UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,	:		
Plaintiff,	:	Civil Action No.:	00-2849 (RMU)
v.	:	Document No.:	143
U.S. FOOD AND DRUG ADMINISTRATION *et al.*,	:		
Defendants.	:		

MEMORANDUM OPINION

GRANTING THE PLAINTIFF'S MOTION FOR ATTORNEYS' FEES AND COSTS

I. INTRODUCTION

This case comes before the court on the plaintiff's motion for attorneys' fees and costs. The plaintiff, Campaign for Responsible Transplantation ("CRT"), is a non-profit organization dedicated to creating awareness regarding the dangers of a cellular treatment therapy called xenotransplantation.[1] The plaintiff brings this action pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, requesting that the court order the defendant, the United States Food and Drug Administration ("FDA"), to compensate the plaintiff for fees and costs incurred as a result of the FDA's delay in disclosing nonexempt documents covered by the plaintiff's FOIA request. After balancing the four factors endorsed by this Circuit to guide the court's decision – public interest, commercial benefit, nature of the plaintiff's interest and reasonableness of the FDA's decision to withhold documents – the court concludes that all four factors tip in favor of the plaintiff. Consequently, the plaintiff is entitled to attorneys' fees.

[1] Xenotransplantation involves the implantation of animal tissues, cells and organs into human beings for treatment of human diseases. Mem. Op. (July 23, 2001) at 1.

II. FACTUAL & PROCEDURAL BACKGROUND

The FDA regulates xenotransplantation products as "investigational new drugs" ("INDs"). *Id.* at 2. The plaintiff, concerned about potential public health risks of xenotransplantation products, submitted a written FOIA request for records related to thirty-five xenotransplantation INDs on March 9, 2000. Mem. Op. (Sept. 3, 2002) at 3. The FDA acknowledged receipt of the request and indicated it would respond to the request "as soon as possible." *Id.* When it did not receive a response to its FOIA request by August 2, 2000, the plaintiff filed an appeal with the FDA. *Id.* After the FDA failed to respond to the plaintiff's appeal, the plaintiff filed suit in this court on November 27, 2000 to compel immediate disclosure of the requested records. *Id.* After commencing suit, the plaintiff narrowed its original FOIA request to include only documents generated by the FDA and documents concerning clinical trials related to nineteen of the thirty-five INDs. Mem. Op. (Sept. 24, 2004) at 3.

The plaintiff, in an effort to further narrow the scope of the litigation, moved for *Vaughn* indices[2] describing documents related to all nineteen INDs. Mem. Op. (July 23, 2001) at 3-4. The FDA countered that such a request would take an estimated two years to complete because it involved review of approximately 240,000 pages of documents. *Id.* at 6. In its cross-motion, the FDA asked the court to allow it instead to produce a sample *Vaughn* index with respect to one of the nineteen INDs. *Id.* at 6-7. The FDA supported its motion by noting that the "same types of FDA-generated documents are found in every xenotransplantation IND file . . . [and that the FDA] would assert the same exemptions for documents in the indexed IND as it would for the

[2] The *Vaughn* index is an affidavit that describes the withheld or redacted documents and justifies, in detail, why each record is exempt from disclosure under FOIA. *King v. U.S. Dep't of Justice*, 830 F.2d 210, 223-24 (D.C. Cir. 1987). The index serves to aid the requester in determining what documents to request, as well as to aid the court in reviewing the validity of the agency's withholding.

same types of documents in the other INDs." *Id.* at 8. The court's 2001 opinion denied the plaintiff's motion for *Vaughn* indices for all nineteen INDs, and instead granted the FDA's motion to produce a sample *Vaughn* index for one IND ("IND G"). *Id.* at 7. The FDA produced a sample *Vaughn* index for IND G on September 4, 2001. Mem. Op. (Sept. 5, 2006) at 3. On December 4, 2001, the court ordered that the FDA release responsive, nonexempt documents before December 17, 2001. Order (Dec. 4, 2001) at 5.

