IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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| SIDNEY M. WOLFE, M.D., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civil Action No. |
| | ) | |
| UNITED STATES FOOD AND DRUG ADMINISTRATION, | ) | |
| | ) | |
| | ) | |
| Defendant. | ) | |
| | ) | |

**PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF HIS MOTION FOR A TEMPORARY RESTRAINING ORDER**

This case involves an agency's closure of a federal advisory committee meeting with no specific reasoning or announcement of what the meeting will discuss. On June 28, 2006, the Food and Drug Administration (FDA) placed a notice in the Federal Register announcing that the Blood Products Advisory Committee will be meeting on July 13 and July 14, 2006. 71 Fed. Reg. 36813 (June 28, 2006). The agency announced that the meeting on July 13 would be mostly open to the public and set forth a list of topics that would be discussed on that day. With regard to the meeting on July 14, however, the agency made no mention at all of the topics to be considered. Instead, it simply declared that the entire July 14 meeting would be closed "to permit discussion and review of trade secret and/or confidential information."

Newspaper articles have revealed that the topic to be considered at the July 14 meeting is a Navy proposal to test a blood substitute, Hemopure, in civilian trauma patients. *See Biopure Moves to Sell Blood Substitute in Europe*, Wall St. J., July 12, 2006, at D2; *FDA to Weigh Test of Blood Substitute Out of Public View*, Wall St. J., July 11, 2006, at D3. Under the proposal, some

trauma patients taken to the hospital in an ambulance would receive in transit a blood substitute instead of blood from a donor, without generally being asked for consent. *Id*. Studies have shown that patients who receive Hemopure have a higher rate of strokes, hypertension, fluid in the lungs, and heart failure than patients who get donor blood. *Biopure Moves to Sell Blood Substitute in Europe*, Wall St. J., July 12, 2006, at D2. Although, in the past, the FDA has repeatedly rejected the Navy's proposal to test Hemopure, it has permitted nonconsent trials of another blood substitute. *FDA to Weigh Test of Blood Substitute Out of Public View*, Wall St. J., July 11, 2006, at D3.

Plaintiff Sidney M. Wolfe, founder and director of Public Citizen Health Research Group (HRG), has a longstanding interest in the safety and efficacy of prescription drugs, medical devices, and blood products such as Hemopure. 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 wishes 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 entire meeting be closed. *See* Wolfe Declaration, ¶¶ 1, 4, attached.

Biopure Corporation, the manufacturer of Hemopure, has informed Dr. Wolfe that it expects that little, if any, of the presentations or discussions at the July 14 meeting are likely to involve information it considers a trade secret or confidential commercial information. Id. ¶ 3. Nonetheless, the FDA has announced that the full day of the meeting will be closed. An immediate order of this Court requiring the FDA either to open the July 14 meeting to the public or not to hold the meeting until it is opened to the public is urgently needed to allow Dr. Wolfe

and others to attend the meeting.

## ARGUMENT

This court weighs four factors in determining whether to grant emergency injunctive relief: 1) the plaintiff's likelihood of success on the merits; 2) the prospective irreparable harm to the plaintiff if relief is withheld; 3) potential harm to the other party if relief is granted; and 4) the interest of the public. *See CSX Transp., Inc. v. Williams*, 406 F.3d 667, 670 (D.C. Cir. 2005); *Apotex, Inc. v. FDA*, 2006 WL 10301, at *7 (D.D.C. April 19, 2006). Here, all four factors point toward opening the July 14 Blood Products Advisory Committee meeting to the public.

**1. Plaintiff is Likely to Succeed on the Merits.**

As a federal advisory committee, the FDA's Blood Products Advisory Committee is subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2. *See Blood Products Advisory Committee*, *Committee Charter*, www.fda.gov/cber/advisory/bp/bpchart.htm (noting that the committee is governed by the provisions of FACA). FACA requires advisory committee meetings to be "open to the public." 5 U.S.C. App. 2 § 10(a)(1). Portions of meetings can only be closed if the President or head of the agency to which the advisory committee reports determines that the portion of the meeting should be closed under one of the exemptions listed in the Government in the Sunshine Act, 5 U.S.C. § 552b(c). 5 U.S.C. App. 2 § 10(d). These exemptions must be narrowly construed. *Common Cause v. Nuclear Regulatory Comm'n*, 674 F.2d 921, 932 (D.C. Cir. 1982). Any determination that a meeting should be closed due to one of the exemptions must be made in writing "and shall contain the reasons for such determination." 5 U.S.C. App. 2 § 10(d). In determining whether one of the exemptions in the Sunshine Act justifies closing a portion of a meeting to the public, the burden of proof is on the government to

demonstrate that the exemption applies. *See Public Citizen v. National Economic Comm'n*, 703 F.Supp. 113, 117 (D.D.C. 1989); *Gates v. Schlesinger*, 366 F.Supp. 797, 800 (D.D.C. 1973).

Here, the only reasoning the FDA has provided for closing the July 14 meeting is that closure will permit discussion and review of trade secret and/or confidential information. Although the Sunshine Act permits portions of meetings to be closed if they would disclose trade secrets or confidential commercial information, *see* 5 U.S.C. § 552b(c)(4), the FDA has given no explanation of why allowing the public to attend the July 14 meeting would lead to the disclosure of such information. Indeed, although the agency's own regulations require that the Federal Register notice of the advisory committee meeting include the "nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting," 21 C.F.R. § 14.20, the FDA has not even mentioned what topics are going to be discussed at the meeting. Instead, it has just conclusorily asserted that it might discuss issues that are trade secrets and/or confidential information. Such conclusory assertions are insufficient for the agency to meet its burden of showing that the meeting should be closed. *See Public Citizen*, 703 F.Supp. at 119 (requiring agency to "demonstrat[e] specifically" the basis on which it seeks closure); *Nader v. Dunlop*, 370 F.Supp. 177, 179 (D.D.C. 1973) (stating that "defendants have not offered any specific reasons for closing the meetings" and requiring the meetings to be opened where the Federal Register notices had simply stated that if the discussions of the exchanges of opinions at the meeting were written, they would fall within Exemption 5 of 5 U.S.C. § 552(b)).

