

U.S. DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

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CAMPAIGN FOR  
RESPONSIBLE TRANSPLANTATION,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,

Defendant,

CIRCE BIOMEDICAL, INC., et al.,

Defendant-Intervenors.

NANCY M.  
MAYER-WHITTINGTON  
CLERK

Civ. No. 00-2849 (RMU)

**PLAINTIFF'S REPLY TO DEFENDANT INTERVENORS' MEMORANDUM IN  
OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

Plaintiff submits this Reply Memorandum to respond to arguments raised by defendant-intervenors in their collective Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ("Int. Memo.") in this Freedom of Information Act ("FOIA") case. Although defendant Food and Drug Administration ("FDA") is withholding thousands of pages of records on the grounds that they contain "trade secrets" and "confidential commercial information" concerning the defendant-intervenors' xenotransplantation products, and, hence, are exempt from disclosure under Exemption 4, the intervenors did not move for summary judgment in this case. Nor, for that matter, did the FDA even purport to rely on the intervenors' declarations to support the agency's contention that information is exempt under Exemption 4. Instead, the intervenors take the unusual position that they should have some further opportunity to assist the government in meeting its burden of proof on this point. However, as plaintiff explains below, since the government has already moved for summary judgment, and the Court gave the intervenors the opportunity to likewise move for summary judgment, their failure to do so or to assist the FDA in demonstrating that the information being withheld qualifies for protection under Exemption 4 should in no way delay a final resolution of this case. As plaintiff further demonstrates, there also is no merit to the intervenors' argument that either the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 331(j), or the Trade Secrets Act, 21 U.S.C. § 1905, bars disclosure of the requested information. Moreover, since the government did not even make these arguments, and the intervenors have not asserted any cross-claim against the government on this basis, the Court need not even address – let alone resolve – these extraneous legal arguments.

## BACKGROUND

Over a year ago, plaintiff Campaign for Responsible Transplantation (“CRT”) consented to defendant-intervenors’ motions to intervene in this case because the intervenors contended that they needed to protect what they believed was a “direct and indisputable interest in the continued confidentiality of th[e] materials” that had been requested by CRT. See, e.g., Circe Biomedical Intervention Memo. (Jan. 12, 2001) at 5; see also Nextran, Inc. Intervention Memo. (Jan. 16, 2001) at 3-5; Diacrin, Inc. and Diacrin/Genzyme, LLC Intervention Memo. (Jan. 24, 2001) at 3; Genzyme, Inc. Intervention Memo. (Feb. 7, 2001) at 4-5; Novartis Pharmaceuticals, Inc. Intervention Memo. (Feb. 12, 2001) at 6-7, 9-10. Indeed, the FDA’s own regulations provide that “[w]henver the [FDA] denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data” under Exemption 4, the FDA “will require that” “the person who submitted the record” “defend the exempt status of the record.” See 21 C.F.R. § 20.53 (emphasis added).

When it moved for a Vaughn index on May 29, 2001, CRT informed the Court that it had narrowed the scope of its FOIA request to include only those responsive records that were actually generated by the FDA – i.e., CRT no longer seeks any records that were submitted by the intervenors. See Motion Requesting A Vaughn Index (May 29, 2001). The intervenors nevertheless emphatically insisted that they needed to “continue their involvement in this lawsuit in order to protect their interest in the confidentiality of Agency-generated documents” because “it is likely that many Agency-generated documents reveal or reflect confidential information about biotechnology companies . . . .” See Diacrin, Inc. and Diacrin/Genzyme, LLC Statement of Non-Opposition (June 8, 2001) at 2; see also Genzyme, Inc. Statement of Non-Opposition

(June 8, 2001) at 2; Novartis Response to Vaughn Index Motion (June 11, 2001) at 2; Circe Biomedical, Inc. Response to Vaughn Index Motion (June 12, 2001) at 2.