After the FDA produced the sample *Vaughn* index and released some documents related to the sample IND, both parties moved for summary judgment over the IND G documents that the FDA continued to withhold. Mem. Op. (Sept. 24, 2004) at 3. The plaintiff moved for the immediate release of all IND G documents that the FDA claimed were exempt. Pl.'s Mot. for Summ. J. (Jan. 15, 2002). The FDA, conversely, moved the court for a ruling that the withheld documents were exempt from disclosure. Mem. Op. (Sept. 5, 2006) at 3. On September 3, 2002, the court granted in part and denied in part both summary judgment motions, concluding that the FDA had conducted an adequate search, but that its sample *Vaughn* index was inadequate to justify the withholdings. Mem. Op. (Sept. 3, 2002) at 16. Rather than rule on the propriety of the FDA's decision to withhold documents by relying on an inadequate *Vaughn* index, the court postponed judgment on the merits of the parties' claims and ordered the FDA to produce a revised sample *Vaughn* index. *Id.*

While preparing its revised *Vaughn* index for IND G, the FDA released additional documents. Mem. Op. (Sept. 5, 2006) at 4. After the FDA produced its revised sample *Vaughn* index, the parties filed renewed cross-motions for summary judgment. Mem. Op. (Sept. 24, 2004) at 3. On September 24, 2004, the court denied the plaintiff's motion for immediate release of withheld documents and instead granted the FDA's motion, holding that the FDA lawfully

withheld contested documents pursuant to FOIA exemptions. *Id.* at 23. Because the *Vaughn* index and the court's ruling related only to the sample IND G, the court also ordered the FDA to release all nonexempt documents related to the other eighteen INDs. *Id.* at 22. Months later, after the FDA had not released the documents with respect to the other eighteen INDs, the plaintiff moved to enforce the court's order. The court denied the plaintiff's request, stating that "[t]he parties' submissions demonstrate that they have not adequately communicated with each other . . . [and] the court is confident that the parties do not wish to further burden the court with the task of unraveling unnecessary disputes." Order (June 3, 2005).

The plaintiff filed its first motion for attorneys' fees on February 3, 2006. Pl.'s 1st Mot. for Attorneys' Fees. After briefing was complete, the court concluded that the plaintiff had not substantially prevailed and that it was, therefore, not eligible for attorneys' fees. Mem. Op. (Sept. 5, 2006). The Circuit, however, reversed, concluding that the plaintiff substantially prevailed because the court's September 24, 2004 order required the FDA to release documents, and that it was irrelevant that the FDA had already agreed to release the documents. *CRT v. FDA*, 511 F.3d 187, 196-97 (D.C. Cir. 2007). Having determined that the plaintiff is *eligible* for attorneys' fees, the Circuit remanded the case to allow this court to determine in the first instance whether the plaintiff is *entitled* to these fees. The plaintiff filed its second motion for attorneys' fees on May 22, 2008. Pl.'s 2d Mot. for Attorneys' Fees ("Pl.'s Mot."). The FDA then filed an opposition, Def.'s Opp'n, to which the plaintiff replied, Pl.'s Reply. The court now turns to the pending motion.

III. ANALYSIS

A. Legal Standard for Attorneys' Fees and Costs Under FOIA

Pursuant to 5 U.S.C. § 552(a)(4)(E)(a), the court may assess "reasonable attorneys' fees and other litigation costs reasonably incurred in any case . . . in which the complainant has substantially prevailed." To award attorneys' fees under FOIA, a court must undertake a two-step inquiry. First, the court must determine whether the claimant is eligible for attorneys' fees. *Pyramid Lake Paiute Tribe v. U.S. Dep't of Justice*, 750 F.2d 117, 119 (D.C. Cir. 1984). To be eligible for fees, the claimant must "substantially prevail" in the underlying FOIA litigation. *Id.* Moreover, "[a]n agency cannot foreclose an award of attorneys' fees and costs by complying with a FOIA request during the pendency of litigation." *Md. Dep't of Human Res. v. Sullivan*, 738 F. Supp. 555, 563 (D.D.C. 1990) (citing *Cuneo v. Rumsfeld*, 553 F.2d 1360, 1365 (D.C. Cir. 1977)). Second, the court must determine that the plaintiff is "entitled" to an award of attorneys' fees and costs. *Id.* In deciding whether a claimant is entitled to an award of attorneys' fees and costs, the court analyzes four factors: "(1) the benefit to the public, if any, derived from the case; (2) the commercial benefit to the complainant; (3) the nature of the complainant's interest in the records sought; and (4) whether the government's withholding of the records had a reasonable basis in law." *Cuneo*, 553 F.2d at 1364. The second and third factors "are closely related and are often evaluated together." *Sullivan*, 738 F. Supp. at 563 n.11 (citing *Fenster v. Brown*, 617 F.2d 740, 743 (D.C. Cir. 1979)). "None of these factors are dispositive," *Piper v. U.S. Dep't of Justice*, 339 F. Supp. 2d 13, 20 (D.D.C. 2004), and "[e]ntitlement is at the discretion of the district court," *Sullivan*, 738 F. Supp. at 565.

