UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFF'S OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Plaintiff, Campaign for Responsible Transplantation ("CRT"), submits this memorandum in opposition to defendant's cross-motion for summary judgment in this case under the Freedom of Information Act ("FOIA"). For the reasons discussed below, as well as those set forth in plaintiff's memorandum in support of its own motion for summary judgment ("Pl. SJ Mem."), the defendant Food and Drug Administration ("FDA") still has not met its burden of proof that the remaining information at issue in this case may be withheld. Accordingly, plaintiff is entitled to summary judgment and the information at issue must be disclosed. Public Citizen Health Research Group v. Food & Drug Administration, 185 F.3d 898, 906 (D.C. Cir. 1999) (where agency fails to meet its burden of proof in FOIA case, court orders the release of the information).

A. The Court Should Order The Disclosure Of The Records Pertaining To The Other 18 Investigational New Drug Applications That Are Similar In Kind To The "IND G" Records That The Government Has Already Disclosed.

As plaintiff explained, SJ Mem. at 7-9, 12, as the result of this Court's previous ruling, CRT v. FDA, 180 F. Supp.2d 29 (D.D.C. 2001), and plaintiff's narrowing of its FOIA request, the government has released hundreds of pages of records concerning Investigational New Drug ("IND") G, which was used as a "representative sample" for responsive records pertaining to 18 other INDs in this case. However, the agency still has not released any records concerning those other INDs. Accordingly, because the agency cannot possibly meets its burden of proof that those additional records are exempt from disclosure – and, indeed, has not even attempted to do so – summary judgment as to those records should be entered for plaintiff and the FDA should be ordered to release them as soon as possible.

In its memorandum, the FDA takes the odd position that "[p]laintiff is not entitled to the disclosure from any of the other responsive INDs because those INDs are to be processed in accordance with the Court's rulings on IND "G", all of which rulings have not yet been issued." Def. Mem. at 18, n.9. However, since the government has already released hundreds of pages of responsive records that, according to the FDA itself, are indistinguishable in kind from those concerning the other 18 INDs, the Court will have no occasion to issue any further "rulings" with respect to those records, other than by issuing the ruling that plaintiff has requested here – i.e., one that orders the FDA to disclose all such records as soon as possible. See also CRT v. FDA, 180 F. Supp.2d at 33-34 (Court accepts FDA's representation that the IND G records are "essentially uniform" to those concerning the other INDs at issue). Accordingly, especially since this litigation has now been pending for over three years, plaintiff respectfully requests the Court

to grant summary judgment for plaintiff on this issue, and to order the immediate release of all such records.

B. The FDA Has Not Met Its Burden Of Proof That Any Of The Withheld Information Is Exempt From Disclosure Under Exemption 4.

For the reasons stated in plaintiff's opening memorandum, Pl. SJ Mem. at 12-18, the government has not met its burden of proof that any of the information that has been withheld under Exemption 4 (portions of Doc. Nos. 773, 2280, 2762, 3476, 3585, and 3591) is exempt from disclosure. To begin with, the government did not submit any new declarations to support its motion, although it did submit a more updated version of its Vaughn index. However, that index, like the prior versions, is not a sworn statement, and hence, simply cannot satisfy the agency's burden to prove that the exemption applies. See Pl. SJ Mem. at 15; see also Rule 56(e), Fed.R.Civ.P. ("[s]upporting . . . affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein"); Carson v. Dep't of Justice, 631 F.2d 1008, 1015 n.30 (D.C. Cir. 1980) (Court will not ordinarily take cognizance of facts supplied by mere assertion of counsel); Founding Church of Scientology v. NSA, 610 F.2d 824, 836 (D.C. Cir. 1979) (to meet its burden under the FOIA, an agency must supply "supporting affidavits" that are "'relatively detailed' and nonconclusory") (citations omitted).[1]

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[1]CRT accepts the government's latest version of the Vaughn index that was submitted with the FDA's renewed motion for summary judgment as an accurate list of the records that are still at issue, in addition to all of the responsive records that relate to the other 18 INDs. However, although the government states that information was withheld under Exemption 4 from only five documents, Def. Mem. at 9, it failed to include a sixth document (Doc. No. 773), which, according to the agency's own Vaughn index includes information that has been withheld pursuant to Exemption 4.