On September 4, 2001, the FDA provided plaintiff with its Sample Vaughn Index – i.e., as of that date, the government had identified the majority of records that are responsive to CRT’s request. See Sample Vaughn Index (Plaintiff’s Exhibit (“Pl. Ex.”) RR). On October 1, 2001, the parties had a conference call, during which plaintiff’s counsel informed defendants’ counsel that CRT was prepared to move for summary judgment since the FDA’s Vaughn index was not sufficient to meet the agency’s burden of proof that thousands of responsive records may be withheld. On December 4, 2001, following a status conference, the Court set forth the briefing schedule for this case, which provided for all briefing to be completed by May 15, 2002 and a final status conference to be held on August 20, 2002 . See Order (Dec. 4, 2001) at 5.<sup>1</sup>

On December 20, 2002, CRT narrowed the scope of its FOIA request even further in a Joint Stipulation with the FDA and intervenor Novartis Pharmaceuticals. See Joint Stip. (Dec. 20, 2002). Pursuant to the terms of that Stipulation, CRT’s request now includes only FDA-generated records that concern applications for approval to conduct xenotransplantation clinical trials involving pig and/or nonhuman primate cells, tissues, and/or organs. See id. (emphasis added). This limitation has essentially eliminated the interests of two of the intervenors – Novartis Pharmaceuticals, Inc. and Genzyme, Inc. – which have represented that their xenotransplantation investigational new drug applications (“IND”) do not involve the use of pig or non-human primate cells, tissues, or organs. See Novartis Response (Mar. 29, 2002) at 2 (“[n]o Novartis [IND] involves the cells, tissues, and/or organs or pigs and/or nonhuman

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<sup>1</sup> The original briefing schedule has since been amended to provide the defendant’s final Reply Memorandum is due on June 10, 2002 and final status conference is scheduled for September 12, 2002. See Orders (Feb. 25, 2002), (Apr. 25, 2002).

primates”); Letter from Jeremy T. Monthy to Amy R. Atwood, Brian Sonfield, and Michael Levy (Feb. 13, 2002) (Plaintiff’s Exhibit (“Pl. Ex.”) XX).<sup>2</sup>

Pursuant to the Court’s briefing schedule, on January 15, 2002, CRT filed a Motion for Summary Judgment, which demonstrated that the FDA had not carried its burden to prove that the records still at issue may lawfully be withheld. In support of its position that the records are not “trade secrets” or “confidential commercial information” within the meaning of Exemption 4, CRT further demonstrated that IND sponsors, including intervenors in this case, have already widely disseminated information about their xenotransplantation INDs – e.g., during public advisory committee meetings and workshops, through publicly accessible filings to the SEC, and on their Internet websites. Pl. Summary Judgment Memorandum (“Pl. Memo.”) at 15-9, 33-4; see also Pl. Ex. V-EE. Indeed, as CRT pointed out, Pl. Memo. at 15, the FDA itself has conceded that sponsors’ “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.” 66 Fed. Reg. 4688, 4691 (Jan. 18, 2001) (emphasis added).

During a February 14, 2002 status conference, counsel for the intervenors expressed their concern that, if plaintiff prevails on its motion for summary judgment and the Court orders the FDA to disclose any of the responsive records, the intervenors should be provided with another opportunity to assert that information that concerns their xenotransplantation INDs should not be

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<sup>2</sup> Intervenor Novartis Pharmaceuticals, Inc. has filed a separate Response to CRT’s Motion for Summary Judgment, in which it asserts that CRT did not “refer” to a particular category of records – i.e., “agency-generated records that concern Novartis applications for approval to conduct xenotransplantation clinical trials involving the cells, tissue, and/or organs of pigs and/or non-human primates” but “which were not generated in connection with an actual Novartis IND that had been submitted to the FDA,” see Novartis Pharmaceuticals, Inc. Response (Mar. 29, 2002) at 1-2 (emphasis added) – and that, accordingly, CRT has foregone access to any such records, if they exist. Id. at 2. Although neither Novartis nor the FDS will clarify whether any such records exist, to the extent that they do exist, they are certainly covered by plaintiff’s FOIA request and the Dec. 20, 2002 Joint Stipulation.



disclosed because it constitutes “trade secret” or “confidential commercial information” that is exempt from disclosure under Exemption 4. However, the intervenors did not move to amend the briefing schedule for this purpose, nor did the Court make any such changes to the schedule for this purpose.