B. The Court Grants the Plaintiff's Motion for Attorneys' Fees and Costs

Because the Circuit ruled that the plaintiff has substantially prevailed in this case, *CRT*, 511 F.3d at 196-97, the court moves directly to whether the plaintiff is entitled to an award of attorneys' fees. The court addresses in turn each of the four factors meant to guide the court in exercising its discretion. *See Nationwide Bldg. Maint., Inc. v. Sampson*, 559 F.2d 704, 714 (D.C. Cir. 1977) (opining that the factors are "intended to provide guidance and direction – not airtight standards" (quoting S. REP. NO. 93-854, at 19 (1974))).

1. The Public Interest

As to the first factor, the plaintiff asserts that "there is a clear public benefit in the public learning more about xenotransplantation and the government's involvement in permitting and overseeing controversial xenotransplantation experiments, and in ensuring that the public is not placed at risk." Pl.'s Mot. at 14. The plaintiff also cites media coverage of the topic over the last decade. *Id.* at 14 n.9. Moreover, the plaintiff notes that the released documents revealed "numerous side-effects and tumors in patients who had undergone xenotransplantation," *id.*, Ex. 2 ("Fano Decl.") ¶ 9, and that even the FDA has acknowledged that "'it is vital that the public . . . be informed and educated about potential infectious disease risks' associated with xenotransplantation," Pl.'s Mot. at 15 (quoting 66 Fed. Reg. at 4695). The FDA rejects the plaintiff's position, noting that the plaintiff "has not been awarded a single *contested* document in this case." Def.'s Opp'n at 12. The FDA further contends that the plaintiff's use of the uncontested documents that the FDA released after the plaintiff filed the complaint "does not substantially serve the public interest" because the plaintiff plans to use the documents to "seek[] a total ban on xenotransplantation," ignoring potential benefits of the procedure. *Id.*

In assessing "the public benefit derived from the case," the court must consider "both the effect of the litigation for which fees are requested and the potential public value of the information sought." *Davy v. CIA*, 2008 WL 5264651, at *2 (D.C. Cir. 2008) (quoting *Tax Analysts v. U.S. Dep't of Justice*, 965 F.2d 1092, 1093 (D.C. Cir. 1992)). The FDA's first argument – that the plaintiff has not been awarded any contested documents – does not undermine the public benefit of the request for and subsequent disclosure of documents showing "numerous side-effects and tumors in patients who had undergone xenotransplantation." Fano Decl. ¶ 9. Indeed, it was the disclosure of the uncontested, non-exempt documents that rendered the plaintiff a prevailing party. *See CRT*, 511 F.3d at 196-97.

Likewise, the FDA's second argument regarding the plaintiff's particular views concerning xenotransplantation is unconvincing. The FDA's request that the court take a narrower view – *i.e.*, ensure that the requester publicly presents disclosed documents in an objective manner, *see* Def.'s Opp'n at 12 (stating that the plaintiff will "ignore[] the possible benefits to the public health from [xenotransplantation]") – improperly attempts to inject the court into the political debate surrounding xenotransplantation. *See Cotton v. Heyman*, 63 F.3d 1115, 1120 (D.C. Cir. 1995) (holding that the public benefits if disclosure "add[s] to the fund of information that citizens may use in making vital political choices" (quoting *Fenster v. Brown*, 617 F.2d 740, 744 (D.C. Cir. 1979))). It is beyond peradventure that CRT is a nonprofit, public interest group designed to alert the public of issues associated with the risks of xenotransplantation, Fano Decl. ¶ 2; CRT designed its document request in furtherance of this mission, *id.* ¶ 6; and the documents released after the plaintiff initiated this lawsuit furthered this mission, *id.* ¶ 9. Accordingly, the court concludes that the public interest prong clearly favors the plaintiff. *Davy*, 2008 WL 5264651, at *2 (noting that "a distinction is to be drawn between

the plaintiff who seeks to advance his private commercial interests and . . . the public interest group seeking information to further a project benefiting the general public").

