attorneys’ fees and costs for having “substantially prevailed” in this case. 5 U.S.C. § 552(a)(4)(E).

ARGUMENT

I. CRT IS ELIGIBLE FOR AN AWARD OF ATTORNEYS’ FEES AND COSTS.

The FOIA provides that “[t]he court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case . . . in which the complainant has substantially prevailed.” 5 U.S.C. § 552(a)(4)(E). A plaintiff has “substantially prevailed” in a FOIA case when the case results in “a court ordered change in the legal

relationship between the plaintiff and the defendant.” Oil, Chemical & Atomic Workers Int’l Union, AFL-CIO v. Dep’t of Energy, 288 F.3d 452, 458 (D.C. Cir. 2002) (citing Buckhannon Board & Care Home, Inc. v. W. Virginia Dep’t of Health & Human Res., 532 U.S. 598, 604 (2001)). The Supreme Court has determined that “enforceable judgments on the merits and court-ordered consent decrees create the ‘material alteration of the legal relationship of the parties’ necessary to permit an award of attorney’s fees.” Buckhannon, 532 U.S. at 604 (quoting Texas State Teachers Ass’n v. Garland Independent School Dist., 489 U.S. 782, 792-93 (1989)); see also Judicial Watch v. Dep’t of Commerce, 384 F. Supp. 2d 163, 168 n. 1 (D.D.C. 2005) (eligibility “means that a plaintiff won *some* court-awarded relief”) (emphasis in original).

Here, there can be no doubt that, as a result of this case – and this Court’s rulings – there has been a “material alteration” in the “legal relationship” between plaintiff and the FDA, Buckhannon, 532 U.S. at 604, and that the plaintiff “won *some* court-awarded relief.” Judicial Watch, 384 F. Supp. 2d at 168 n.1; see also Oil, Chemical & Atomic Workers, 288 F.3d at 458 (“there must be some sort of ‘judicial relief’ in favor of the party seeking an award of fees”) (internal citations omitted). As demonstrated, *supra*, the Court first granted plaintiff’s motion for summary judgment concerning the inadequacy of the FDA’s Sample Vaughn Index – and hence the agency’s failure to meet its statutorily imposed burden of proof – and ordered the agency to prepare a sufficient Vaughn Index with respect to IND G. See CRT II, 219 F. Supp. 2d at 115–16 (finding that the “conclusory statements” in the agency’s Vaughn index “cannot support summary judgment,” citing King v. Dep’t of Justice, 830 F.2d 210, 219 (D.C. Cir. 1987)). As a direct result of that ruling, the FDA disclosed to plaintiff thousands of responsive records that it could no longer justify withholding. See *supra* at 7.

In addition, although the agency had represented to the Court that all of the IND G records were “representative” of records pertaining to the other 18 INDs – which meant that there were thousands of additional records that were also not exempt from disclosure – the agency nevertheless continued to withhold all of those records from CRT for over five years. Thus, it was not until this Court issued its September 24, 2004 order that the FDA “shall disclose all FDA generated records that pertain to the other 18 INDs that are similar in kind to the IND G records that the FDA has already released,” and plaintiff filed its motion to enforce that order, that the FDA released thousands of additional responsive records to plaintiff between April - October 2005. See Order (September 24, 2004); see also supra at 9-10. Therefore, clearly, as a direct result of CRT’s litigation, plaintiff obtained ““a court ordered change in the legal relationship between the plaintiff and the defendant.”” Oil, Chemical & Atomic Workers, 288 F.3d at 458 (quoting Buckhannon, 532 U.S. at 604).

Moreover, although plaintiff was not successful in obtaining all of the records that it sought in bringing this case, in fact, CRT would not have obtained any of those records had it not obtained court-ordered relief here. Indeed, CRT obtained thousands of responsive records as a direct result of this Court’s scrutiny of defendants’ exemption claims and its attendant rulings requiring the government to release those records. Therefore, the mere fact that CRT was not 100% successful in obtaining all of the records it requested does not defeat its eligibility to fees. See, e.g., Edmonds v. F.B.I., 417 F.3d 1319, 1322-23 (D.C. Cir. 2005) (court order merely requiring the expedited processing of a FOIA request supplies the requisite “judicially sanctioned change in the legal relationship of the parties” required for fees eligibility) ; see also Judicial Watch v. Dep’t of Commerce, 384 F. Supp. 2d at 168 n.1 (eligibility “means that a plaintiff won

some court-awarded relief”) (emphasis in original); Piper v. U.S. Dep’t of Justice, 339 F. Supp. 2d 13 (D.D.C. 2004) (plaintiff is eligible for fees where court makes agency comply with procedures applicable to FOIA, grants partial summary judgment for plaintiff, and orders the government to release documents).

