

Exposing Corruption *Exploring Solutions*
Project On **Government Oversight**

August 3, 2011

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
White Oak Building I
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via Email: Margaret.Hamburg@fda.hhs.gov

Dear Commissioner Hamburg:

The Project On Government Oversight is a nonpartisan independent watchdog that champions good government reforms. As such, we take a keen interest in the U.S. Food and Drug Administration (FDA), which receives around \$4 billion a year in federal taxpayer dollars to regulate aspects of almost 25 percent of the U.S. economy.

We are writing with concerns about Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the FDA. Dr. Woodcock has made comments in recent months that seem to support a loosening of the conflict-of-interest rules for scientists serving on FDA advisory panels. For several reasons, her statements do not seem to accurately portray the situation and appear to ignore relevant information.

The facts indicate that FDA is not having difficulty recruiting experts without conflicts of interest, that there are large numbers of qualified experts without industry ties, and that CDER appears to have significant leeway to issue waivers for researchers with financial conflicts. The current conflict-of-interest rules do not create an unreasonable burden and are not preventing the agency from getting expert advice.

- The number of conflict of interest waivers granted for FDA advisory members has never exceeded 5 percent, well below the legal cap of around 13 percent. (Attachment A)
- The vacancy percentage for CDER advisory members continues to fall, from 30 percent in 2009 to the mid-20s now. (Attachment B)

- Federally funded research gathered by Harvard University’s Dr. Eric Campbell, published in *Health Affairs*,¹ and presented in June at a Georgetown University conference finds that almost 50 percent of research academics have no ties to industry; approximately one-third of these researchers are full professors.
- A study in the *Archives of Internal Medicine*² surveyed participants who created clinical care guidelines for cardiology. These guidelines were published by the American College of Cardiology and the American Heart Association. Of those participants, 44 percent had no financial conflicts of interest.
- Two journalists published a list of nearly 100 medical experts with no corporate ties in the *British Medical Journal* in 2008.³

These rules do create an additional hurdle, but that is exactly the point: we want expert advice that is as free as possible from the influence of industry.

In light of this information, we are troubled that Dr. Woodcock is making public statements that it is difficult to find experienced, unconflicted experts to serve on FDA advisory panels. It also alarms us that, in a talk you gave last week at Public Citizen, you have repeated Dr. Woodcock’s misleading statements. According to *Bloomberg*, you said, “Patient-advocacy groups and academic researchers have expressed ‘valid concerns’ about the conflict-of-interest policy, prompting an agency rules review.”⁴ We would like to add that press accounts have found that patient advocacy groups,⁵ professional societies,⁶ and academic physicians⁷ receive a great deal of funding from pharmaceutical groups. It is not surprising that those with conflicts of interest would argue for a loosening of the rules.

Last year, you raised concerns in a letter to FDA staff about the possibility for conflicted experts to undermine the public’s confidence in your agency. You wrote:

¹ Darren E. Zinner, et al., “Participation of academic scientists in relationships with industry,” *Health Affairs*, Vol. 28, Issue 6, November 1, 2009, pp. 1814-1825. <http://content.healthaffairs.org/content/28/6/1814.abstract> (Downloaded August 2, 2011) (hereinafter *Health Affairs* study)

² Todd B. Mendelson, et al., “Conflicts of Interest in Cardiovascular Clinical Practice Guidelines.” *Archives of Internal Medicine*, Vol. 171, No. 6, March 28, 2011, pp. 577-585. <http://www.bioethics.upenn.edu/documents/COICardio-ArchIntMed.pdf> (Downloaded August 2, 2011) (hereinafter *Archives of Internal Medicine* study)

³ Jeanne Lenzer and Shannon Brownlee, “Naming names: is there an (unbiased) doctor in the house?” *British Medical Journal*, 337:a930, July 23, 2008. <http://www.bmj.com/content/337/bmj.a930.full?ijkey=51VaCZNnRtCQvUz&keytype=ref> (Downloaded August 2, 2011) (hereinafter *British Medical Journal* study)

⁴ Jeffrey Young, “Conflict-of-Interest Rules May Be Relaxed in 2012, Hamburg Says,” *Bloomberg*, July 25, 2011. <http://www.bloomberg.com/news/2011-07-25/conflict-of-interest-rules-may-be-relaxed-in-2012-hamburg-says.html> (Downloaded August 2, 2011)

⁵ Gardiner Harris, “Drug Makers Are Advocacy Group’s Biggest Donors,” *The New York Times*, October 21, 2009. <http://www.nytimes.com/2009/10/22/health/22nami.html> (Downloaded August 2, 2011)

⁶ Charles Ornstein and Tracy Weber, “Financial Ties Bind Medical Societies to Drug and Device Makers,” *ProPublica*, May 5, 2011. <http://www.propublica.org/article/medical-societies-and-financial-ties-to-drug-and-device-makers-industry/single> (Downloaded August 2, 2011)

⁷ “Dollars for Doctors: How Industry Money Reaches Physicians,” *ProPublica*. <http://www.propublica.org/series/dollars-for-docs> (Downloaded August 2, 2011)

Conflict-of-interest waivers for scientific advisers have been controversial, however. If FDA is perceived to rely heavily on conflicted experts, then confidence in the agency's decision making can be undermined.

