DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 19, 2012

Danielle Brian
Executive Director
Ned Feder, M.D.
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1100 G Street, N.W.
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Washington, D.C. 20005

Subject: Joint meeting of the Reproductive Health Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee held December 8, 2011

Dear Ms. Brian and Dr. Feder:

Thank you for your letter to Dr. Hamburg dated January 11, 2012, concerning the joint meeting referenced above. I have coordinated the review of your concerns within the agency and am responding on Dr. Hamburg's behalf.

You are concerned that several of the members participating in the December 8, 2011, advisory committee meeting on drospirenone had conflicts of interest that affected the committee's consideration of the questions before the committee. Based on our review of the members' reported interests, we did not identify any disqualifying financial interests that would have precluded their participation.

You request that FDA convene a new advisory committee to reevaluate the safety of drospirenone contraceptive products. This is not necessary. While FDA seriously considers the recommendations made by advisory committees, including the discussion and exchange that occurs among members and individual recommendations and suggestions made during the discussion, the agency engages in its own review of the scientific data (as well as the meeting materials, transcripts, information submitted to the dockets and, during the public portion of the meeting, any other relevant materials or comments). Although advisory committees provide recommendations to the agency, it is FDA that makes the final decisions.[1] In this case, FDA has concluded that drospirenone-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills, and has added information about this risk to

[1] 21 CFR 14.5(b).

the labeling of these products.[2] The agency will continue to closely monitor the safety of these drugs and take appropriate regulatory action as necessary.

You request that FDA draft guidelines that "include stronger requirements for public disclosure" of committee members' financial interests. Special government employee committee members report all relevant financial interests to FDA before every advisory committee meeting on FDA Form 3410. You argue for full disclosure of committee members' financial interests by posting online each completed Form 3410 before every committee meeting. However, the Ethics in Government Act and federal Privacy Act prohibit FDA from posting this form.[3]

FDA has made progress in increasing the transparency of its screening process for advisory committee members. Section 712(c) of the Federal Food, Drug, and Cosmetic Act requires that, notwithstanding the Ethics in Government Act, FDA disclose on its website the type, nature, and magnitude of the financial interests of each advisory committee member who has received a waiver under certain statutory provisions, as well as FDA's reasons for granting the waiver. The agency concluded that, under this directive, it is appropriate to disclose information regarding individuals receiving a waiver of conflict of interest prior to participating in an FDA advisory committee meeting. Accordingly, on March 9, 2012, FDA issued a guidance document entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers."[4] The guidance provides for disclosure of the name of the company or institution associated with a member's financial interest, the nature of the financial interest, and the magnitude of the financial interest. FDA's disclosures regarding financial interests and waivers are broader than those of many other Federal agencies.

You also recommend that the agency should have authority to take a range of disciplinary actions short of criminal prosecution in the event that an SGE does not accurately report financial interests. FDA, like other federal government agencies, has authority to initiate a range of appropriate corrective or disciplinary actions, including suspension and removal, for violations of the standards of ethical conduct for employees (including SGEs).[5] Consistent with our regulations, allegations concerning violations of the conflict of interest statutes or standards of ethical conduct regulations are referred to our Office of Internal Affairs or the HHS Office of Inspector General for investigation.[6]

Finally, you claim that "FDA appears not to be following the federal regulation (5 CFR 2635.502) regarding personal and business relationships" that create an appearance of a lack of impartiality. You further assert that under the federal regulation at 5 CFR 2635.502 past financial interests—not merely current financial interests—may preclude a committee member's

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[2] *See* Drug Safety Communication at http://www.fda.gov/Drugs/DrugSafety/ucm299305.htm.
[3] See 5 USC. app. 107(a)(2) and 5 USC 552a.
[4] http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm. This guidance finalizes the draft guidance of the same title dated March 2010 and replaces the guidance of the same title dated August 2008.
[5] See 5 CFR 2635.106; *see* Department of Health and Human Services *Human Resources Manual*, Instruction 752 (Discipline and Adverse Action) (Mar. 20, 2009), available at http://www.hhs.gov/ohr/manual/752.pdf.
[6] 21 CFR 19.21.

participation in a committee meeting. Under 5 CFR 2635.502, unless authorized to do so by FDA, a committee member may not participate in a particular matter involving specific parties where an entity with whom he has a "covered relationship" is or represents a party to the matter and that relationship would cause a reasonable person to question the member's impartiality. Under the regulations, a member has a covered relationship with, among others, any entity for whom the member served as an officer, director, consultant, or employee within the previous 12 months. FDA followed these regulations and agency guidance in carefully screening committee members for appearances of a lack of impartiality and concluded that committee member interests and relationships did not preclude their participation in the December 8, 2011, meeting.

We are currently reviewing our internal processes and evaluating whether additional clarification is warranted to help SGEs identify interests that may implicate these provisions and therefore should be reported.

As part of the ongoing agency wide transparency initiative, we continue to evaluate ways, within the parameters of existing laws and regulations, to increase the information available to the public concerning the operations of our advisory committees. Our efforts reflect a careful balancing of the importance of safeguarding the public trust in the advisory committee system and the importance of receiving sound advice from well-qualified external experts.

On behalf of FDA, I thank you for your interest in the integrity of the advisory committee process, and I look forward to your organization's continued support of our efforts to protect and promote public health.

Sincerely,

Jill Hartzler Warner, J.D.
Associate Commissioner for
Special Medical Programs (Acting)