IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SIDNEY M. WOLFE, M.D., 1833 Mintwood Street, N.W. Washington, D.C. 20009 Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane Rockville, Maryland 20857 Defendant.	)	Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Introduction

1. In this action, filed under the Federal Advisory Committee Act, 5 U.S.C. App. 2, and the Administrative Procedure Act, 5 U.S.C. § 706, plaintiff Sidney M. Wolfe, M.D., the Director of Public Citizen's Health Research Group, challenges a determination by the United States Food and Drug Administration (FDA) to close a meeting of its Blood Products Advisory Committee, scheduled for this coming Friday, July 14, 2006. Dr. Wolfe has been informed that, on that date, the advisory committee is scheduled to discuss a United States Navy proposal for testing a blood substitute product in civilian trauma patients. The FDA has stated that it decided to close the meeting to prevent the public disclosure of supposedly confidential commercial information or trade secrets. However, Dr. Wolfe has learned that the private, for-profit company that makes the blood substitute, Biopure Corp., considers little if any of the information that likely will be

discussed at the meeting to be confidential commercial information or a trade secret. Because the FDA's decision to close the July 14, 2006 meeting violates the Federal Advisory Committee Act and the Administrative Procedure Act, Dr. Wolfe is entitled to an immediate order either requiring the FDA to open the meeting to the public, or prohibiting the FDA from holding the meeting unless it is opened to the public, and declaring the FDA's closure decision unlawful.

Jurisdiction

2. This Court has jurisdiction under 28 U.S.C. § 1331.

Parties

3. Plaintiff Sidney M. Wolfe is a citizen and resident of the District of Columbia. Dr. Wolfe is the founder and director of Public Citizen Health Research Group (HRG), a division of the national advocacy group Public Citizen. Dr. Wolfe and HRG have a longstanding interest in the safety and efficacy of prescription drugs, medical devices, and blood products, such as the substitute blood product that will be discussed at the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee. Dr. Wolfe has an interest in the safe and efficacious development of blood substitute products, and he wants access to information concerning the testing of such products, including protocols for obtaining the informed consent of patients who are to be tested with such products. Dr. Wolfe intends to attend the July 14, 2006 meeting, but will not be able to do so as things now stand because of the FDA's determination that the meeting be closed. Dr. Wolfe is injured by that determination. An immediate order of this Court either requiring the FDA to open the July 14 meeting to the public, or prohibiting the FDA from holding the meeting unless it is open to the public, and declaring the FDA's closure determination unlawful, would redress Dr. Wolfe's injury.

4. Defendant FDA is an executive branch agency of the United States government. The FDA made the determination that the July 14, 2006 meeting of its Blood Products Advisory Committee should be closed to the public.

The Federal Advisory Committee Act

5. The Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, governs the terms and conditions under which committees, boards, commissions, and similar groups provide advice to officers and agencies of the executive branch of the United States government. *See* FACA, § 2 (congressional findings).

6. Under FACA, § 10(a), every meeting of an advisory committee "shall be open to the public," unless, under FACA, § 10(d), the President or the head of the agency to which the advisory committee reports determines that a "portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination."

7. Subsection (c) of section 552b of title 5 of the United States Code is the section of the Government in the Sunshine Act that sets forth the exceptions to that Act's general requirement that meetings of certain federal agencies be open to the public. In particular, 5 U.S.C. § 552b(c)(4) permits the closure of a portion of a meeting if the agency properly determines that holding that portion of the meeting in public "is likely to . . . disclose trade secrets and commercial or financial information obtained from a person and privileged and confidential[.]"

Facts Relevant to the FDA's Closure of the July 14, 2006 Advisory Committee Meeting

8. The FDA's Blood Products Advisory Committee is an advisory committee within the meaning of FACA, § 3(2), and, therefore, is subject to FACA's requirements, including the open-

meeting requirements of FACA, § 10.

9. On June 28, 2006, the FDA published a notice in the *Federal Register* announcing that a meeting of its Blood Products Advisory Committee would be held in Gaithersburg, Maryland on July 13, 2006, from 8 am to 4:30 pm, and on July 14, 2006, from 8 am to 3:30 pm. *See* 71 Fed. Reg. 36813 (June 28, 2006). The notice states in detail particular topics to be discussed on July 13, and notes that, with the exception of one small portion, the July 13 meeting will be open to the public. *See id.* at 36812, col. 1 - col. 2. However, with respect to the meeting on July 14, the notice states that the *entire* day's meeting "will be closed [to the public] to permit discussion and review of trade secret/and or confidential information (5 U.S.C. 552b(c)(4))." *Id.* at 36813, col. 2. Moreover, neither the *Federal Register* notice nor any other official FDA announcement of which plaintiff is aware makes any mention of the topic or topics to be discussed at the July 14, 2006 advisory committee meeting or provides any further explanation about why the FDA decided to close the July 14, 2006 meeting in its entirety.

10. After the issuance of the June 28, 2006 *Federal Register* notice, Dr. Wolfe learned that the topics to be discussed at the July 14, 2006 advisory committee meeting were the safety and efficacy of a blood substitute product and/or the protocol for testing that product on civilian trauma patients to be conducted by the United States Navy. Because of Dr. Wolfe's interest in the safety and efficacy of such blood substitute products and the protocols for testing such products, Dr. Wolfe decided that he would attend the July 14 meeting if permitted to do so.

11. The FDA's basis for closing the July 14, 2006 — that the meeting would likely involve discussion of trade secrets or confidential commercial information — has no basis in law or fact. The blood substitute product to be discussed at the meeting has been developed for

commercial distribution by Biopure Corp. Biopure Corp. has informed Dr. Wolfe that little if any of the information likely to be discussed at the July 14, 2006 meeting involves Biopure's confidential commercial information or a trade secret.

Claims for Relief

12. The FDA's determination to close the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee is final agency action under 5 U.S.C. § 704, and that determination violates FACA, § 10(a) and is arbitrary, capricious, and not in accordance with law under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

13. The June 28, 2006 *Federal Register* notice announcing the closure of the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee violated FACA, § 10(d) because it did not adequately provide the reasons for the closure. As a result, the FDA's determination to close the meeting cannot lawfully be implemented because the FDA has, in attempting to carry out that closure, failed to observe procedure required by law under the Administrative Procedure Act, 5 U.S.C. § 706(2)(D).

14. Assuming that there is a lawful basis for closing one or more portions of the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee, the FDA's decision to close the meeting for the entire day of July 14 violates FACA, § 10(a) and is arbitrary, capricious, and not in accordance with law under the Administrative Procedure, 5 U.S.C. § 706(2).

* * *

Therefore, plaintiff requests the following relief:

A. A declaration that the FDA's decision to close the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee is unlawful for the reasons set forth above;

B. A temporary restraining order, preliminary injunction, and/or permanent injunction either ordering the FDA to open the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee to the public or prohibiting the FDA from holding the meeting until it is opened to the public;

C. An award of reasonable costs, expenses, and attorney's fees under 28 U.S.C. § 2412; and

D. All other appropriate relief.

Respectfully submitted,

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