Moreover, in a letter dated February 22, 2002, counsel for plaintiff informed the intervenors and the FDA that, under the briefing schedule set by the Court, both the agency and the intervenors had an obligation to make their substantive exemption arguments at the time they responded to plaintiff’s motion for summary judgment. See Letter from Amy R. Atwood to Counsel for Defendant and Defendant-Intervenors (Feb. 22, 2002) at 2 (Pl. Ex. YY) (“the intervenors’ opportunity to demonstrate that portions of the records that are exempt takes place when they submit their briefs in this case”); Order (Feb. 25, 2002). Accordingly, plaintiff’s counsel recommended that the defendants use their time wisely, and “ascertain precisely what information that pertains to their clients the FDA claims is exempt from disclosure” under Exemption 4, “so that they may prepare to make these arguments in their oppositions or cross-motions for summary judgment, as is clearly contemplated by the FDA’s regulation on this matter.” Id., citing 21 C.F.R. § 20.53.

Nevertheless, on March 29, 2002, the date that all cross-motions for summary judgment were due, defendant-intervenors Circe Biomedical, Diacrin, Diacrin/Genzyme, and Nextran filed a joint Memorandum in Opposition to Plaintiff’s Motion for Summary Judgment, in which they asserted their view that records identified by the FDA in its Sample Vaughn index may be lawfully withheld because they fall within Exemptions 4 and 5 – although the intervenors also acknowledged that they did not know, with certainty, what information is reflected in the agency-generated records at issue here, and whether it even pertains to their clients. See Int.

Memo. at 2-3. Thus, the intervenors did not move for summary judgment on these grounds, nor did the FDA even rely on any of the intervenors' declarations in support of its cross-motion for summary judgment that was also filed on March 29.

Moreover, although they have not asserted any cross-claims against the government, the intervenors nevertheless contend that the FDA is required to withhold certain unidentified records from plaintiff pursuant to section 331(j) of the FDCA and section 1905 of the Trade Secrets Act, id. at 16-7 – even though the FDA, which has the burden of proof in this case, has not asserted either of these grounds for withholding the records. Finally, the intervenors contend that “[i]f there should ever come a time when the Court is considering ordering that the FDA-generated documents are to be released outside the FDA,” the intervenors should be given yet another chance “to review first . . . the documents that pertain” to them, and “show[], in detail, which portions of these documents are confidential.” See Affidavit of E. Michael Egan, Chief Operating Officer, Diacrin, Inc. (“Egan Aff.”) (Mar. 28. 2002) at ¶ 38. However, once again, the intervenors did not move the Court to change the briefing schedule for this purpose, nor did they explain – at all – why they had failed to use the more than six months since the FDA had produced its Vaughn index to ascertain from the agency what responsive information of theirs is “trade secrets” or “confidential commercial information” that they contend must be shielded from public disclosure.

## ARGUMENT

### **I. THE INTERVENORS' RUMINATIONS ABOUT THE DISCLOSABILITY OF THE RECORDS AT ISSUE IN THIS CASE ARE IRRELEVANT TO THE ISSUES THAT MUST BE RESOLVED BY THE COURT.**

#### **A. The Intervenor's Have Failed To Assist The Agency In Proving That Records Are Exempt.**

At virtually every stage of this litigation, the intervenors have repeatedly protested that disclosure of records to which CRT seeks access will necessarily result in the public disclosure of proprietary business information and the loss of huge investments in their xenotransplantation products. See, e.g., Diacrin, Inc. and Diacrin/Genzyme, LLC Statement of Non-Opposition at 2; Genzyme, Inc. Statement of Non-Opposition (June 8, 2001) at 2; Novartis Response to Vaughn Index Motion (June 11, 2001) at 2; Circe Biomedical, Inc. Response to Vaughn Index Motion (June 12, 2001) at 2; see also Int. Memo. at 1-2. Indeed, this was the entire reason for their participation in this case, and they have maintained that position since plaintiff narrowed the scope of its request to expressly exclude all sponsor-generated records. See Circe Biomedical Intervention Memo. (Jan. 12, 2001) at 5; see also Nextran, Inc. Intervention Memo. (Jan. 16, 2001) at 3-5; Diacrin, Inc. and Diacrin/Genzyme, LLC Intervention Memo. (Jan. 24, 2001) at 3; Genzyme, Inc. Intervention Memo. (Feb. 7, 2001) at 4-5; Novartis Pharmaceuticals, Inc. Intervention Memo. (Feb. 12, 2001) at 6-7, 9-10.