To compound matters, none of the declarations that are relied on by the agency – including one by an agency official and two by the intervenors, see Def. Mem. at 10 , address any of the actual records that have been withheld on Exemption 4 grounds. Therefore, there simply is no basis upon which this Court can determine *de novo* that the Exemption in fact applies to each of those documents, and grant summary judgment for defendants.

Moreover, the agency's general reliance on its own regulations, 21 C.F.R. § 601.51, as a basis for withholding any information that is contained in an IND submission, Def. Mem. at 8-9, must fail. It is well established that the nine exemptions to the FOIA are exclusive, and must be construed narrowly. Department of the Air Force v. Rose, 425 U.S. 352, 361 (1976). Therefore, they cannot be expanded by agency regulation. Id. In fact, while Exemption 3 of the FOIA allows an agency to withhold information that is "specifically exempted from disclosure by statute," 5 U.S.C. § 552(b)(3) (emphasis added), neither it nor any other provision of the statute allows an agency to carve out, by regulation or other means, additional categories of information that may be withheld from the public. See, e.g., Founding Church of Scientology v. Bell, 603 F.2d 945, 952 (D.C. Cir. 1979) (agency may only rely on "statutes" enacted by Congress as basis for Exemption 3 of the FOIA). Therefore, either the information can be withheld because it otherwise qualifies for exempt status as "confidential commercial information" under the standards that apply to Exemption 4, or it must be disclosed.

The agency's reliance on its own regulations as a basis for withholding this information is also particularly strange in light of the fact that plaintiff made it absolutely clear seven months ago that it does not seek any information that would identify a particular sponsor or product. Plaintiff's Memorandum In Support Of Cross-Motion For Summary Judgment (July 9, 2003) at 1. Rather, plaintiff seeks information that would demonstrate the health and safety risks

associated with xenotransplantation in general, or that would shed light on how the agency is regulating this new – and extremely risky – biotechnology. Id. The agency simply fails to explain how disclosure of information from these documents, without identifying a sponsor's name or a specific product being tested, is nevertheless "likely" to cause "substantial" competitive injury to a particular sponsor, as required to meet the FDA's burden of proof under Exemption 4. National Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); see also Pl. SJ Mem. at 14-17.

As plaintiff also explained, Pl. SJ Mem. at 17-18, the government also cannot meet its burden of proof that information is "confidential" under this Exemption, if any such information has already been publicly disclosed. Nevertheless, although plaintiff long ago furnished the FDA with voluminous exhibits reflecting public disclosures concerning pending INDs, see Pl. SJ Mem. at 17-18, the agency continues to dodge the issue of whether it has ever actually gone through those materials to determine whether any of the information it continues to withhold has already been disclosed by sponsors to the public. Instead, the agency curiously states only that "[i]nformation from IND submissions that FDA recognizes as publicly released has already been produced to Plaintiff." SJ Mem. at 9 (emphasis added), *citing* Second Ryan Decl. ¶ 10. It is not clear what this meticulously worded sentence means, and whether it covers – at all – any of the information that CRT has made available to the agency on this point.[2]

Finally, in addition to the fact that the agency fails to address in its declarations any of the specific information that has been withheld under Exemption 4, the extremely broad, non-specific, explanations provided by the agency are far too conclusory to satisfy the government's

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[2]Should the court deny plaintiff's motion for summary judgment, and instead allow plaintiff to take discovery, see Pl. SJ Mem. at 3, note 2, this would be one area of such inquiry.

burden of proof. Thus, the affidavit cites provided by the government for its Exemption 4 claims are (1) Second Brockner Ryan Decl. ¶¶ 11-12; (2) Stewart/Egan Decl. (Dec. 16, 2002), ¶ 4; (3) Egan Decl. (June 4, 2003), ¶3. See Def. SJ Mem. at 10. However, all but paragraph 11 of the Second Brockner Ryan Decl., address documents that are no longer even at issue in this case, and say absolutely nothing about any of the information that the government is continuing to withhold under Exemption 4 (again, Doc. Nos. 773, 2280, 2762, 3476, 3585, and 3591).