In my view, it is clearly better for the agency in fulfilling its public health mission when advisers have no conflicts of interest. FDA staff should search far and wide for experts who have the requisite knowledge without conflicts of interest.⁸

We agree wholeheartedly with these statements, and ask that you maintain FDA's high standards in this area. In the following pages we lay out our concerns in greater detail.

Dr. Woodcock's Statements and Evidence to the Contrary

At the Reuters Health Summit back in May, Dr. Woodcock told reporters, "There is no doubt it is difficult finding highly experienced people who do not have conflicts."⁹

Dr. Woodcock made a similar statement during a congressional hearing in early July. She responded to a question from Congressman John Shimkus (R-IL). He asked if she knew of cases where someone was disqualified from serving on an advisory committee because they worked on a clinical trial for an unrelated product, and if that caused a "time lag" in drug approval. Dr. Woodcock responded:

Yes, it is true. It is also true, we have difficulty recruiting qualified people and having highly qualified panels. And in some cases we've had to delay advisory committees because of difficulty—because once we go through in great detail all the financials of the individuals we've nominated, we find that they have to be excused from participating.¹⁰

We feel that these statements run contrary to FDA's own data on advisory committees and statements you made in a letter sent last year to FDA officials. In that letter, you wrote:

The law permits FDA to grant waivers for experts on its advisory committees. FDA may not exceed a cap set in the law on the number of waivers to be granted. For fiscal year 2010, this cap is set at about 13% of all advisory committee members participating in advisory committee meetings; we currently are granting waivers for less than 5%.¹¹

According to FDA's published data on waivers for this year, the Agency is still granting waivers below 5 percent, which is well below the 12.78 percent target. (Attachment A)

⁸ Letter from Dr. Margaret A. Hamburg, Commissioner, Food and Drug Administration, to FDA staff, "Commissioner's letter to FDA staff on disclosure of financial conflicts of interest," April 21, 2010.

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm209001.htm> (Downloaded August 2, 2011) (hereinafter Hamburg letter)

⁹ Lisa Richwine, "FDA official sees drug approvals rising," *Reuters*, May 9, 2011.

<http://www.reuters.com/article/2011/05/09/us-summit-fda-approvals-idUSTRE7485B120110509> (Downloaded August 2, 2011)

¹⁰ House Energy and Commerce Committee, "Hearing: PDUFA V: Medical Innovation, Jobs, and Patients," July 7, 2011.

<http://energycommerce.house.gov/hearings/hearingdetail.aspx?NewsID=8765> (Downloaded August 2, 2011)

¹¹ Hamburg letter

If FDA is not close to exceeding the cap for granting waivers (therefore has many non-conflicted experts) then why is Dr. Woodcock making statements to the contrary?

Furthermore, FDA's published data finds that the vacancy rate for advisory committees fell another 2 percent this year, and has fallen 10 percent overall, from 33 percent in 2009 to the present rate of 23 percent. (Attachment C) This indicates that FDA is having fewer problems finding experts without industry ties—maintaining the current rules and undermines Dr. Woodcock's argument.

According to a federally funded study of 2914 academics published in *Health Affairs*¹² and presented at Georgetown University in June, almost half of U.S. academic researchers have no relationship with industry. Around one-third of these researchers are full professors. Furthermore, a study published in the *Archives of Internal Medicine*¹³ surveyed hundreds of experts who helped create clinical care guidelines published by the American College of Cardiology and the American Heart Association. Forty-four percent of those participants had no financial conflicts.

Three years ago, journalists Jeanne Lenzer and Shannon Brownlee compiled a list of medical experts with no ties to industry. While some of these experts are former reporters, many have advanced degrees. Lenzer and Brownlee published their list in the *British Medical Journal* in 2008.¹⁴ If these two reporters are capable of finding experts without ties to industry, then why can't the FDA? We have attached that article along with the names for your perusal. (Attachment D)

The facts at this time do not support a loosening of the FDA's conflict of interest rules, despite Dr. Woodcock's statements to the contrary. If anything, the FDA should work harder to find unconflicted experts to serve on advisory committees. To gain the public trust, we must ensure that the FDA relies on the best available information for its policies, rather than personal opinions and biases.

I appreciate your review of this letter and the attached documents. If you have any questions, please do not hesitate to contact Paul Thacker at thacker@pogo.org or (202) 347-1122.

Sincerely,



Danielle Brian
Executive Director

Enclosures: 4

cc: Chair and Ranking Member, House Energy and Commerce Committee
Chair and Ranking Member, Senate Finance Committee
Chair and Ranking Member, Senate Aging Committee
Chair and Ranking Member, Senate HELP Committee
Public Citizen
Union of Concerned Scientists

¹² *Health Affairs* study

¹³ *Archives of Internal Medicine* study

¹⁴ *British Medical Journal* study