IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANT'S REPLY MEMORANDUM IN SUPPORT OF ITS RENEWED MOTION FOR SUMMARY JUDGMENT

Defendant, the U.S. Food and Drug Administration ("FDA"), respectfully submits this Reply Memorandum in Support of its Renewed Motion for Summary Judgment in response to Plaintiff's Opposition to Defendant's Cross-Motion for Summary Judgment ("Plf. Opp."). Plaintiff's opposition raises several new arguments and repeats many of its earlier arguments concerning FDA's response to Plaintiff's FOIA request. FDA has fulfilled all of its obligations under FOIA and properly withheld the remaining sixteen documents pursuant to Exemptions 4 and/or 5. All of Plaintiff's arguments lack merit and should be rejected by the Court.

I. Argument

A. FDA has Met its Burden of Proof Under Exemption 4

At the outset, Plaintiff scolds the government for failing to "submit any new declarations to support its [pending] motion." Plf. Opp. at 3, 8. Plaintiff, however, fails to acknowledge the

Court's December 2, 2003 Order, which specifically states that "[i]t is not necessary [for the parties] to re-submit exhibits; references may be made to existing exhibits." Order at 3 (emphasis added). Thus, it was wholly appropriate for the government to rely on its previously submitted declarations in support of the current motion.

Plaintiff also argues that FDA's updated Vaughn index "is not a sworn statement, and hence, simply cannot satisfy the agency's burden to prove that the exemption applies." Pl"s Opp. at 3. However, as explained more fully in the government's opposition brief, FDA's initial New Sample Vaughn Index accompanied a sworn declaration by an FDA employee, and the more recent abbreviated index supplied with the pending motion is merely a condensed version of the original and there is no need for yet another sworn statement. See Def. Mem. of P.&A. in Opp'n to Plf. Mot. for Summ. J. ("Def. Opp.") at 6; Third Abbreviated New Sample Vaughn Index ("third Vaughn index"), Mem. of P.&A. in Supp. of Def. Renewed Mot. for Summ. J. ("Def. Mem."), Ex. A.

Plaintiff next contends that FDA improperly relied on one of its own regulations, specifically 21 C.F.R. § 601.51, instead of a FOIA exemption, as the basis for withholding documents in response to Plaintiff's FOIA request. Plf. Opp. at 4-5. However, as is clear from FDA's Vaughn index, all sixteen of the documents that remain in contention were withheld pursuant to FOIA Exemptions 4 and/or 5, not 21 C.F.R. § 601.51. See third Vaughn index.

FDA referenced 21 C.F.R. § 601.51 in its earlier brief to further illustrate the confidential nature of the portions of documents that FDA withheld pursuant to Exemption 4, not, as Plaintiff suggests, as the ultimate or sole basis for FDA withholding such documents. Section 601.51 provides, in relevant part, that no data or information contained in an IND file is available for

public disclosure "[i]f the existence of a biological product file has not been publicly disclosed or acknowledged," or if FDA has not approved a biologics license application. 21 C.F.R. §§ 601.51(c), (d)(1). The regulation was one of many promulgated by FDA to govern "the handling of all public information requests by the Food and Drug Administration," and the regulations were issued "in conformance with" the FOIA. Freedom of Information, 39 Fed. Reg. 44,602, 44,656 (Dec. 24, 1974). As set forth in FDA's third Vaughn index, the portions of all five of the documents that FDA withheld under Exemption 4 contain confidential commercial information, and are thus exempt from disclosure. See third Vaughn index. In sum, FDA has fulfilled its burden of proof that the portions of the remaining five documents it withheld under Exemption 4 are exempt from disclosure.

Plaintiff further contends that the declarations submitted by FDA are too broad and conclusory to sufficiently demonstrate the likelihood of substantial competitive harm that would result from disclosure, and that the FDA is improperly withholding, as "confidential," information that has been publicly disclosed. Plf. Opp. at 5-7. FDA fully briefed these arguments already. See Def. Mem. at 9-11, Def"s Opp. at 11-13 (discussing the likelihood of competitive harm); Def"s Opp. at 13-14 (discussing purportedly publicly disclosed information).

