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FDA Advisory Committee Conflict of Interest

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January 2, 2009

Abstract. On September 27, 2007, a comprehensive law reauthorizing existing Food and Drug Administration (FDA) programs and expanding the agency's authority to ensure the safety of prescription drugs, medical devices, and biologics was signed into law: the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85; H.R. 3580). FDAAA Title VII focused on the topic of conflicts of interest. It was added following some negative publicity about the FDA's process for addressing conflicts of interest within its advisory committees. FDAAA requires changes in the way that FDA recruits and vets advisory committee members, and in the circumstances under which conflict of interest exceptions may be granted. This report details FDA's new policies for addressing conflicts of interest in its advisory committees.

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Summary

On September 27, 2007, a comprehensive law reauthorizing existing Food and Drug Administration (FDA) programs and expanding the agency's authority to ensure the safety of prescription drugs, medical devices, and biologics was signed into law: the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85; H.R. 3580). FDAAA Title VII focused on the topic of conflicts of interest. It was added following some negative publicity about the FDA's process for addressing conflicts of interest within its advisory committees. FDAAA requires changes in the way that FDA recruits and vets advisory committee members, and in the circumstances under which conflict of interest exceptions may be granted.

This report details FDA's new policies for addressing conflicts of interest in its advisory committees. It will be updated as necessary.

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Background

The Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), regulates the safety of foods, and the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices. In order to help inform its activities, FDA solicits input from advisory committees, which make recommendations on specific regulatory actions that the agency is contemplating.[1] Typically, the FDA Commissioner follows those recommendations, but may choose to disregard them.

To be most credible and useful, many say that committees need to minimize the possibility of, or be free from conflicts of interest. However, others note that the most expert people in the field are often those involved directly or indirectly in the activities about which FDA is seeking advice, creating the potential for such conflicts. In 2006 and 2007, the media reported that FDA advisory committees were biased in favor of drug approval, and that many committee members had conflicts of interest.[2]

General Requirements for Federal Advisory Bodies

FDA's process for establishing and administering its advisory committees is rooted in several sets of laws and regulations, the requirements of all of which are binding on the agency. The general processes for establishing, operating, overseeing, and terminating governmental advisory bodies—including FDA advisory committees—are laid out in the *Federal Advisory Committee Act* (5 U.S.C. Appendix; FACA).[3] A requirement that committee members file a report disclosing a broad range of potential conflicts of interest is based upon the *Ethics in Government Act of 1978* (5 U.S.C. Appendix; EGA). The scope of permissible actions for government employees—including advisory committee members—in matters in which they have a financial interest is spelled out in *Acts Affecting Personal Financial Interest* (18 U.S.C. 208; AAPFI).

New Requirements under FDAAA

Congress enacted a major FDA law, reauthorizing expiring FDA user fee authorities and enhancing the agency's ability to ensure drug, device and biological product safety: the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85). FDAAA Title VII, entitled *Conflicts of Interest*, changed the law governing FDA's treatment of conflicts of interest in its advisory committees. (21 U.S.C. 371 et seq.)[4] It contains numerous requirements to minimize conflicts of interest among FDA advisory committee members, and applies to all FACA committees that advise the HHS Secretary on matters for the FDA.[5] The following summarizes FDA's new advisory board policies in the wake of FDAAA.

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[1] Linda Ann Sherman, "Looking Through a Window of the Food and Drug Administration: FDA's Advisory Committee System," *Preclinica*, vol. 2 no. 2, p. 99 (March/April 2004), at http://www.preclinica.com/pdf/articles/sherman_2-2.pdf.

[2] For example, see "Public Citizen Exposes Frequent Financial Conflicts of Interest at FDA Advisory Committee Meetings," Public Citizen website (April 25, 2006), at http://www.citizen.org/pressroom/release.cfm?ID=2184.

[3] For more information, see CRS Report RL30260, *Federal Advisory Committees: A Primer*, by Stephanie Smith.

[4] Federal Food, Drug and Cosmetic Act, §712.

[5] FDAAA supplanted the conflict of interest provisions in the law governing FDA scientific advisory panels related to (continued...)

Recruitment

The FDAAA requires advisory committee member recruitment mechanisms to focus on reaching experts from academia, professional and medical societies, and patient and consumer groups. The HHS Secretary is required to develop outreach strategies to recruit from these sectors, and to seek input and advice from professional and medical societies with respect to recruitment. Recruitment activities may include advertising at conferences, electronic communications, and outreach to entities receiving federal grant funding.

Financial Interest Defined

In its definition of *financial interest*, the FDAAA refers to the AAPFI. AAFPI §208(a) defines the term to include activities such as a person's or their family members' current or future employment, trusteeship, or directorship. On its face, it does not apply to activities such as stock ownership, former employment, or receipt of a grant or contract. However, the scope of disqualifying financial interests under AAPFI have been interpreted broadly in regulation. Regulations include any potential for gain or loss to the employee, which would include interests such as stock ownership, for example (5 C.F.R. 2640.103(b)).

Disclosure of Candidates' Interests

The EGA requires potential committee members to file a report specifying their potential conflicts (5 CFR § 2634.903(b)(3)). The FDAAA requires the Secretary to review the reports when considering a term appointment to an advisory committee. The review is to be conducted so as to reduce the likelihood that general rules will have to be excepted (via written determination, written certification, or waiver—see "Exceptions to Prohibitions" below).