Moreover, paragraph 11 of the Ryan Declaration states only the following with respect to the government's burden to prove that disclosure of the withheld information is likely to cause "substantial" competitive harm to the sponsors:

> Disclosing such proprietary information as contained in INDs could cause substantial competitive harm to a sponsor by giving a rival sponsor a competitive advantage. For example, maintaining the confidentiality of study designs and protocols for investigational new drug products is important for encouraging innovation. Sponsors would not be as willing to invest in new study methods, the details of which must be included in an IND, if FDA freely disclosed such information to the public, including other competing companies developing or marketing similar drug products. The release of such information would likely cause substantial competitive harm to sponsors by permitting competitor sponsors to utilize valuable information from the initial sponsor's IND in their own IND without having to invest their own time, money, and effort in developing that information.

Second Declaration of Brockner Ryan ¶ 11. However, this explanation is completely conclusory, and, particularly when CRT has made it clear that is does not seek information that would identify a sponsor or product, fails to provide the Court with any basis for concluding that disclosure of the specific information at issue is likely to cause anyone "substantial" competitive harm.

In this regard, the government's reliance on Public Citizen Health Research Group v. FDA, 185 F.3d at 905-06, Def. Mem. at 10, is completely misplaced. Indeed, in that case, which

involved a request for access to actual INDs that had been submitted by a drug company to the FDA – as opposed to the FDA-generated documents at issue here – the Court of Appeals rejected as wholly insufficient an affidavit that provided much more detail than is provided by the affidavit relied on by the government here. Thus, the Court explained:

> The affidavit of Schering's Dr. Ronald J. Garutti contains only conclusory assertions that disclosure would cause substantial competitive harm. For example, the affiant states that disclosure "would reveal substantial basic research" as well as "disease models . . . that have been developed by Schering at great expense," and that "[t]oxicology data . . . have significant value beyond the compound under investigation . . . [and would be applicable] to any drug product any of whose metabolites were identical or similar to those of IND 18113 . . . [and] other drugs [of] similar chemical type. Dr. Garutti attests that the clinical protocols also "have applicability beyond the specific drug being tested" and that disclosure "would have substantial commercial value to any company attempting to develop cardiovascular therapies generally."

185 F.3d at 906 (emphasis added)

Moreover, in Public Citizen, the name of the sponsor of the drug was identified, as was the fact that the compound was intended as a "cardiovascular therapy." Id. Here, however, in sharp contrast, particularly in light of CRTs exclusion of any information that identifies either a sponsor or any of the specific products being tested its investigation, would any of such information be revealed by disclosure of the remaining information.

Furthermore, like the affidavit that was rejected in Public Citizen, Ms. Ryan's declaration is extremely conclusory, and simply repeats the same boilerplate statement that release of the information would likely "cause substantial competitive harm." See Second Ryan Decl. at ¶ 11 ("[d]isclosing such proprietary information . . . could cause substantial competitive harm;" [t]he release of such information would likely cause substantial competitive harm"). However, the FDA's naked reliance on such boilerplate assertions of competitive harm -- without any specific explanations of how disclosure of the actual information at issue would cause such harm --

makes a complete mockery of this Court's duty to conduct a meaningful *de novo* review of the agency's withholding and to "narrowly construe" the exemptions to the FOIA. Dep't of the Air Force v. Rose, 425 U.S. at 361. Accordingly, the government is not entitled to summary judgment with respect to any of the information that has been withheld under Exemption 4, and all such information must be released. Public Citizen, 185 F.3d at 906.

