PROJECT ON GOVERNMENT OVERSIGHT
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November 9, 2012

Jill Hartzler Warner, J.D.
Associate Commissioner for Special Medical Programs (Acting)
Office of Special Medical Programs
Food and Drug Administration
10993 New Hampshire Avenue
Silver Spring, MD 20993

Via email: jill.warner@fda.hhs.gov

Subject: Questions about your recent letter to the Project on Government Oversight

Dear Ms. Warner:

Thank you for your September 19 reply on behalf of Dr. Hamburg to our January 11 letter to her.[1] We are gratified that the FDA decided to strengthen the warning about the risks of Yaz, Yasmin, and other drospirenone-containing oral contraceptives. However, it is not well established that any of these drugs should be marketed with FDA approval, even with relabeling. We continue to believe that a new committee should be convened to advise the FDA on this important public health issue.

You discuss waivers at some length and note that the FDA makes publicly available certain financial information about committee members to whom it grants waivers. However, this point is one that we barely discussed and certainly did not contest in our January 11 letter to Dr. Hamburg. Instead, we argued that the public release of information about financial arrangements should apply to all advisory committee members, not just those with waivers.

No disqualifying financial interests

At the beginning of your letter you write: "Based on our review of the members' reported interests, we did not identify any disqualifying financial interests that would have precluded their participation."

First, we note that the phrase "members' reported interests" refers to interests reported by the members themselves. However, you provide no indication that the FDA tried to verify the accuracy and completeness of the information provided by the members. Has the FDA tried to verify—either before or since the committee meeting—the accuracy and completeness of the information provided on the form FDA 3410 by members of the advisory committee that met on December 8, 2011?

[1] Letter to Margaret Hamburg, Food and Drug Administration, from Danielle Brian and Ned Feder, Project On Government Oversight. January 11, 2012. http://www.pogo.org/pogo-files/letters/public-health/ph-fda-20120111-pogo-letter-fda-advisors.html (Downloaded November 8, 2012). Letter to Danielle Brian and Ned Feder, Project On Government Oversight, from Jill Hartzler Warner, Food and Drug Administration. September 19, 2012. http://www.pogoarchives.org/m/ph/fda/warner-to-pogo-20120919.pdf (Downloaded November 8, 2012)

Furthermore, you indicated that FDA officials "did not identify any disqualifying interests that would have precluded the members' participation." It's obvious that an advisory committee member could not have participated if the FDA had found, before the meeting, any disqualifying financial interests that would have precluded that member's participation.

Conspicuously omitted from your letter is a related statement—that on reconsideration of the members' interests described in detail in our letter of January 12 to Dr. Hamburg, you and other FDA officials *continue to believe* that there were no financial interests that were disqualifying. Specifically, after examining our letter, did you and your colleagues conclude that, at the time of the committee meeting, the members' interests described in our letter created conflicts of interest, or did you conclude that these interests did not create such conflicts?

Even if the financial interests of advisory committee members are not disqualifying (in the opinion of FDA officials), there is a strong case for disclosing those interests publicly in order to help reassure the public about the objectivity of committee members. Repeatedly, for at least a decade, the financial arrangements of some advisory committee members, reported in the press, have created doubts about these committee members' objectivity. The doubts are bound to be strengthened if the financial arrangements are kept confidential within the FDA for those not granted waivers, who are the great majority of committee members.

Disqualifying financial interests in the past (within the preceding 12 months)

In your letter, you write about a 12-month period of coverage for relationships:

> 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.

In looking for further information on this point, we noted that the FDA's guidance document of March 2007 includes a detailed comment on the subject of previous financial interests:

> Although financial interests that are not currently held do not constitute a conflict of interest under 18 U.S.C. 208, we believe that the public may perceive some previously held financial interests in organizations potentially affected by advisory committee recommendations as problematic. Accordingly, *we intend to implement* a policy of generally limiting participation when a member has a financial interest within the preceding twelve months that would be a disqualifying financial interest if it were currently held, even though full participation would be permitted under 18 U.S.C. 208.[2] (Emphasis added)

This passage in the March 2007 guidance document seems to confirm your statement quoted above. However, this apparent confirmation is undermined by the FDA's next guidance document, dated August 2008.[3]

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[2] Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees. U.S. Department of Health and Human Services, Food and Drug Administration. March 2007. http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0101-gdl0001.pdf (Downloaded November 8, 2012)

[3] Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees. U.S. Department of Health and Human Services, Food and Drug Administration. August 2008. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf (Downloaded November 8, 2012)

Nowhere in the August 2008 guidance document is there any indication of a "policy of generally limiting participation when a member has a financial interest within the preceding twelve months that would be a disqualifying financial interest if it were currently held" (as stated in the guidance document of March 2007). Furthermore, the August 2008 guidance document appears to be the definitive document; it contains a boxed statement on page 2: "This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic," namely, the topic of procedures for determining conflict of interest and eligibility for participation in advisory committees.

