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Summary: Patients' health is put at risk when outside experts advising the FDA have private financial interests that are undisclosed to the public. We propose specific ways to start correcting the problem. In short: POGO to FDA on conflicts of interest: Disclose them!

Dear Dr. Hamburg:

In a letter to you three years ago we warned that decisions by the FDA on the marketing of new drugs and medical devices may be compromised by undisclosed conflicts of interest.

The FDA bases its approval of new drugs and medical devices in large part on recommendations by advisory panels that are composed of experts recruited from outside the agency.

Even the members of an advisory panel may be unaware of the questionable financial arrangements of other members of the same panel. After a meeting in 2010 on a controversial drug (Avandia), one panel member said he wished the FDA had disclosed that another member had been a paid speaker for the manufacturer of the drug. "I'm surprised we weren't told," he said, according to the *Wall Street Journal*.¹ Arthur Caplan, a medical ethicist not serving on the panel, said, "In the middle of a firestorm over a drug, all connections to the company involved should be disclosed."

The FDA is still struggling with this problem. A recent *Wall Street Journal* article (December 8, 2014) highlights the FDA's continuing lack of success. The headline:

FDA Advisers' Financial Ties Not Disclosed: Many Doctors Who Sit on Food and Drug Administration Panels Reviewing Medical Devices Have Links to Device Makers Undisclosed by the FDA

¹ The article, "Panelist Who Backed Avandia Gets Fees From Glaxo," by Alicia Mundy, was published July 20, 2010, by the *Wall Street Journal*. One of us (NF) discussed this episode in a Comment (FDA-2010-D-0094-0407) submitted to FDA's Division of Dockets Management on August 16, 2010 (posted [here](#) and [here](#)).

The article, by Joseph Walker, begins with one example among many:

David Kandzari, an Atlanta cardiologist, also has worked as a consultant to makers of medical devices. He received at least \$100,000 from them in five years, according to corporate and government data.

Another organization he works with, the Food and Drug Administration, doesn't appear to mind. In October, the FDA put Dr. Kandzari on a panel reviewing a medical device made by Boston Scientific Corp., one of the companies he has advised.

The FDA didn't disclose the connection.

As you know, members of the FDA's advisory panels are experts from outside the agency who are recruited to give the FDA advice on the safety and effectiveness of drugs and medical devices. The FDA usually follows the panel's advice—pro or con—by afterwards either approving or denying a manufacturer's request for permission to put its drug or device on the market.

Candidates for panel membership are required to notify the FDA about certain private financial interests. The FDA then evaluates this information when choosing the members of its advisory panels. However, for most panel members, the FDA does not disclose any of this information to the public.²

We believe that the nondisclosure of financial interests of panel members is a serious defect in the FDA's system for approving new drugs and devices.³

There are well-established ways to deal with financial conflicts of interest. Biomedical researchers who want to publish their findings in most of the world's top medical journals—in the *New England Journal of Medicine*, for example—must enter their financial information into a standard form. They send the completed form to the journal along with a draft of their article. When the journal publishes the article, it also posts the completed form online. Thus readers of

² The FDA is permitted by law to appoint a few advisory panel members who have financial conflicts of interest, if these members have unique or unusual expertise. The FDA grants these members a waiver that lets them serve on the panel, despite the conflicts. Panel members with a waiver must allow the FDA to publicly disclose some of their financial interests. However, these members are in the distinct minority. More than 98 percent of all panel members serve without a waiver and without public disclosure of their financial interests.

³ There is a wide range of opinion on the harm caused by financial conflicts of interest. There is also a lack of agreement on the value of public disclosure in mitigating this harm. We believe that the public would benefit from a high level of transparency in the FDA's handling of information about panel members' finances.

the article can decide for themselves whether the authors' private financial interests may have compromised their objectivity. Readers can then take this possibility into account when judging reliability of the research and its conclusions.⁴

We wrote you previously about undisclosed financial interests in our [letter](#) of January 2012. Your associate, Jill Hartzler Warner, sent us a [reply](#), but her reply avoided some important issues. Her omissions were surprising, as we pointed out in detail in a [letter to her](#). Later we met with her, but the meeting did not resolve the central issue: the FDA's policy of nondisclosure of panel members' financial interests. As is apparent from the recent *Wall Street Journal* article, the policy of nondisclosure is as much of a problem today as it was three years ago.