C. The Government Has Not Met Its Burden Of Proof Under Exemption 5.

For the reasons stated in CRT's summary judgment memorandum, Pl. SJ Mem. at 18- 23, the FDA has also failed to meet its burden of proof with regard to the two documents withheld in their entirety (Doc. Nos. 1913, 3024) and those withheld in part (Doc. Nos. 201, 773, 1088, 1357, 1364, 1863, 2093, 2280, 2610, 2762, 3098, 3476, 3585, and 3591) under Exemption 5.

First, as with the agency's Exemption 4 claim, the agency has failed to submit a sworn statement that addresses any of the specific documents that have been withheld under this Exemption. The unsworn explanations now provided for the first time by government's counsel in defendant's brief, Def. SJ Mem. at 15-18, simply do not suffice to carry the government's burden here. See *supra* at 3.

Second, it now appears that, in at least two instances, the agency is withholding information under this Exemption that was either produced by or shared with a sponsor. Thus, as pointed out in CRT's memorandum, Pl. SJ Mem. at 20, Doc. No. 3024 is described in the agency's Vaughn index as having been received "from" a "sponsor." Defendant's 3rd Abbreviated New Sample Vaughn Index at 4. In addition, in its brief, the government describes Doc. No. 3585 as hand-written notes that "describe a telephone conference between FDA employees and a sponsor regarding a clinical trial issue." Def. Mem. at 17 (emphasis added). However, because Exemption 5 only applies to "inter" or "intra" agency memoranda, any

information prepared by or shared with someone outside the government – such as IND sponsors – is simply not exempt from disclosure. See, e.g., Center for International Environmental Law v. Office of the U.S. Trade Representative, 237 F. Supp.2d 17, 30 (D.D.C. 2002) (documents or portions "produced by or shared with the Government of Chile do not qualify as 'inter-agency or intra-agency' documents and thus are not protected from disclosure by Exemption 5"); Dep't of the Interior v. Klamath Water Users, 532 U.S. 1, 12 (2001) (Exemption 5 does not apply to communications between Klamath Tribe and agency).

Third, the agency also may not withhold information that describes "what Regulations and Laws apply to xenotransplantation" (Doc. No. 1863) or "Laws applying to the use of animals in xenotransplantation" (Doc. No. 2610), since such documents simply are not "pre-decisional" in nature. See Pl. SJ Mem. at 22-23. Thus, as the Court of Appeals for this Circuit has explained, Exemption 5 does not allow the agency to withhold information concerning "simply straightforward explanations of agency regulations in specific factual situations," since "[n]o 'decision' is being made or 'policy' being considered; rather the documents discuss *established* policies and decisions – the agency regulations – in the light of a specific, and often hypothetical, fact pattern." Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 868 (D.C. Cir. 1980) (first emphasis added) (second emphasis in original).

Fourth, as plaintiff has demonstrated, Pl. SJ Mem. at 20-21, the FDA has also failed to demonstrate that the withheld information is "pre-decisional," because the agency has failed to identify the specific role each of the withheld documents or portions thereof played in an actual decision or policy-making undertaking by the agency. See Pl. SJ Mem. at 21-23; see also Senate of the Com. of Puerto Rico v. DOJ, 823 F.2d 574, 585 (D.C. Cir. 1987) (the court "must be able 'to pinpoint an agency decision or policy to which the document contributed'"), *quoting*

Paisley v. CIA, 712 F.2d 686, 698 (D.C. Cir. 1983). In this regard, the agency's contention that "[t]he existence of predecisional documents does not depend on the agency's ability to identify a specific decision to which the documents relate," Def. Mem. at 13, is not entirely accurate. See e.g., id. While it is true that the agency need not demonstrate that the decision or policy to which the document relates actually reached finality, it is well established that the agency must nevertheless establish "what deliberative-process is involved, and the role played by the documents in issue in the course of that process." Coastal States, 617 F.2d at 868 (emphasis added); see also Gutman v. U.S. Dep't of Justice, 238 F. Supp.2d 284, 292 (D.D.C. 2003) ("[i]n determining whether a document is predecisional, an agency does not necessarily have to point specifically to an agency's final decision") (emphasis added).

