

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,)
PO Box 2751)
New York, New York 10163)
)
Plaintiff,)
) Civ. No.
v.)
)
)
)
U.S. FOOD AND DRUG ADMINISTRATION,)
5600 Fishers Lane)
Rockville, Maryland 20857)
)
Defendant.)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, as amended, to compel the United States Food and Drug Administration ("FDA") to provide plaintiff with records concerning clinical trials involving "xenotransplantation," an experimental and unregulated form of biotechnology in which animal organs, tissues, and cells are implanted into humans for the treatment of human diseases.

JURISDICTION

2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B).

3. Plaintiff Campaign for Responsible Transplantation ("CRT") is a non-profit organization dedicated to education and

dissemination of information concerning the health risks and ethical and policy considerations of xenotransplantation -- as well as the federal government's role in funding, promoting, and approving this untested and risky form of biotechnology.

4. Defendant Food and Drug Administration is an agency of the United States, and has possession and control of the records plaintiff seeks.

FACTS GIVING RISE TO PLAINTIFF'S CLAIMS FOR RELIEF

5. The FOIA requires agencies of the federal government, upon request, to release information to the public, unless one of nine specific statutory exemptions applies to the records. 5 U.S.C. § 552, as amended.

6. For almost two decades, FDA has approved numerous protocols by several drug and/or biotechnology companies to conduct clinical trials involving xenotransplantation -- thus extending its permission for the implantation of, among other things, pig cells and tissues into ailing human patients. FDA approval for these trials is routinely granted without any further federal oversight regarding health and ethical considerations -- despite the Department of Health and Human Services' acknowledgement that "concerns have arisen in the last few years about the potential infectious disease and public health risks associated with xenotransplantation"; "infectious diseases of animals...can be transmitted to humans via...exposure

to animals;" "xenotransplantation may facilitate transmission of known or as yet unrecognized infectious agents to humans;" and "xenotransplantation necessitates disruption of the recipient's usual protective physical and immunologic barriers[.]" 64 Fed. Reg. 73562 (December 30, 1999).

7. By letter dated March 9, 2000, CRT requested all FDA records concerning applications for approval to conduct clinical trials in humans that involve xenotransplantation, and all information concerning currently ongoing and concluded clinical trials involving xenotransplantation. CRT made it clear that it was not seeking the names or personal information about any particular patients, but rather information that would shed light on the health risks of the experiments and whether the government was adequately performing its statutory duties to insure that the public was protected from the risks of exposure to any transmitted animal viruses.

8. In its request, CRT explained that many drug companies had publicized extensive details about their sponsorship of these clinical trials through press releases and the Internet. CRT also explained that articles in scholarly journals and public statements made by FDA officials had further alerted the public to the existence of clinical trials involving xenotransplantation. Accordingly, CRT explained that the requested information should not be exempt from disclosure under

Exemption 4 of the FOIA, 5 U.S.C. § 552(b)(4), which pertains to trade secrets and confidential commercial information, since the sponsors of these clinical trials were themselves disclosing information about the experiments to the media and the public.

9. By letter dated March 14, 2000, FDA acknowledged receipt of CRT's request for records and indicated that the agency would respond to the request "as soon as possible."

10. By letter dated August 2, 2000, after having received no further response to its initial request nor any indication as to when FDA would substantively respond to its request -- and after having been informed via telephone conversations with agency officials that it could be "years" before FDA would substantively respond -- CRT appealed the constructive denial of its initial request.

11. To date, FDA has not provided CRT with records responsive to its request, and the twenty working days for a determination with respect to CRT's appeal, see 5 U.S.C. § 552(a)(6)(A)(ii), has expired.

PLAINTIFF'S CLAIM

12. There is no statutory basis for the defendant's failure to disclose the requested information, and CRT has right of access to this information under the FOIA. There are many records, responsive to CRT's requests, which FDA has neither released to plaintiff nor claimed to be subject to any FOIA

exemption.

13. By failing to respond to CRT's March 9, 2000 FOIA request, the defendant is in violation of the FOIA. 5 U.S.C. § 552(a)(6).

14. By failing to respond to CRT's August 2, 2000 FOIA appeal, the defendant is in violation of the FOIA. 5 U.S.C. § 552(a)(6).

WHEREFORE, plaintiff requests that this Court:

(1) Declare that defendant has violated the FOIA by improperly withholding the records requested by plaintiff;

(2) Order defendant to make the requested records immediately available to plaintiff;

(3) Award plaintiff its costs and reasonable attorneys' fees in this action;

(4) Grant such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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