The FDAAA also requires that, prior to an advisory committee meeting on a particular matter, each committee member disclose to the Secretary financial interests in accordance with AAPFI §208(b). Section 208(b) articulates various exceptions to the general prohibition against acting with a financial interest defined in 208(a).

Member Requirements and Prohibitions

Restrictions on committee participation and voting eligibility, as well as the potential for waivers and exemptions from the restrictions, are defined in two locations. One, the FDAAA, precludes a member from participating on a committee considering a particular matter in which the member or their immediate family has a financial interest that could be affected by the advice given to the Secretary.

The second law, AAFPI, applies broadly to government employees, including FDA advisory committee members. It generally imposes criminal penalties on any person participating in an advisory committee who has conflicts based on certain financial interests, such as current or future employment, or on a directorship role in an organization.

(...continued)

drugs and biologics. (21 U.S.C. 355(n)).

Exceptions to Prohibitions

There are two sources of exceptions to the FDA advisory committee membership financial interest prohibitions. One is AAFPI 208(b). As noted above, this section lists several exceptions to the financial interest restriction spelled out in 208(a). The FDAAA contains the second set of exceptions. It specifies two exceptions to the general prohibition. In addition, because the FDAAA uses the AAFPI 208(a) definition of financial interest, it incorporates the 208(b) exceptions to the definition. The following are the FDAAA and AAFPI exceptions:

- *Written determination that an interest is not substantial.* The AAFPI 208(b)(1) allows the government official responsible for a committee members' appointment to make, in advance of the meeting, a written determination that an interest is not so substantial as to be deemed likely to affect the integrity of the member's service. To facilitate this, a member is required to advise the government official responsible for his or her appointment of the nature of the particular matter and make full disclosure of the financial interest.
- *Written certification that the need for participation outweighs potential conflict.* The AAFPI 208(b)(3) provides that the official responsible for a committee member's appointment, after review of the EGA-required financial disclosure report, certify in writing that the need for the individual's services outweighs the potential for a conflict of interest.
- *Waiver for essential expertise.* The FDAAA enables the Secretary to grant a waiver to permit a member to participate despite a financial interst if that person's expertise is essential to the committee. The waiver may allow the person to participate as a voting or non-voting member.
- *Interest exempted as too remote*. One additional exception is contained within the FDAAA's general prohibition on waivers and participation. It permits participation by a person with an interest in a particular matter if the interest has been exempted in regulations issued by the Director of the Office of Government as too remote or inconsequential to affect the integrity of the member's services. This exemption is also articulated in AAFPI 208(b)(2).

Utilizing authority under this final exception (AAFPI 208(2)(b)(2)), the FDA Commissioner has issued a blanket regulation making exemptions for a category of interests as too remote:

> ... because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services (21 C.F.R. 14.80(2)).

In other words, an industry representative on an advisory committee is allowed to have a financial interest in that industry. This exemption was made prior to the enactment of the FDAAA, but should not be affected by the law.

Limitation on Exceptions

The FDAAA restricts the percentage of committees' membership that may consist of people having received one of three types of exceptions to the financial conflict prohibitions: (1) FDAAA waivers for essential expertise, (2) AAFPI written determinations, and (3) AAFPI written certifications. For FY2007, the Secretary was required to determine the number and proportion of advisory members who received exceptions. For FY2008 through FY2012, the Secretary must reduce the proportion of excepted members by an additional 5% per year from the FY2007 number. This limitation does not apply to financial interest exemptions made under 18 USC 208(b)(2), or the parallel provisions in the FDAAA.

Public Disclosure of Exceptions

The FDAAA requires public disclosures for conflict-of-interest determinations, certifications, and waivers (but not 208(b)(2) exemptions), except for those exempted from disclosure under the Freedom of Information Act of 1974 (5 USC 522). It requires the Secretary to submit annual reports regarding advisory committee membership, and conflict-of-interest waivers. It also requires the Secretary to review and update FDA conflict-of-interest guidance not less than once every five years.

FDA regulations that precede the FDAAA generally specify that the agency will make the fullest possible disclosure of records to the public, consistent with the privacy rights of individuals, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption (21 C.F.R. 20.20). FDA has articulated a policy of disclosing copies of AAFPI waiver determinations, except where a foreseeable harm would be caused by disclosure.[6]

FDA Actions Subsequent to the Passage of FDAAA

Following the passage of the FDAAA, the FDA took several actions to implement, and in some cases, exceed the terms of the FDAAA. According to the agency, its policies on advisory committees continue to be informed by new studies on conflicts of interest. FDA asked a consultant, Eastern Research Group, to study 16 recent advisory committees. The report highlighted the difficulty of assembling highly qualified experts who were free of conflicts, and found that those who had received waivers appeared to be significantly more qualified than those who had not received waivers.[7]

[6] "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," (January 2002), at http://www.fda.gov/oc/guidance/advisorycommittee.html.

[7] Nyssa Ackerley, John Eyraud, and Marisa Mazzotta, "Measuring Conflict of Interest in FDA Advisory Committees," Eastern Research Group, (October 26, 2007), at http://www.fda.gov/oc/advisory/ERGFDAAAreport.pdf.

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