II. CRT IS ENTITLED TO AN AWARD OF ATTORNEYS’ FEES AND COSTS.

Once a plaintiff is found to be eligible for an award of fees and costs, the plaintiff must show that it is entitled to such an award. In determining whether to make an award, the reviewing court should consider several factors including: “(1) the public benefit derived from the case; (2) the commercial benefit to the plaintiff; (3) the nature of the plaintiff’s interest in the records; and (4) the reasonableness of the agency’s withholdings.” Tax Analysts v. U.S. Dep’t of Justice, 965 F.2d 1092, 1093 (D.C. Cir. 1992); see also S. Rep. No. 93-854, 93d Cong., 2d Sess. 19 (1974); reprinted in Freedom of Information Act and Amendments of 1974 (P.L. 93-502), Source Book, Joint Committee Print, 94th Congress, 1st Sess. (March 1975) (hereinafter “Source Book”) at 171.

An applicant for fees need not demonstrate that all of the criteria are met, and a strong showing on one factor may weigh heavily in favor of granting fees. See Crooker v. United States Parole Comm’n, 776 F.2d 366, 369 (1st Cir. 1985) (even where agency’s position was reasonable, an award of fees was still appropriate); see also LaSalle Extension University v. F.T.C., 627 F.2d 481, 484-85 (D.C. Cir. 1980) (while all four factors should be considered, not all may be deserving of same weight). Applying these criteria here, there can be no doubt that plaintiff should be awarded its fees and costs.

A. There Is A Definite Public Benefit From The Release Of The Requested Information.

There is a clear public benefit derived from the disclosure of information concerning xenotransplantation and the government's involvement in permitting and scrutinizing such experiments. As demonstrated *supra* and in plaintiff's summary judgment memorandum, see Pl. 1st SJ Mem. at 6-13, there is significant public interest in this extremely controversial experimental technology.⁴

Moreover, the agency's own officials have acknowledged that "it is vital that the public . . . be informed and educated about potential infectious disease risks" associated with xenotransplantation. 66 Fed. Reg. at 4695 (emphasis added); see also Statement of FDA Deputy Commissioner Mary Pendergast, Transcript, Biological Response Modifiers Advisory

⁴See also, e.g., The Washington Post (July 12, 2000) at A09 ("FDA Faults Penn Animal Tests That Led to Fatal Human Trial"); Los Angeles Times (August 17, 2000) ("Study Suggests Pig Organ Transplants Could Imperil Humans"); The New York Times (March 8, 2001) (story about using xenotransplantation to treat Parkinson's disease); The Wall Street Journal (August 28, 2000) ("From A Small Pig, A Big Advance for Transplanting Animal Organs"); Nature, "FDA Turns Down Moratorium Demand On Xenotransplants" (Vol. 391) (January 29, 1998); The Roanoke Times (March 19, 2000) ("Cloning brings hopes, fears, doubts"); Associated Press (January 4, 2002) ("Experts Question Pig Transplants"); Chicago Sun Times (March 27, 2000) ("Rush, U. of I. seeking pig-human transplant"); The Boston Globe (December 11, 1998) ("Group Asks end to transplants from animals"); Des Moines Sunday Register (February 9, 2003) ("Cloning Gold"); The New York Times (January 4, 2002) (Breakthrough In Pig Cloning Could Aid Organ Transplants"); The Daily Express UK (September 21, 2000) ("Terrible Despair Of Animals Cut Up In Name Of Research"); The UK Health (February 20, 2001) ("Pig Organ Transplants 'Too Risky' for Humans"); Wired (February 27, 2001) ("This Little Piggy Goes To Steve"); The Wall Street Journal (August 8, 2001) ("Transplant Researchers Favor Miniature Pig for Donor Organs"); The Washington Post (August 24, 2001) ("Stem Cell Research Faces FDA Hurdle – With Mouse Cell Base, Tough Rules Apply"); The British Medical Journal (September 23, 2000) ("Infection In Xenotransplantation) (copies of these and other articles concerning xenotransplantation are included collectively as Exhibit A).