Yet, now, when the government is required to prove that the records actually contain “trade secret” or “confidential commercial information” and thus may be withheld under Exemption 4 of the FOIA, the intervenors concede that they do not know precisely what information is even at issue, nor, apparently, have they made any effort to ascertain this extremely relevant information from the FDA. Int. Memo. at 2-3, 14; Egan Decl. at ¶¶ 28, 33; see also Declaration of Elizabeth Chen, Senior Vice President and Chief Operating Officer, Circe

Biomedical, Inc. (“Chen Decl.”) at ¶ 10 (stating that she “believe[s]” the “FDA-generated documents” generally “contain trade secrets and confidential commercial information”) (emphasis added). However, it is well settled that in order for an agency to satisfy its burden that Exemption 4 applies, it must prove several different factors, depending on whether the records are “trade secrets” or “confidential commercial information.” See, e.g., Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288-9 (D.C. Cir. 1983) (“Public Citizen I”) (“for the purpose of FOIA Exemption 4,” “trade secret” means “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities that can be said to be the end product of either innovation or substantial effort”); Nat’l Parks and Conservation Ass’n v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976) (“to show substantial competitive injury,” the agency must prove that the submitters of the information actually face competition and that “substantial competitive injury would likely result from disclosure”); ALDF v. Dep’t of the Air Force, 44 F. Supp. 2d 295, 303 (D.D.C. 1999) (agencies must prove “that all essential elements of the exemption exist”) (emphasis added).

Indeed, this is precisely why the FDA has a regulation that specifically requires intervenors to “defend the exempt status of the records[s]” at issue, 21 C.F.R. § 20.53, since, obviously, the companies who have a proprietary interest in the information the agency seeks to withhold are uniquely qualified to make the showings that are required by Exemption 4, if in fact those factors are present. Therefore, particularly when both the plaintiff and the FDA have already moved for summary judgment in this case, having failed to do the work necessary to assist the government in meeting its burden of proof, the intervenors cannot legitimately ask the Court to postpone this exercise for another day. Rather, because the case has been submitted on cross-motions for summary judgment, the Court must decide the matter on the record that is

already before it. Cf. Jordan v. Department of Justice, 591 F.2d 753, 779-80 (D.C. Cir. 1978) (en banc), overruled on other grounds, Crooker v. Bureau of Alcohol, Tobacco and Firearms, 670 F.2d 1051 (D.C. Cir.1981) (failure of the government to raise an exemption claim when it moves for summary judgment is considered a waiver of that exemption); see also American Broadcasting Cos. v. U.S. Information Agency, 599 F. Supp. 765, 768 (D.D.C. 1984) (“government agencies involved in FOIA litigation should be prepared to raise all claims under the FOIA . . . so that the plaintiff may respond, and the court rule, in the most expeditious manner”).

While the intervenors will no doubt insist that they do not know the precise proprietary information that is at issue here because the government is also asserting Exemption 5 with respect to many of the same records which it contends also contain information that is exempt under Exemption 4, they have not explained why they would have been unable to ascertain from the agency what, if any, specific information about their products is actually at risk of disclosure. Indeed, since they have had over six months to obtain this information – and it certainly would have been in the FDA’s interest to provide it in order for the government to meet its burden of proof in this case – there does not seem to be any legitimate basis for the intervenors’ failure to do so.

In any event, there is ample case law demonstrating the kind of showing that must be made to sustain the government’s invocation of Exemption 4 on behalf of the proprietary interest of a submitter. Thus, for example, Public Citizen II demonstrates the level of specificity in intervenors’ affidavits that is required to meet the government’s burden under Exemption 4, and the kind of “conclusory assertions that disclosure would cause substantial competitive harm” that do not satisfy that burden. Public Citizen Health Research Group v. FDA, 185 F.3d 898, 905-06

(1999) (“Public Citizen II”). Here, because the intervenors concede that they have not taken steps to ascertain what information the FDA records would reveal about their products, their declarations offered in opposition to plaintiff’s summary judgment motion have no probative value at all to the Court. Compare Public Citizen II, 185 F.3d at 906 (intervenors’ affidavit was “conclusory” when it merely asserted that “disclosure ‘would reveal substantial basic research’ as well as ‘disease model . . . that have been developed by Schering at a great expense’”) with Egan Aff. at ¶¶ 17, 29 (“[r]elease of [FDA-generated] information would severely harm Diacrin by giving rivals a competitive advantage” and “this information is developed at great expense); see also Chen Decl. at ¶ 10 (“I believe that numerous . . . FDA-generated documents contain trade secrets and confidential commercial information”); Logan Decl., at ¶ 19 (“Allowing FDA-generated documents to become part of the public domain will stifle the development of promising therapies to treat organ failure and impair access of patients to novel biotechnologies.”).