2. The Commercial Benefit and the Nature of the Plaintiff's Interest in the Records

The second and third factors are often considered together, *id.* at *3, and the plaintiff addresses them together, arguing that it "realized no 'commercial benefit' at all from the requested materials" as it is "dedicated to informing the public about the public health risks and ethical concerns posed by xenotransplantation," Pl.'s Mot. at 16. The FDA retorts that "the documents sought by CRT have both significant commercial and personal value." Def.'s Opp'n at 13. Specifically, the FDA cites the potential commercial benefit that the plaintiff's professional membership would derive by banning xenotransplantation. *Id.* (asserting that the plaintiff's "members . . . could have commercial and personal interests in a xenotransplantation ban"). In addition, to bolster its claim that the plaintiff's motivation is commercial, the FDA references "trade secret and confidential commercial information" contained in the documents that the plaintiff seeks. *Id.*

The FDA's arguments fly far afield from the relevant interests at stake in this case. Notably, the FDA does not argue that the plaintiff, a nonprofit organization, was seeking the information to benefit commercially, but rather that the membership would receive a derivative commercial benefit if the documents led to a ban on xenotransplantation or if trade secrets were disclosed. *Id.* Assuming that it is appropriate for the court to inquire into such derivative benefits, this argument is too attenuated to be of great import. The FDA does not reference any members or members' projects that would receive a financial boon from a xenotransplantation ban. *Cf. Davy*, 2008 WL 5264651, at *4 (reasoning that "the mere intention to publish a book does not necessarily mean that the nature of the plaintiff's interest is 'purely commercial'").

Even more telling, the FDA fails to state how the release of the requested documents will necessarily lead to a prohibition of xenotransplantation, Def.'s Opp'n at 13, and the court is unwilling to make that logical leap. In any event, as its uncontested statements clearly demonstrate, Fano Decl. ¶¶ 2-5, the plaintiff's motivations are far from "purely commercial," *Davy*, 2008 WL 5264651, at * 4 (recognizing that "ferret[ing] out and mak[ing] public worthwhile, previously unknown government information [is] precisely the activity that FOIA's fees provision seeks to promote).

As to the FDA's second argument that the plaintiff seeks the materials to obtain trade secretes, the court notes that FOIA expressly exempts from production "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The plaintiff (or its membership) would, therefore, have no reasonable expectation to receive trade secrets and no commercial incentive for making the document request. The FDA's argument cannot overcome this plain reading of the law, and the plaintiff's uncontroverted public interest concerns tilt the second and third factors, like the first, in its favor. *Davy*, 2008 WL 5264651, at *4 (observing that "the first three factors assist a court in distinguishing between requesters who seek documents for public informational purposes and those who seek documents for private advantage").

3. The Reasonableness of the Government's Withholding

Turning to the last factor, the plaintiff contends that the FDA "had no reasonable basis for refusing to provide *any* documents in response to [the plaintiff's] FOIA request more than eight months after it was submitted, thereby forcing [the plaintiff] to file this suit." Pl.'s Mot. at 18. In addition, the plaintiff asserts that the FDA did not have a reasonable basis in law for delaying the disclosure of nonexempt documents after the start of litigation because "it might make

different withholding determinations" for them. *Id.* The FDA protests that "*all* of [its] withholdings . . . had a reasonable basis in law, because all were upheld by the Court and uncontested on appeal" and because the parties reached an agreement regarding the disclosure of nonexempt documents.[3] Def.'s Opp'n at 8-9. The FDA also suggests that this factor is dispositive.[4] *Id.*

The FDA is wrong on all accounts. First, the FDA incorrectly focuses on the contested documents that it lawfully withheld under the appropriate FOIA exemptions and ignores the nonexempt documents that it delayed disclosing, despite eventually acknowledging that the documents were nonexempt. *See LaSalle Extension Univ. v. FTC*, 627 F.2d 481, 486 (D.C. Cir. 1980) (determining whether "the information [the plaintiff] requested [as opposed to the information contested] would inflict an unwarranted invasion of privacy"); *Piper*, 339 F. Supp. 2d at 23 (explaining that the central focus of the reasonableness prong is on the documents that

---

[3] The FDA also asserts that delay was needed to redact "confidential commercial and trade secret information from the documents, and in some cases, consult with the IND sponsor companies that submitted the information." Def.'s Opp'n at 10. The FDA does not, however, allege that this process qualifies it for an extension to FOIA's twenty day time limit for processing requests, 5 U.S.C. § 552(a)(6)(A)(i), which requires a showing of "exceptional circumstances," *id.* §§ 552(a)(6)(B)(ii), (a)(6)(C). Accordingly, the court does not credit the FDA's assertion. *Davy*, 2008 WL 5264651, at *6 (holding that it is the government's burden to show "that it had any colorable or reasonable basis for not disclosing the material until after" the plaintiff files the lawsuit); *cf. Sampson*, 559 F.2d at 714-15 (recognizing that the government's failure to comply with FOIA's time requirements does not preclude a court from rejecting a fee request).