Committee. (Dec. 17, 1997) (“BRMAC Transcript”) (Pl. Ex. 9) at 16 (“extensive public discussion and debate will be needed” concerning xenotransplantation because public health decision makers “have a duty to the public at large”) (emphasis added).

Furthermore, CRT is uniquely qualified to analyze and disseminate such information to the public, through its website, press releases, and other public forums. CRT’s Director, Alix Fano, is recognized as a leading policy expert on this subject, see, e.g., Press Releases (attached as Exhibit B); see also supra at 3; Declaration of Alix Fano, attached as Exhibit C, ¶ 3, and CRT is currently working with another organization to analyze, report on, and disseminate information obtained from the thousands of documents that it obtained as a result of its FOIA suit. See Fano Decl. ¶ 4.

Accordingly, the release of this information serves the public interest by (1) educating the public about the potential benefits and risks associated with this biotechnology; (2) adding to the fund of public knowledge that in turn will assist the government in deciding whether, and under what circumstances, to permit such technology; and (3) keeping the public informed about what its government is up to with respect to approving and monitoring the use of such technology on an experimental basis. See Dep’t of Justice v. Reporters Comm. for Freedom of the Press, 489 U.S. 749, 752 (1989) (noting that “basic purpose” of FOIA is “to open agency action to the light of public scrutiny,” quoting Dep’t of Air Force v. Rose, 425 U.S. 352, 372 (1976)); see also Cotton v. Heyman, 63 F.3d 1115, 1120 (D.C. Cir. 1995) (release of FOIA information serves the public when it is “likely to add to the fund of information that citizens may use in making vital political choices”); see also Tax Analysts, 965 F.2d at 1096 (noting that “a court would generally award fees if the complainant’s interest in the information was . . . journalistic”). Therefore,

under the “public benefit” criterion, CRT is plainly entitled to an award of fees.

Furthermore, although the disclosure of this particular information has a clear public benefit, the D.C. Circuit’s decisions “make clear that the court must also consider ‘the public benefit derived *from the case*’” itself. Chesapeake Bay Found., Inc. v. Dep’t of Agriculture, 108 F.3d 375, 377 (D.C. Cir. 1997) (emphasis in the original) (quoting Tax Analysts, 965 F.2d at 1093-94). Here, CRT has vindicated the public’s right to know how the FDA is dealing with an extremely dangerous experimental biotechnology that raises many serious health and ethical issues.

Therefore, there can be no question that this case has resulted in the disclosure of information that is “likely to add to the fund of information” available to the public for use in monitoring the FDA’s regulation and scrutiny of these highly risky experiments, as well as the agency’s actions in protecting the public health. Cotton, 63 F.3d at 1120; see also Piper, 339 F. Supp. 2d at 20-21 (there is a “public benefit from the case” when the information released “will assist the citizenry in making informed judgments and opinions about the [agency] and how it is operating”).

**B. There Is No Commercial Benefit To The Plaintiff
And Plaintiff’s Interest Is Public-Interest Oriented.**

The second and third criteria – “the factors of ‘commercial benefit’ and ‘plaintiff’s interest’” – “are closely related and often considered together.” Tax Analysts, 965 F.2d at 1095. Here, plaintiff realized no “commercial benefit” at all from release of the requested materials. Fano Decl. ¶ 5. Rather, CRT is a non-profit organization dedicated to informing the public about the public health risks and ethical concerns posed by xenotransplantation. Fano Decl. ¶ 2. Thus, its sole interest in pursuing the records at issue in this case was to find out and disseminate to the

public information concerning the FDA's decisions to approve INDs for clinical trials involving xenotransplantation, and to ensure that the FDA is abiding by all relevant requirements of laws governing such experiments. Fano Decl. ¶ 5.