Therefore, since the FDA has also necessarily failed to carry its burden of proof on this issue – for many reasons, including its failure to submit a single declaration from the sponsors in support of the agency’s assertion that thousands of pages of records may be withheld from plaintiff under Exemption 4, see Pl. Memo. at 30-4; Pl. Reply at 9-14 – the intervenors have placed their “confidence” in the agency’s ability to prove that the Exemption applies at their own peril. See Int. Memo. at 2-3 (intervenors are “confident” in the FDA’s determination that the documents contain sponsors’ trade secrets and confidential commercial information) (emphasis added); see also Greenberg v. FDA, 803 F.2d 1213, 1214 n. 1 (D.D.C. 1986) (“[u]nder” 21 C.F.R. § 20.53, “when a challenge is made to an FDA decision to deny a FOIA request under

Exemption 4, the party who submitted the information to the agency is required to defend the exempt status of the information”).

**B. None Of The Additional Bases For Nondisclosure Asserted By The Intervenor Has Any Merit.**

Intervenors also raise several legal arguments that they claim establish that the FDA is legally barred from releasing the records at issue here – i.e., that information must be withheld under the FDCA and Trade Secrets Act – even though the agency, which bears the burden of proof in this case, has not made any of these arguments. See Int. Memo. at 16-7. However, since the government has not moved for summary judgment on either of these grounds, and the intervenors have not asserted any cross-claims against the government on this basis, see, e.g., Chrysler Corp. v. Brown, 441 U.S. 281, 317 (1979), there is no reason for the Court to resolve these additional arguments.

In any event, these arguments would fail because both of the cited statutes only protect information that may be lawfully withheld under Exemption 4, and, as plaintiff has demonstrated, the government simply has not met its burden of proof that Exemption 4 applies to any of the records at issue in this case. See Pl. Memo. at 30-34; Pl. Reply at 9-14. Indeed, as one Court has observed, FDCA “[s]ection 331(j) is arguably narrower than Exemption 4 in that it is limited to information relating to methods or processes whereas Exemption 4 applies to all trade secret information.” Anderson v. DHHS, 907 F.2d 936, 951 (10th Cir. 1990) (emphasis added). Similarly, it is well established that the Trade Secrets Act is “coextensive” with Exemption 4, and, therefore, can only apply inasmuch as the government has first proved that information may be lawfully withheld under that Exemption. See, e.g., CNA Financial Corporation v. Donovan, 830 F.2d 1132, 1151-2 (D.C. Cir. 1987); McDonnell Douglas Corporation v. NASA, 180 F.3d 303, 305 (D.C. Cir. 1999) (“when a person can show that

information falls within Exemption 4, then the government is precluded from releasing it under the Trade Secrets Act”).

Here, as demonstrated in plaintiff’s opening and reply memoranda, the government certainly has not met its burden to prove that Exemption 4 applies to all of the records that have been withheld on this basis. See Pl. Memo. at 30-34; Pl. Reply at 9-14. Indeed, intervenors’ implicit suggestion to the contrary, Int. Memo. at 7-9, information from IND files is not exempt, per se, under Exemption 4. Thus, for example, information concerning dangerous side effects contained in adverse event reports is certainly not exempt from disclosure as a “trade secret.” See, e.g., Public Citizen I, 704 F.2d at 1283, 1290 (holding that “summary reports of complications and adverse reactions,” “several thousand adverse reaction reports,” FDA letters to sponsors, and “memorandums of telephone conference and a meeting in which the participants discussed adverse reactions” did not constitute “trade secrets”). And, whether any such information could qualify for protection as “confidential commercial information” has simply not been proven by the agency. See Pl. Reply at 9-14; see also Public Citizen I, 704 F.2d at 1290 (“not every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4”); see also Anderson, 907 F.2d at 940, 944 (remanding to district court to determine whether 16,000 documents contained in IND file and comprised of protocols, [p]reclinical test data,” [c]linical test data including adverse reaction reports and interim data,” and “[p]atient information” were exempt under Exemption 4 as confidential commercial information).