Next, Plaintiff again contends that FDA must immediately disclose all documents relating to the other 18 responsive INDs that are similar in kind to those documents FDA has already released from IND G. Plf. Opp. at 2-3. Since FDA has addressed this issue in detail in its opposition brief, it will not repeat that discussion here, but refers the Court to its Opposition to Plaintiff's Motion for Summary Judgment, at pages 2-5.

B. FDA Sustained its Burden of Proof Under Exemption 5

Plaintiff contents that "the agency is withholding information under this Exemption [5] that was either produced by or shared with a sponsor," and is therefore not exempt. Plf. Opp. at 8 (emphasis in original). By way of example, Plaintiff references document 3585, which consists of a single page of hand-written notes concerning a telephone conference between FDA and a sponsor of a clinical trial.[1] Third Vaughn index at 5. Plaintiff argues that, because the telephone conference was between agency employees and a non-agency party, the document referencing that call is not exempt from disclosure under Exemption 5. Plf. Opp. at 8-9.

Document 3585, however, is not a transcript of the telephone conference between FDA and the sponsor. Rather, document 3585 contains an agency employee's personal thoughts, impressions, and comments as the employee reacted to the underlying telephone conversation. Third Vaughn index at 5. The deliberative process privilege, incorporated within Exemption 5, protects documents that are both pre-decisional and deliberative, including "recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency." Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980). Document 3585 represents the FDA employee's personal opinions and judgments, which were a by-product of a telephone call with

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[1] Plaintiff notes that, based on the entry in the Vaughn index, document 3024 appears to have been created by a sponsor and FDA cannot withhold it pursuant to Exemption 5. Plf. Opp. at 8. In fact, the author of document 3024 is an unknown agency employee, whose withheld comments refer to his/her involvement in agency deliberations. The column in the Vaughn index should have been labeled "unknown agency employee" rather than "sponsor." See also Def. Opp. at 15, n.4. Additionally, by Plaintiff's own modification of its FOIA request, Plaintiff seeks only FDA-generated documents, so even if document 3024 were created by a sponsor, it would not be responsive.

the sponsor, and do not represent a final agency position. Document 3585 is therefore exempt from disclosure under Exemption 5.

Plaintiff next asserts that documents 1863 and 2610 are not pre-decisional because they describe laws and/or regulations applicable to xenotransplantation, and are not part of an FDA decision-making process. Plf. Opp. at 9. Plaintiff is mistaken. As FDA previously explained in its Renewed Motion for Summary Judgment, both documents 1863 and 2610 consist of internal e-mail discussions between FDA employees about the laws and/or regulations that may apply to xenotransplantation. Third Vaughn index at 2, 4; see also Def. Mem. at 17. Contrary to Plaintiff's statement that these documents are merely "straightforward explanations of agency regulations in specific factual situations," where no decision or policy matter is being considered, Plf. Opp. at 9 (quoting Coastal States, 617 F.2d at 868), in fact these documents show FDA employees attempting to determine for the first time, through discussion with one another, the applicability of certain laws and/or regulations to xenotransplantation. Such discussion about the potential applicability of statutory provisions and regulations to given facts are particularly within the purview of Exemption 5.

Plaintiff's reliance on Coastal States is misplaced. Plaintiff admits that xenotransplantation is "a relatively new experimental biotechnology," Plf. Mem. in Supp. of Plf. Mot. for Summ. J. at 2. Accordingly, the advent of xenotransplantation has required FDA to create and/or consider new interpretations and applications of its statutes and regulations. Documents 1863 and 2610, e-mail exchanges between FDA employees, express the authors' personal thoughts and opinions regarding statutes and regulations as they could relate to xenotransplantation, prior to a final agency position on the matter. Such brainstorming and

discussion are at the heart of Exemption 5. The documents are not merely a restatement of how the agency already interprets its underlying regulations or laws in a given factual situation, as was the case in Coastal States, but rather reflect the give-and-take of the agency's consultative process, working to create initial interpretations of laws and regulations in the evolving context of xenotransplantation.