How can the current FDA policy of nondisclosure be changed? At present, before the meetings of an advisory panel, all candidates must provide the FDA with a formal statement of information about their finances. The candidates fill out a standard government form—the [FDA 3410 form](#) is the one most commonly used—and send it to the FDA.

The FDA keeps the contents of the completed 3410 forms completely confidential. Officials in the FDA evaluate the forms behind closed doors. The information in the forms is not disclosed to the public and is not available under the Freedom of Information Act. The information in a panel member's 3410 form is not disclosed to the other members of the same panel.

In our previous letter to you we proposed, and indeed urged, that the FDA make public the contents of the 3410 forms of advisory panel members. We continue to believe that it would be in the public interest to disclose this information.

We suggested two ways to proceed. The first is a simple, direct, voluntary disclosure of information in the FDA 3410 form. We believe the mood may be right in the medical and scientific community for the voluntary public disclosure of this information.

⁴ The standard form, *ICMJE Form for Disclosure of Potential Conflicts of Interest* (posted [here](#)), is worth examining.

Authors about to submit an article to one of the participating journals are told in the ICMJE form that the information they provide is for the edification of readers: "The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work." Authors are asked about financial relationship "in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work." (The word "ANY" is capitalized in the form.) Authors are also asked to report relationships, other than financial relationships, "that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work."

It seems to us that biomedical scientists who routinely make this information available to the public would not object to and might welcome and authorize the public disclosure of similar information on a website provided by the FDA. We will return to this point later.

Public disclosure of financial interests is not a radical idea:

- o Some medical journals do it, as we noted above.
- o Some leading universities and medical schools require their faculty to disclose their financial interests publicly.
- o The National Institutes of Health has a public disclosure requirement for the many universities and medical schools that have NIH-funded investigators. Each of these institutions must either post the information about the financial interests of these investigators on its website or make the information available to anyone who requests it.
- o Under the Physician Payment Sunshine Act passed in 2010, data on certain payments (for example, consulting fees paid by drug companies to physicians) must be submitted to the Department of Health and Human Services for disclosure in a searchable public database.

The disclosures listed above are not voluntary. We again propose that, as an experiment, you offer voluntary disclosure to members of FDA advisory panels—many of whom have already made this information public in one or more of the ways listed above. We believe that many panel members would therefore welcome an offer by the FDA to publicly release the information in the 3410 form.⁵ The FDA could do this by publishing on its website the contents of the completed 3410 forms—for example, by posting a photocopy of the completed forms of panel members who grant the agency permission to do this.⁶

There is another, more difficult way that might enable the FDA to disclose the financial information of advisory panel members. In her letter of September 2012 to us, Ms. Warner stated that the Ethics in Government Act and federal Privacy Act prohibit FDA from posting the 3410 form. In our reply we described a specific way to start dealing with this objection. We wrote:

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. . . .

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 Sibelius⁷ could pursue possible changes in the current constraints on disclosure. . . .

⁵ Under this voluntary arrangement, the FDA's decision to appoint an expert to an advisory panel would be independent of that expert's decision to permit or not permit posting of the 3410 form.

⁶ The contents of the posted forms might be made subject to redactions based on the same exclusions as those in the Freedom of Information Act.

⁷ When we wrote to Ms. Warner in September 2012, Kathleen Sebelius was Secretary of Health and Human Services. Since then she has been replaced as Secretary by Sylvia Mathews Burwell.

Conclusion

We urge you to consider a reversal of the current policy of the FDA—the policy of withholding from the public the financial information it receives (in their 3410 forms) from members of advisory panels. You might begin by asking your FDA colleagues and interested parties outside the FDA for their views on reversing the agency's current policy.

The *Wall Street Journal*'s well-documented article raises troubling concerns about the possible bias of those panel members who have financial ties to the industry whose products they are judging. Having read the article, you and other FDA leaders must surely be less confident that your agency is making the right decisions when the decisions by the FDA are based in large part on the advice of these panels.

We look forward to your response.

Sincerely,



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