Moreover, it is particularly noteworthy that, like the FDA, the intervenors have also conspicuously failed even to respond to one of plaintiff’s major arguments with regard to whether the agency may lawfully assert that records may be withheld as “trade secrets and/or



confidential commercial information” – i.e., that IND sponsors, including intervenors in this case, have already publicly disclosed information about their xenotransplantation INDs during public advisory committee meetings and workshops, through publicly accessible filings to the SEC, and on Internet websites. Pl. Memo. at 15-9, 33-4; Pl. Ex. V-EE; see also 66 Fed. Reg. 4688, 4691 (Jan. 18, 2001) (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”). In fact, in response to plaintiff’s statement of material facts, intervenors concede that this is true to some extent. See Int. Resp. to Pl. Mat. Facts at ¶¶ 48, 49 (“sponsors of xenotransplantation INDs have disclosed the existence of some INDs”), 50-57, 61. Accordingly, intervenors’ do not, and cannot, prove that this already publicly-available information is either a “trade secret” or “confidential commercial information” within the meaning of Exemption 4. See e.g., CNA Financial Corp. v. Donovan, 830 F.2d at 1154 (where the “assertion” that “much of the information sought . . . is already publicly available” is not contested, the submitter is unable to make any claim to confidentiality – a sine qua non of Exemption 4) (emphasis added). Therefore, with respect to all of the information that CRT has painstakingly demonstrated is already publicly available, including information regarding adverse events that have been observed in xenotransplantation patients during these clinical trials, “no meritorious claim of confidentiality can be made” by the intervenors or the agency. Anderson, 907 F.2d at 952; see also Pl. Memo. at 17-9 (discussing publicly available information about adverse events that have occurred in connection with Diacrin xenotransplantation INDs).

Finally, to the extent that intervenors suggest that, in submitting information to the FDA, they have relied on FDA assurances that the requested records would remain confidential, and

that therefore, such information must remain confidential, see, e.g., Egan Aff. at ¶ 25, Declaration of John S. Logan, Nextran, Inc. (“Logan Decl.”) at ¶ 20, such reliance is certainly not “determinative” of whether this information may lawfully be withheld. See Center for Public Integrity v. DOE, 191 F. Supp. 2d 187, 195 n. 4 (D.D.C. 2002) (“the test of confidentiality is an objective one and the parties’ expectations are not determinative”); see also Public Citizen I, 704 F.2d at 1287 (“agencies cannot alter the dictates of the Act by their own express or implied promises of confidentiality”). Similarly, the agency may not withhold information about adverse events in xenotransplantation patients simply to assuage the intervenors’ concern that “if this information were to be made public . . . then opponents of xenotransplantation could use [the] information to inaccurately depict the risks associated with clinical trials.” See Logan Decl. at ¶ 17. Rather, it is well settled that the agency may only withhold the information if it can prove that its release is likely to cause the submitters “substantial competitive” harm – not harm to their public relations. See, e.g., CNA Financial, 830 F.2d at 1154 (“complaints” of “unfavorable publicity” are “unrelated to the policy behind Exemption 4 of protecting submitters from external injury” and “simply do not amount to ‘harm flowing from the affirmative use of proprietary information by competitors’”); Public Citizen I, 704 F.2d at 1291 n. 30 (“[c]ompetitive harm should not be taken to simply any injury to competitive position, as might flow from customer . . . or from the embarrassing publicity attendant upon public revelations”).

## **II. THE FDA IS NOT “ENTITLED TO DEFERENCE” IN ITS DETERMINATION THAT RECORDS ARE EXEMPT FROM DISCLOSURE UNDER EXEMPTION 5.**

For its substantive arguments as to why the FDA has not demonstrated that information may be withheld under the deliberative process privilege incorporated in Exemption 5, plaintiff refers the Court to its Summary Judgment Memorandum, at 34-7 and Reply Memorandum, at

[?]. However, plaintiff wishes to respond to two assertions made by intervenors with respect to the application of this Exemption.

