

FDA Draft Guidance, Docket No. 2007D-0101

TITLE OF THIS COMMENT: Lack of transparency under proposed new rules

According to this draft guidance document, the FDA plans to introduce new rules implementing a “more stringent approach for considering eligibility for participation in FDA advisory committee meetings.” The purpose is to “increase the transparency . . . of the process” and “enhance public trust in this important function.”

Transparency is proclaimed as a goal under the proposed new rules, but in fact a lack of transparency will continue. Writing as a member of the Project on Government Oversight (POGO), I propose here a simple way to help correct this deficiency.

At present, when the advisory committees are chosen, the FDA officials making the choice receive detailed information about the finances of each prospective member of advisory committees. The information is provided by the prospective members themselves on a Form FDA 3410 (Confidential Disclosure Report for Special Government Employees).

Although the information in this form is known to FDA officials, it is censored before it is disclosed to the public. (The disclosure is ordinarily made verbally at advisory committee meetings and through documents related to waivers.) Thus at present, the financial arrangements made by advisory committee members may be known in detail to FDA officials inside their private offices, but the details are not disclosed to members of the public.

This means that members of the public, the press, or Congress, who may be suspicious about conflicts of interest that are not fully disclosed, cannot easily verify in detail whether FDA officials have acted reasonably in choosing advisory committee members and granting waivers. Events at the FDA over the past few years provide good reason for suspicion.

The solution is a simple two-step process. First, each prospective member of an FDA advisory committee should be asked to authorize the public release of all the information on his or her completed Form FDA 3410. (Those who do not grant permission would be excluded from membership on the committees.) Next, the FDA should release to the public all the information provided on the form. Probably the simplest way to do this would be to post copies of each completed Form FDA 3410 on the Internet. That would be real transparency – full public disclosure.

Full public disclosure of financial arrangements is now accepted widely as a requirement of public office for members of Congress and judges, as well as presidential appointees and some high-ranking decision makers in the Executive Branch. Members of the FDA’s advisory committees should not be exempt from this practice.

I urge that the new rules, when enacted, include the change in disclosure procedures recommended here. One point is worth noting. Prospective members have been asked for several years to authorize disclosure of information – but only some of the information – that they provide on Form FDA 3410. Under the change I suggest, prospective members would simply be asked to broaden the extent of their authorization. What is the objection to doing this?

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