

LANCASTER PA

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JAN 5 1994

PUBLIC CITIZEN HEALTH)
RESEARCH GROUP)
2000 P St., N.W. Suite 700)
Washington, D.C. 20036,)

Plaintiff,)

v.)

FOOD AND DRUG ADMINISTRATION)
5600 Fishers Lane)
Rockville, Maryland 20857,)

Defendant.)

Civil Action No 94 0018

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 production of all records concerning pre-clinical and clinical studies for all prescription drugs for which the clinical trials were discontinued after January 1, 1990, because of death or serious injury of patients or because of safety concerns from pre-clinical studies.

2. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B).

3. Plaintiff Public Citizen Health Research Group is a non-profit consumer advocacy organization devoted to promoting consumer health and safety, and is the requester of the withheld records.

4. Defendant Food and Drug Administration ("FDA") is an agency of the United States, and it has possession of and control over the records that plaintiff seeks.

5. By letter dated July 12, 1993, plaintiff requested copies of all records concerning pre-clinical and clinical studies for all prescription drugs for which the clinical trials were discontinued because of death or serious injury of patients or because of safety

concerns arising from pre-clinical studies. The request was limited to drugs whose clinical trials were stopped between January 1, 1990 and the date of the request.

6. By letter dated August 6, 1993, defendant denied plaintiff's request, stating that the FDA's Center for Drug Evaluation and Research does not have a central file and has not compiled the documents which would be responsive to plaintiff's request. FDA neither released any of the requested records nor asserted that any of them are exempt from disclosure under FOIA.

7. By letter dated November 17, 1993, plaintiff appealed defendant's denial of its request.

8. By letter dated December 1, 1993, FDA acknowledged receipt of plaintiff's administrative appeal.

9. More than 20 working days have passed, defendant has not responded substantively to plaintiff's administrative appeal, and to date it has not indicated when a substantive response can be anticipated.

10. Plaintiff has a statutory right to the records it seeks, and there is no legal basis for defendant's refusal to disclose them to him.

WHEREFORE, plaintiff prays that this Court:

(A) Declare that defendant's withholding of the requested records is unlawful;

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

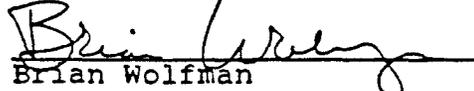
(C) Award plaintiff its costs and reasonable attorneys' fees pursuant to 5 U.S.C. § 552(a)(4)(e); and

(D) Grant all other appropriate relief.

Respectfully submitted,



Lucinda A. Sikes
D.C. Bar No. 431949



Brian Wolfman
D.C. Bar No. 427491

Public Citizen Litigation Group
2000 P Street, N.W.
Suite 700
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(202) 833-3000

Attorneys for Plaintiff

January 5, 1994

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN HEALTH)
 RESEARCH GROUP)
 2000 P St., N.W. Suite 700)
 Washington, D.C. 20036,)
)
 Plaintiff,)
)
 v.)
)
 FOOD AND DRUG ADMINISTRATION)
 5600 Fishers Lane)
 Rockville, Maryland 20857,)
)
 Defendant.)
)

HARRIS, J. SCH

Civil Action No. 94 0017

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 production of all records concerning pre-clinical and clinical studies involving the drug Fialuridine ("FIAU"). The clinical trials relating to FIAU were discontinued because of irreversible liver damage to the participants in the trial which resulted in the deaths of at least five patients.

2. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B).

3. Plaintiff Public Citizen Health Research Group is a non-profit consumer advocacy organization devoted to promoting consumer health and safety, and is the requester of the withheld records.

4. Defendant Food and Drug Administration ("FDA") is an agency of the United States, and it has possession of and control over the records that plaintiff seeks.

5. By letter dated July 12, 1993, plaintiff requested copies of all records concerning pre-clinical and clinical studies involving FIAU.

6. By letter dated August 20, 1993, defendant furnished plaintiff some basic information about FIAU, but failed to provide plaintiff with any of the studies he requested. On November 16, 1993, defendant provided plaintiff with a copy of an FDA report that purported to summarize some of the data plaintiff requested, but again did not provide plaintiff with any of the requested studies.

7. By letter dated November 17, 1993, plaintiff appealed defendant's denial of his request for access to the pre-clinical and clinical studies involving FIAU.

8. In a phone conversation on December 30, 1993, with plaintiff's counsel, Lucinda Sikes, Ms. Fanona Joyner of the Public Health Service's Freedom of Information Office acknowledged receipt of plaintiff's administrative appeal on November 30, 1993.

9. More than 20 working days have passed, defendant has not responded substantively to plaintiff's administrative appeal, and to date it has not indicated when a substantive response can be anticipated.

10. Plaintiff has a statutory right to the records it seeks, and there is no legal basis for defendant's refusal to disclose them.

WHEREFORE, plaintiff prays that this Court:

(A) Declare that defendant's withholding of the requested records is unlawful;

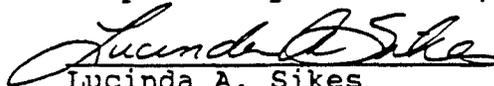
(B) Order defendant to make the requested records available to plaintiff;

(C) Award plaintiff its costs and reasonable attorneys' fees

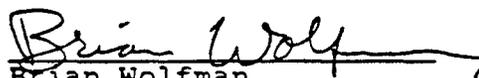
pursuant to 5 U.S.C. § 552(a)(4)(e); and

(D) Grant all other appropriate relief.

Respectfully submitted,



Lucinda A. Sikes
D.C. Bar No. 431949



Brian Wolfman
D.C. Bar No. 427491

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