Here, the government identifies two different "processes" that each of the withheld documents or portions may relate to: either the IND review process or the "develop[ment] [of] FDA policy on xenotransplantation-related issues." Def. Mem. at 14. However, the agency's only sworn declaration on this issue, Second Declaration of Dr. Joyce Frey-Vasconcells, does not identify which documents relate to which process, nor does the unsworn Vaughn index. The agency's latest brief provides more details about some of the documents, Def. Mem. at 14-17, but also does not delineate which process in implicated by each document. Moreover, the descriptions in the unsworn Vaughn index and agency brief raise more questions than they answer concerning the applicability of Exemption 5.

For example, the agency states in its brief (but not in a sworn affidavit or even in its Vaughn index) that it has withheld from Document 201 "the author's opinion regarding an issue involving xenotransplantation in human subjects," and that "[t]hese opinions were provided to the recipients in order to assist their decision-making on the issue." Def. Mem. at 15. However,

the agency has failed to explain (1) what "issue" is being discussed, or (2) what kind of "decision" is involved, and hence has utterly failed to meet its burden to "pinpoint an agency decision or policy to which the document contributed." Senate of the Com. of Puerto Rico v. DOJ, 823 F.2d at 585. Moreover, although for that particular document the agency actually lists the names of the author and recipients – which it does not do for several other documents (Doc. Nos. 773, 2762, 3024, 3476, 3585) – the agency has failed to identify the positions of these individuals within the FDA. Accordingly, there is no way for this Court to determine, *de novo*, whether this document is truly pre-decisional. See, e.g., Animal Legal Defense Fund v. Dep't of Air Force, 44 F. Supp.2d 295, 300-301 (D.D.C. 1999) (agency does not prove applicability of Exemption 5 where it fails to "indicate[] the titles and positions of the documents' authors and recipients"); see also Pl. SJ Mem. at 20-21.

Similarly, the agency's brief (but not its affidavit) describes Document 1364 as "internal memoranda that discuss potential solutions to problems concerning PERV screening," and states that the withheld portion "involves the author employee's judgment in her contribution to FDA's attempt to resolve issues concerning PERV screening." Def. Mem. at 16. However, the agency does not describe what "problems" it was wrestling with, or what specific "attempt to resolve issues concerning PERV screening" the document refers to. In addition, although the Vaughn index identifies the names of the author and the recipient, the agency has not revealed their positions within the agency. For all of these reasons, there simply is no way for this Court to determine that, in fact, this document is a predecisional deliberative document that may be withheld from plaintiff within the meaning of the cases that have construed Exemption 5.

The agency further describes this document (No. 1364) as containing "an interpretation of data on PERV," Vaughn index at 2. In its brief – but nowhere in a sworn declaration – the

agency summarily asserts that this particular data interpretation (by someone named Amy Patterson, who not further identified) "is very different from the purely factual materials that courts have found must be disclosed pursuant to FOIA," Def. Mem. at 16, but, other than including a quote from a different case concerning a "draft audit report," the agency provides absolutely no further explanation as to why this particular "interpretation of data" – presumably scientific data – is nevertheless "deliberative" in nature. See, e.g., Pl. SJ Mem. at 23 (cases holding that factual information, versus advice and recommendations, may not be withheld under Exemption 5.[3]

Therefore, because the agency has failed to meet its burden of proof that any of the information withheld from CRT under Exemption 5 is actually exempt from disclosure, its motion for summary judgment should be denied. Alternatively, plaintiff should be given an opportunity to take discovery on these matters, see 2d Declaration of Alix Fano Pursuant to Rule 56(f), or the Court should conduct an *in camera* inspection of the remaining materials, see Trans-Pacific Policing Agreement v. U.S. Customs Service, 177 F.3d 1022, 1028 (D.C. Cir. 1999).