Moreover, not only has the FDA not met its burden of showing that the meeting should be closed, it is *unable* to meet that burden. The agency claims it is closing the July 14 meeting to permit disclosure of trade secret and/or confidential information. But Biopure Corporation, the

company whose product will be discussed at the meeting, has informed Dr. Wolfe that little, if any, of the meeting is likely to involve a discussion of information Biopure claims is confidential or a trade secret. For information to be a trade secret or confidential commercial information so as to justify closing a meeting to prevent its disclosure, it must, at the very least, be information the company wants kept secret. *See Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 872 (D.C. Cir 1992) (holding that information voluntarily submitted to an agency will be exempt under the trade secret exemption to the Freedom of Information Act if it is "of a kind that the provider would not customarily make available to the public"); *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983) (defining trade secret as a "*secret*, commercially valuable plan, formula, process or device that is used for the making, preparing, compounding of trade commodities . . .") (emphasis added).

In addition, even if closure of some portion of the July 14 meeting were necessary to prevent disclosure of trade secret or confidential commercial information, which is not the case, agencies can only close the *specific portions* of meetings that meet one of the exemptions in the Sunshine Act, and those portions can only be closed "on an individual and particularized basis." *Public Citizen*, 703 F.Supp. at 117 (quoting *Common Cause*, 674 F.2d at 936); *id*. at 119*; see also Gates*, 366 F.Supp. at 800 (noting that the Freedom of Information Act requires non-exempt portions of records to be disclosed and stating that "by like reasoning, the government should bear the burden of showing specifically that *all sessions* of an advisory committee meeting should be closed") (emphasis added). Any meeting on a proposal to perform non-consent trials of Hemopure on civilian trauma patients would clearly include discussions of many topics that would not even arguably lead to the disclosure of trade secret or confidential commercial

information: discussion of existing, publicly-available studies on the safety of the product, discussion of the possible uses of an effective blood substitute, discussion of the ethical considerations involved in testing products on non-consenting patients. Nonetheless, the agency has made no attempt to open those portions of the July 14 meeting in which trade secret and confidential commercial information will not be discussed.

Given that the FDA has provided no specific reasoning for its determination that the July 14 meeting should be closed to the public, let alone that all portions of that meeting require closure, Dr. Wolfe has a strong likelihood of success on the merits of the case.

**2. The Plaintiff and Public Interest Will Be Harmed if Relief Is Denied.**

If this court does not require the FDA to open the July 14 meeting to the public, both Dr. Wolfe and the public will be irreparably harmed. They will be denied "that which Congress expressly protected through FACA." *Public Citizen*, 703 F.Supp. at 129. "The right to view the advisory committee's discussion of policy matters in public and the right to confront, through observation, the decision-making process as it occurs, will be obviated." *Id*; *see also Ass'n of Am. Physicians and Surgeons, Inc. v. Clinton*, 813 F.Supp. 82 (D.D.C. 1993), *rev'd on other grounds*, 997 F.2d 898 (D.C. Cir. 1993) (finding irreparable injury standard met because FACA's goal, "to open – contemporaneously – to the light of public scrutiny the workings of advisory committees subject to FACA . . . cannot be met if the court does not enter a restraining order "). If the meeting is not opened, Dr. Wolfe will be denied the ability to attend the meeting and gain information about Hemopure, the Navy's proposal to test the product, and the establishment of protocols for obtaining the informed consent of patients who are to be tested with such products. In addition, Dr. Wolfe will not be able to participate in the open, public session of the meeting. In

turn, the public will be denied access to the information that Dr. Wolfe, were he to attend the meeting, would be able to disseminate to the public through HRG's websites, newsletters, and publications. *See*, *e.g.*, www.citizen.org/hrg; www.worstpills.org. On the other hand, if the meeting is opened, the public interest will be furthered both by the public's acquisition of information and by benefits that accrue when the public is able to monitor the activities of the government acting on its behalf.

In contrast to the injury Dr. Wolfe and the public will incur if the July 14 meeting is closed, the FDA and Blood Products Advisory Committee will suffer no harm if the meeting is opened. *See Gates*, 366 F.Supp. at 801 ("The Court finds no injury to Defendants in being obliged to conform to the open meeting requirement imposed by statute."). Opening the meeting to the public will not interfere with the Advisory Committee's activities and deliberations; the FDA itself has no trade secret or confidential commercial information that may be disclosed at the meeting; and the only company that conceivably has a confidential commercial interest in the topic of the meeting has no objections to at least most of the meeting being open. Balancing the agency's non-existent harm against the real harm Dr. Wolfe and the public will suffer if the meeting remains closed weighs heavily toward requiring the FDA to open the July 14 meeting.

## CONCLUSION

For the foregoing reasons, this Court should issue an immediate temporary restraining order ordering the FDA either to open the July 14, 2006 meeting of the FDA's Blood Products Advisory Committee to the public or not to hold the meeting until it is opened to the public.

Respectfully submitted,

s/_____
Adina H. Rosenbaum
D.C. Bar No. 490928

s/_____
Brian Wolfman
D.C. Bar No. 427491
Public Citizen Litigation Group
1600 20th Street, N.W.
Washington, D.C. 20009
(202) 588-1000

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