[4] The FDA's argument that the production of the nonexempt documents "was in no way 'obdurate' or 'recalcitrant,'" Def.'s Opp'n at 10-11, is a red herring for two independent reasons: First, the FDA must show that it "had a *reasonable basis in law* for concluding that the information in issue was exempt *and* that it had not been recalcitrant in its opposition to a valid claim or otherwise engaged in obdurate behavior." *LaSalle Extension Univ. v. FTC*, 627 F.2d 481, 486 (D.C. Cir. 1980) (second emphasis added) (quoting *Fenster*, 617 F.2d at 744). Second, the Committee reports as quoted by the Circuit indicate that "recalcitrant" or "obdurate" behavior is necessary for an award of attorneys' fees if "the suit is to advance the private commercial interests of the complainant" because "there is usually no need to award attorneys' fees to insure that the action will be brought." *Sampson*, 559 F.2d at 712 (quoting S. REP. NO. 93-854, at 19 (1974)).

were ordered released). Indeed, the Circuit cited these documents in particular in determining that the plaintiff was a substantially prevailing party. *CRT*, 511 F.3d at 196-97.

Second, the FDA alleges that the parties and the court agreed to delay the disclosure of these nonexempt documents "as a practical matter," but the FDA fails to ground this practical concern to a legal basis. *See* Def.'s Opp'n at 9. Nevertheless, the court notes that FOIA contemplates such practical concerns by allowing for mutually agreed upon "alternative time frame[s] for processing [] request[s]." 5 U.S.C. § 552(a)(6)(B)(ii). In this case, though, the parties reached no such agreement for, at a minimum, the eight months between the plaintiff's FOIA request and the filing of this lawsuit. *See* Def.'s Opp'n at 9. In fact, the plaintiff insists that it never consented to delay the disclosure of nonexempt documents. Pl.'s Reply at 13 n.5. Accordingly, the court concludes that the FDA has not met its burden of showing an objectively reasonable basis in law for the delay. *Davy*, 2008 WL 5264651, at *6 (stating that "[f]ailing to explain the basis for deferring its response" to a FOIA request "is exactly the kind of behavior the fee provision was enacted to combat").

Finally, even if this factor aided the FDA, which it does not, the factor is not dispositive. The Circuit has repeatedly asserted that "the court must be careful not to give any particular factor dispositive weight." *Sampson*, 559 F.3d at 714; *Davy*, 2008 WL 5264651, at *2 (stating that "[n]o one factor is dispositive"). The only instance in which the fourth factor would be dispositive is if "the legal basis for holding the records is correct." *Chesapeake Bay Found., Inc. v. U.S. Dep't of Agric.*, 11 F.3d 211, 216 (D.C. Cir. 1993). That is not the case here because the documents are nonexempt, and the FDA disclosed them only after the plaintiff brought this action and the court issued two orders requiring disclosure. *See* Order (Dec. 1, 2001) at 5; Mem. Op. (Sept. 24, 2004) at 3, 22. Because the FDA has not demonstrated a reasonable basis in law

for withholding nonexempt documents beyond the twenty day deadline set forth in FOIA, this factor also favors the plaintiff, and the court concludes that the plaintiff is entitled to attorneys' fees. *Davy*, 2008 WL 5264651, at * 4 (noting that "a court would generally award fees if the complainant's interest in the information sought was scholarly or journalistic or public-interest oriented, [unless] . . . his interest was of a frivolous or purely commercial nature" (quoting *Fenster*, 617 F.2d at 742 n.4)).

IV. CONCLUSION

For the foregoing reasons, the court grants the plaintiff's motion and refers the matter to Magistrate Judge Facciola for a calculation of attorneys' fees and costs. An Order consistent with this Memorandum Opinion is separately and contemporaneously issued this 22nd day of January, 2009.

RICARDO M. URBINA
United States District Judge