It is well-settled that documents containing agency employee recommendations that are part of the decision-making process are protected by the deliberative process privilege. See, e.g., Dep't of the Interior & Bureau of Indian Affairs v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8-9 (2001) ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news."); Wolfe v. HHS, 839 F.2d 768, 774 (D.C. Cir. 1988) ("advice and recommendations may be withheld [pursuant to Exemption 5]"). In other words, documents containing advice that is used by the agency to reach a decision are "precisely the kind of pre-decisional and deliberative advice and recommendations contemplated by Exemption 5 which must remain uninhibited and thus undisclosed." Renegotiation Bd. v. Grumman Aircraft Engineering Corp., 421 U.S. 168, 190 (1975). Documents 1863 and 2610 are precisely the sort of internal deliberative documents that must remain protected by Exemption 5 to prevent the chilling of open and frank discussion within the agency.

Finally, Plaintiff contends that FDA failed to demonstrate that some of the withheld documents are pre-decisional by not identifying a specific decision to which each document relates. Plf. Opp. at 9-12. Plaintiff acknowledges FDA's point that the existence of pre-decisional documents does not depend on the agency's ability to identify a specific decision to

which the documents relate. Id. at 10. Plaintiff nevertheless asserts that FDA's failure to identify the deliberative process that each withheld document was involved with renders its withholdings improper. Id. at 10. See also NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 n.8 (1975). FDA, however, has already, in as much detail as possible, explained the deliberative processes to which the withheld documents, or parts thereof, relate. See Def. Mem. at 14-18; Def. Opp. at 15-16. An agency is not required to divulge so many details concerning withheld documents that the protected information itself is disclosed. See, e.g., Oglesby v. Dep't of the Army, 79 F.3d 1172, 1176 (D.C. Cir. 1996) ("The description and explanation the agency offers should reveal as much detail as possible as to the nature of the document without actually disclosing information that deserves protection."). Therefore, FDA's descriptions suffice to demonstrate that the documents, and parts thereof, withheld under Exemption 5 are protected by the deliberative process privilege, and are exempt from disclosure.

C. Plaintiff's Request for Discovery is Meritless.

Plaintiff also requests an opportunity to take discovery. Plf. Opp. at 12. As discussed in more detail in FDA's earlier opposition brief, discovery is not appropriate in this case because the adequacy of FDA's search was definitively established by this Court, and Plaintiff has not questioned FDA's good faith in processing its FOIA request. See Def. Opp. at 19-20.

II. Conclusion

FDA has complied with its obligations in response to Plaintiff's FOIA request, and has provided Plaintiff with all reasonably segregable, non-exempt, responsive documents and parts thereof. The sixteen documents that remain at issue in this case are exempt from disclosure

pursuant to FOIA Exemptions 4 and/or 5. Therefore, defendant's renewed motion for summary judgment should be granted and Plaintiff's cross-motion for summary judgment should be denied.

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Respectfully submitted,

ROSCOE C. HOWARD, JR., DC Bar #246470
United States Attorney

MARK E. NAGLE, DC Bar #416364
Assistant United States Attorney

ALAN BURCH
Assistant United States Attorney
555 4th Street, NW, room 10-409
Washington, D.C. 20530
202-514-7204

OF COUNSEL:

ALEX M. AZAR II
General Counsel
Department of Health and Human Services

DANIEL E. TROY
Chief Counsel
Food and Drug Administration

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation
Food and Drug Administration

SHOSHANA HUTCHINSON
Assistant Chief Counsel for Enforcement
Food and Drug Administration
5600 Fishers Lane, Room 6-64
Rockville, MD 20857
301-827-8579