The explicitly stated intent of the March 2007 guidance document was evidently set aside during the transition to the final guidance document of August 2008. The latter document, which the FDA describes as representing its current thinking, fails to confirm your statement, quoted above, on the subject of covered relationships within the previous 12 months.[4]

We request that you provide us with a clarification of this important point.

Laws that prohibit public release of information

You state that "the Ethics in Government Act and federal Privacy Act prohibit FDA from posting this form," i.e., the 3410 form. Similarly, in the next-to-last paragraph of your letter, you state that FDA officials continue to evaluate ways "within the parameters of existing laws and regulations" to increase the information available to the public about the operations of the FDA's advisory committees.

There may well be legal barriers to the public release of the form FDA 3410. If so, these barriers need not be the final word on fuller disclosure. There are two alternative steps that FDA officials could take in order to greatly improve the current level of disclosure.

Encourage voluntary disclosure by committee members. This alternative may legitimately and ethically allow the public disclosure of important information, while not violating the Ethics in Government Act or the federal Privacy Act. As you and others at the FDA are well aware, many experts in the medical

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[4] Form FDA 3410 requests information from committee members on their present and past financial arrangements. However, it is the guidance documents, regulations, and laws that determine how the FDA uses this information to decide on financial conflicts of interest and eligibility for participation in advisory committees. The August 2008 guidance document refers (on page 18) to a 12-month period and a one-year period, but these periods are cited in order to allow FDA staff to calculate the value of *future* financial interests.

There is no reference in the August 2008 guidance to a financial interest within the preceding 12 months that would be a disqualifying financial interest if it were currently held. Furthermore, the March 2012 guidance document (cited below) refers in footnote 6 to a regulation (5 CFR 2635.502) that contains phrases similar to those quoted above from your letter of September 19. The full footnote of this guidance document states:

> In addition, FDA screens advisory committee members broadly for covered relationships that could present even the appearance that they have conflicts of interest that could affect their impartiality. *See* 5 CFR 2635.502. This guidance does not address this screening process.

Because of this statement (with the phrase "does not address"), the March 2012 guidance document does not throw light on whether a financial interest within the 12 months preceding an advisory committee meeting would be a disqualifying financial interest if it were currently held.

The March 2012 guidance document is posted on the FDA website. Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers. U.S. Department of Health and Human Services, Food and Drug Administration. March 2012. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM295372.pdf (Downloaded November 8, 2012)

and scientific community have reached a useful accommodation with the journals that publish their research. The authors of research papers and other communications must disclose their financial interests to the journal editors at the time of submission. For many of the leading journals, that same information about financial interests is disclosed to the public when the paper is published. That is how we learned about some of the possible conflicts of interest that we discussed in our letter to Dr. Hamburg. Many of the experts sought by the FDA have accepted, and some have welcomed, the journals' requirements for public disclosure. Furthermore, some academic institutions require disclosure of their faculty members' financial interests on the institutional websites. The number of institutions with this requirement is growing.

All advisory committee members who are SGEs are now required to submit the confidential 3410 form. However, some of these members, while complying with the requirement to file the 3410 form, may welcome the idea of voluntary and full public disclosure of their current and past financial arrangements. The FDA—while continuing to use the 3410 form exactly as it does now—could offer space on the FDA website to committee members who want to post documents in which they disclose their financial interests.

We believe the mood may be right in the medical and scientific community—at least for many members of advisory committees—for government-assisted voluntary public disclosure of private financial information. Based on your understanding of the trends toward greater financial disclosure in the medical and scientific community, would you favor this kind of action by the FDA—an action that requires no change in the use and confidentiality of the 3410 form?

Seeking a change in the limits imposed by the Ethics in Government Act and the Privacy Act. You undoubtedly know that the initiatives for new regulations for an agency often come from those within the agency, since they are closest to the work of the agency and best understand its problems and the public's needs. It's possible that you and other senior FDA officials believe that a requirement for fuller disclosure would be in the public interest, but that such a requirement is blocked by the Ethics in Government Act and the federal Privacy Act. If so, there are steps toward new regulations or laws that you could recommend to Dr. Hamburg so that she and Secretary Sebelius could pursue possible changes in the current constraints on disclosure. Would you favor this kind of action—first, by officials like you who advise Dr. Hamburg, and then by Dr. Hamburg and Secretary Sebelius?

We again thank you for your response to the letter we sent Dr. Hamburg. We await with interest your replies to our questions.

Sincerely,

Danielle Brian
Executive Director
dbrian@pogo.org

Ned Feder, M.D.
Staff Scientist
nfeder@pogo.org

cc: Commissioner Margaret Hamburg
Secretary Kathleen Sebelius