

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.)

94 0169

Civil Action No. FEB 1 1994

JOHNSON, J. NHJ

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 distributed by the Food and Drug Administration ("FDA") to its advisory committees in preparation for the advisory committees' discussion on Oralet (transmucosal fentanyl). Oralet is a lollipop containing a potent narcotic called fentanyl, and was recently approved by the FDA as a premedication for children who are about to undergo anesthesia.

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 January 5, 1994, plaintiff requested copies of all records distributed by FDA to its Anesthetic and Life

Support Advisory Committee and its Drug Abuse Advisory Committee in preparation for the August 24, 1993 advisory committees' discussion on Oralet.

6. More than ten working days have passed since the FDA received plaintiff's letter, defendant has not responded to plaintiff's FOIA request, and to date it has not indicated when a substantive response can be anticipated.

7. 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:

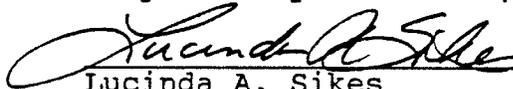
(A) Declare that defendant's withholding of the requested records is unlawful;

(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

Public Citizen Litigation Group
2000 P Street, N.W., Suite 700
Washington, D.C. 20036
(202) 833-3000

Attorneys for Plaintiff

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