Accordingly, because CRT does not have a commercial interest in the requested information, a fee award is appropriate. See, e.g., United Ass'n of Journeyman and Apprentices of the Plumbing and Pipe Fitting Indus., Local 598 v. Dep't of Army, Corps of Engineers, 841 F.2d 1459, 1461-62 (9th Cir. 1988) (finding of no commercial interest weighs heavily in favor of awarding fees, since the attorney's fee provision of the statute "was intended to encourage complainants who lack substantial pecuniary incentives to pursue their claims"), quoting Lovell v. Alderete, 630 F.2d 428, 433, n.6 (5th Cir. 1980), overruled on other grounds by U.S. Dep't of Def. v. Fed'l Labor Relations Auth., 510 U.S. 487, 497 (1994).

Similarly, under the plaintiff's interest factor, "a court would generally award fees if the complainant's interest in the information sought was scholarly or journalistic or public interest oriented, but would not do so if his interest was of a frivolous or purely commercial nature." Source Book at 171 (emphasis added); see also Nationwide Bldg. Maintenance, Inc. v. Sampson, 559 F.2d 704, 712 (D.C. Cir. 1977); Local 598, 841 F.2d at 1462 (explaining that "[i]nquiry into the 'nature of the interest' should lead the court to consider whether the claimant seeks to protect a private, purely commercial interest, as opposed to a scholarly, journalistic, or public interest"). Here, as demonstrated, *supra*, plaintiff's interest was clearly "public interest oriented," and one that is completely consonant with the FDA's own avowed interest in ensuring that the public be informed and educated about potential infectious disease risks" associated with xenotransplantation. 66 Fed. Reg. at 4695 (emphasis added).

C. The FDA Did Not Have A Reasonable Legal Basis For Withholding Non- Exempt Records from Plaintiff.

The final criterion – whether the government's withholding decision had a “reasonable basis in law” – also counsels in favor of awarding fees in this case. Indeed, one of the purposes of this factor is to “weed out those cases in which the government was ‘recalcitrant in its opposition to a valid claim or otherwise engaged in obdurate behavior.’” Tax Analysts, 965 F.2d at 1097 (quoting Cuneo v. Rumsfeld, 553 F.2d 1360, 1366 (D.C. Cir. 1977)). It is precisely this type of behavior in which the FDA engaged here.

First, the FDA simply refused to respond to CRT’s FOIA request, requiring CRT to hire lawyers to file a lawsuit to force the agency to process its request. Second, as this Court ruled, the agency then submitted a Vaughn index in support of its cross-motion for summary judgment that was entirely inadequate to justify its withholding of any of the records requested by plaintiff. See CRT II, 219 F. Supp. 2d at 112-116. Third, after the Court ruled that the agency’s original Vaughn index could not sustain the agency’s withholding of all of the records, and the agency finally released hundreds of records concerning IND G, the FDA continued to withhold thousands of additional records concerning the other 18 INDs for more than two more years, even though the agency knew that those records were also not exempt from disclosure, since the agency had represented to the Court that all of those records were “essentially uniform” to the non-exempt records that were generated with respect to IND G. Moreover, even after the Court’s September 24, 2004 Order, the agency continued to delay releasing these records, until plaintiff filed its motion to enforce the Court’s Order. See *supra* at 9-10.

Accordingly, it took CRT approximately five and a half years to obtain access to thousands of records that were not exempt from disclosure under the FOIA, but which the agency

nevertheless continued to withhold from CRT, simply because it believed this was the most efficient way for the agency to proceed – i.e., to wait until the Court ordered it to release all of the non-exempt documents at once. See Defendant’s Sur-Reply at 2 (explaining its position that it should not have to release any of the non-exempt documents until after the Court rules on the parties’ cross-motions for summary judgment concerning the records that the agency contends are exempt from disclosure). However, having chosen that particular litigation tactic, the FDA cannot now avoid plaintiff’s right to obtain a fee award on the grounds that the agency had a “reasonable basis in law” for withholding all of those documents. See Piper, 339 F. Supp. 2d at 23.⁵

Rather, under such circumstances, the agency’s withholding of non-exempt records simply was not “reasonable.” As one court has observed, such “practical explanations” – like those asserted by the government here – do not supply the necessary “reasonable legal bases” for withholding requested records that is required to deny a successful plaintiff an award of attorney’s fees. Miller v. U.S. Dep’t of State, 779 F.2d 1378, 1390 (8th Cir. 1985). Rather, “[w]hen a private citizen is obliged to seek legal services in order to wrest from the government information which the government had no legal reason to withhold from him, he is entitled under the Act to be reimbursed for the cost to which he has been put.” Id.; see also Piper, 339 F. Supp.