CONCLUSION

For all of the foregoing reasons and for the reasons set forth in CRT's memorandum in

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[3]The only other document that is specifically discussed in defendant's brief, that the plaintiff has not addressed here, is Document No. 1088, which, in the agency's brief (but not in the sworn declaration or even the agency's unsworn Vaughn index), the agency describes as relating to some "policy" on the issue of "what, if any, long-term requirements FDA ought to impose on sponsors who withdraw INDs relating to xenotransplantation." However, not only is it not appropriate for the Court to rely on this unsworn explanation from defendant's brief to satisfy the government's burden here, see *supra* at 3, but this new description falls far short of demonstrating that this particular entry would reveal the "give and take" between a subordinate and his superior. See, e.g., Coastal States Gas Corp., 617 F.2d at 866 (the exemption serves "to assure that subordinates within an agency will feel free to provide the decisionmaker with their uninhibited opinions and recommendations without fear of later being subject to public ridicule or criticism").

support of its motion for summary judgment, the defendant's motion should be denied, and the Court should order the release of all of the responsive records that are similar in kind to the IND G records that have already been released, as well as the remaining documents and information listed in defendant's latest Vaughn index.

Respectfully submitted,

/s/ Filed electronically

Katherine A. Meyer
(D.C. Bar No. 244301)
Meyer & Glitzenstein
1601 Connecticut Ave., N.W.
Suite 700
Washington, D.C. 20009
(202) 588-5206

UNITED STATES DISTRICT COURT
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PLAINTIFF'S RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS

Pursuant to Local Rule 7.1(h), plaintiff Campaign for Responsible Transplantation ("CRT") submits this response to defendant's statement of material facts as to which there is no genuine issue.

1. Plaintiff does not dispute this paragraph.

2. Plaintiff does not dispute this paragraph, except that it disagrees with defendant's characterization of the Vaughn index as providing an adequate "explanation" and legal authority for each withholding, which is a matter of law to be decided by the Court.

3. Plaintiff agrees that there are only 16 documents at issue from the pool of general and IND G records that are responsive to plaintiff's request. However, in addition, all of the other records concerning the additional 18 Investigational New Drug applications that are not

exempt and that are similar in kind to the "representative" IND G records that have already been released by the agency also remain at issue in this case. See, e.g., CRT v. FDA, 180 F. Supp.2d 29, 33-34 (D.D.C. 2000).

4. According to the agency's own latest Vaughn index, a sixth document, Doc. No. 773, contains information that was deleted throughout the document on the basis of Exemption 4. See Third Abbreviated New Sample Vaughn Index (Defendant's Exhibit A) at 1.

5. Plaintiff agrees with this statement.

Respectfully submitted,

/s/ Filed electronically

Katherine A. Meyer
(D.C. Bar No. 244301)
Meyer & Glitzenstein
1601 Connecticut Ave., N.W.
Suite 700
Washington, D.C. 20009
(202) 588-5206

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ORDER

Upon consideration of defendants' motion for summary judgment, plaintiff's opposition, plaintiff's cross-motion for summary judgment, and the entire record of this proceeding, it is this

day of , 2004

ORDERED that defendants' motion is denied, and it is further

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

ORDERED that, within 30 days of the date of this Order, defendant Food and Drug Administration shall provide to plaintiff's counsel (a) copies of all documents that are still at issue, including the sixteen records referenced in the parties' cross-motions for summary judgment, and (b) all of the documents concerning the other eighteen Investigational New Drug ("IND") applications that are at issue in this case and that are similar in kind to the "IND-G" records that have already been released by the FDA and that will further be released pursuant to

(a).

United States District Judge