First, intervenors make the surprising assertion that “FDA’s conclusion that the documents at issue are covered by the deliberative process privilege is entitled to deference by the Court.” Int. Memo. at 18, citing Chemical Mfrs. Ass’n v. Consumer Product Safety Comm’n, 600 F. Supp. 114, 118 (D.D.C. 1984). However, as the FOIA itself makes perfectly clear, and as the Court of Appeals for this Circuit has repeatedly ruled, it is a basic tenet of FOIA law that the agency must prove that the Exemptions to the FOIA’s disclosure mandate apply to requested information, and the trial Court must make this determination de novo, without any deference to the agency. See 5 U.S.C. § 552(a)(4) (B) (“the burden is on the agency to sustain its action”); Vaughn v. Rosen, 484 F.2d 820, 823 (D.C. Cir. 1973) (“when the Government declines to disclose a document the burden is upon the agency to prove de novo in trial court that the information sought fits under of the exemptions to the FOIA”); accord, Smith v. DOJ, 251 F.3d 1047, 1050 (D.C. Cir. 2001); Maydak v. DOJ, 218 F.3d 760, 764 (D.C. Cir. 2000); see also Anderson, 907 F.2d at 941, citing United States Dep’t of Justice v. Julian, 486 U.S. 1 (1988) (additional citation omitted) (“the district court must review de novo the agency’s decision not to disclose the requested materials” and “must determine whether all of the requested materials fall within an exemption to the FOIA and may not simply conclude that an entire file or body of information is protected without consideration of the component parts”).

Moreover, as the Court of Appeals has also recently reiterated, no deference is owed to an agency's view of the FOIA’s meaning because “[n]o one federal agency administers FOIA” and, therefore, “[o]ne agency’s interpretation of FOIA is therefore no more deserving of judicial

respect than the interpretation of any other agency.” See Al-Fayed v. CIA, 254 F.3d 300, 307 (D.C. Cir. 2001), citing Tax Analysts v. IRS, 117 F.3d 607, 613 (D.C. Cir. 1997).

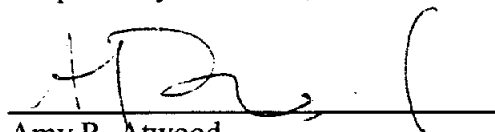
Second, intervenors appear to make the remarkable assertion that the agency may invoke the deliberative process privilege to withhold records that have been shared with the xenotransplantation IND sponsors. See Int. Memo. at 11-12 (the FDA may “withhold documents from disclosure” under the deliberative process privilege to “facilitate open communication with IND sponsors”); see also id. at 12 (“comments and questions generated from internal FDA meetings have been communicated between the FDA and IND sponsors by telephone, teleconference, fax, and by letters sent via US mail”) (emphasis added); see also Pl. Ex. ZZ at § II (listing examples of records withheld under the deliberative process privilege that appear to contain information that has been shared with IND sponsors).

However, under its plain language, Exemption 5 applies only to internal agency deliberations. 5 U.S.C. § 552(b)(5) (the Exemption applies to “inter-agency or intra-agency” records). Id. Accordingly, the deliberative process privilege is waived if the information contained in the records has been disclosed to third parties. See, e.g., Mehl v. EPA, 797 F. Supp. 43, 47 (D.D.C. 1992), citing Mead Data Central v. Dep’t of the Air Force, 566 F.2d 242, 253 & n. 24 (D.C. Cir. 1977) (“[v]oluntary disclosure of information may waive an otherwise valid FOIA exemption”) (additional citations omitted); cf. Cottone v. Reno, 193 F.3d 550, 554 (D.C. Cir. 1999) (materials normally immunized from disclosure under FOIA lose their protective cloak once they are disclosed outside the government). Therefore, to the extent that the FDA is claiming the privilege for any information that has been shared with xenotransplantation IND sponsors, see Pl. Ex. ZZ, § 2 this information may not be withheld under Exemption 5.

**CONCLUSION**

For all of the foregoing reasons, as well as those set forth in CRT's opening brief and its brief in opposition to the FDA, plaintiff's motion for summary judgment should be granted.

Respectfully submitted,

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

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