⁵Although the agency insisted that “it always has been understood by the parties that the processing of these additional INDs would take place **after** the Court ruled on the parties’ cross-motions for summary judgment,” Sur-Reply at 2 (emphasis in original), the government cited nothing to support that self-serving statement, and, as thoroughly demonstrated, see supra at 7-10, this simply is not correct. Rather, plaintiff – who had been seeking access to all of the non-exempt responsive records since March 9, 2000, wanted to obtain all such records as quickly as possible, and consistently took the position that all of the non-exempt records should be promptly released.

2d at 22 (government acts unreasonably where it fails “to justify the withholding of” many of the documents at issue); Judicial Watch, 384 F. Supp. 2d at 169 (the agency’s “earlier inadequate justifications” which “led the court to order the filing of supplemental *Vaughn* indices and disclosure of documents” “weigh[ed] in favor of awarding fees”); see also 5 U.S.C. § 552(b) (agency is required to respond to FOIA requests within “twenty working days”).

* * *

As the foregoing demonstrates, plaintiff is both eligible for, and entitled to, an award of attorneys’ fees and costs in this case. Indeed, to deny a small public interest group like CRT attorneys’ fees and costs in a case like this would sanction the government’s tactical decisions to (a) ignore a small public interest group’s FOIA request completely until it files a lawsuit and vigorously pursues access to the requested records and (b) continue to withhold for years thousands of responsive records that the government itself concedes are non-exempt, simply because this is more administratively convenient for the agency.

Denying plaintiff its reasonable fees and costs would also greatly deter such groups – and the public interest lawyers who are willing to represent them at reduced market rates – from pursuing the litigation that is necessary to vindicate the public’s statutory right of access, in direct contravention of Congress’s intent in including the attorneys’ fees provision in the statute. See S.Rep. No. 93-854, 93rd Cong., 2nd Sess. (1974), reprinted in Source Book at 170 (explaining that the attorney’s fees provision was “crucial to effectuating the original congressional intent that judicial review be available to reverse agency refusals to adhere strictly to the Act’s mandates,” and to “encouraging individuals ‘to seek judicial relief’ for the purpose of vindicating national policy”) (citations omitted) (emphasis added); see also id. (Congress wanted to ensure

that “the average citizen can take advantage of the law to the same extent as the giant corporations with large legal staffs”) (emphasis added); see also Cuneo, 553 F.2d at 1363-64 (fee provision in FOIA was designed to lower the “often insurmountable barriers presented by court costs and attorneys fees to the average person requesting information under the FOIA”); Fano Decl. ¶ 6 (explaining that the only reason CRT was able to find a law firm that would take this case was the possibility of obtaining a statutory award of fees). Accordingly, the Court should grant plaintiff’s request for an award of fees and costs in this case.

CONCLUSION

For all of the foregoing reasons, plaintiff respectfully requests that the Court grant its motion for an award of attorneys’ fees and costs.

Respectfully submitted,

/s/ Filed electronically

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Date: February 3, 2006

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR)	
RESPONSIBLE TRANSPLANTATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 00-2849 (RMU/AK)
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION,)	
)	
Defendant,)	

ORDER

Upon consideration of plaintiff's motion for an award of reasonable attorneys' fees and costs, the defendants' response thereto, and the entire record of this proceeding it is this day of , 2006

ORDERED that plaintiff's motion is hereby granted, and it is further

ORDERED that, within 60 days of the date of this Order, defendant Food and Drug Administration shall reimburse plaintiff for all of its reasonable attorneys' fees and costs in pursuing this litigation.

United States District Judge