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CRS Report for Congress

FDA Advisory Committee Conflict of Interest Reform Efforts in the 110th Congress

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Summary

Legislation to reauthorize the Food and Drug Administration's prescription drug and medical device user fee programs — the *Food and Drug Administration Revitalization Act* (S. 1082), and the *Food and Drug Administration Amendments Act of 2007* (H.R. 2900) — contains proposals to change the process of recruiting advisory committee members, as well as some circumstances under which and processes by which conflict of interest exceptions may be granted. Each of these bills has been passed by its respective chamber of Congress, leaving differences between them to be addressed in conference. This report will be updated as necessary.

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 has reported that FDA advisory committees are biased in favor of drug approval, and that many committee members have conflicts of interest.[2]

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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
(continued...)

Current Law

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). A second section of law, *Scientific Advisory Panels* (21 U.S.C. 355(n); SAP), applies specifically to members of FDA advisory committees on drugs and biologics, but not medical devices or food. It requires that each member of a drug or biologic advisory committee publicly disclose all conflicts of interest that he or she may have with the work to be undertaken by the panel.

Restrictions on committee participation and voting eligibility, as well as the potential for waivers and exemptions from the restrictions, are articulated in two locations. One, the SAP, precludes a member from voting on any matter where the member or the immediate family of such member could gain financially from the advice given to the HHS Secretary. The SAP permits the Secretary to grant a *waiver*, upon public disclosure of the conflict of interest, if the waiver is necessary to afford the panel essential expertise. The Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

The second law, *Acts Affecting Personal Financial Interest* (18 U.S.C. 208; AAPFI), 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. The scope of disqualifying financial interests under AAPFI have been interpreted broadly in regulation to 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)).

According to 18 U.S.C. 208(b), *waivers* of the AAPFI requirements are available from the government official responsible for appointing the committee member if the official either: (1) makes a written determination that the interest is not so substantial as to be deemed likely to affect the integrity of the government service; or (2) certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest. FDA regulations 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).

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[2] (...continued)
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.

FDA has articulated a policy of disclosing copies of AAFPI waiver determinations, except where a foreseeable harm would be caused by disclosure.[4]

Section 208 also allows for *exemptions* from AAPFI, if the Director of the Office of Government Ethics issues a regulation applicable to all similarly situated advisory committee members that the financial interest is too remote or too inconsequential to affect the integrity of the government services. In fact, the FDA Commissioner has issued such an exemption for advisory committee members representing specific interests:

> ... 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 is allowed to have a financial interest in that industry.

Conflicts of Interest Proposals in S. 1082 and H.R. 2900

The Senate passed S. 1082 on May 9, 2007, and the House passed H.R. 2900 on July 11, 2007. The bills' conflict of interest provisions are similar, but not identical. Differences between them are expected to be addressed in conference.

Both S. 1082 and H.R. 2900 would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) Chapter VII, Subchapter A, by inserting certain provisions regarding conflicts of interest and advisory committee membership. No provisions regarding conflicts of interest or advisory committees currently exist in that particular section of the FFDCA. Several of the provisions are similar to some present in the SAP (which only applies to drug and biologic advisory committees), and their removal from that section would make their terms applicable to all advisory committees. A summary and comparison of the bills' provisions is presented below.

Definitions. Both bills define *advisory committee* as a FACA-covered entity that provides the Secretary with advice and recommendations regarding activities of the FDA. In contrast, current FDA regulations also cover non-FACA, *ad hoc* committees. The bills define *financial interest* as it is defined under AAFPI (18 U.S.C. 208(a)). Current FDA regulations governing *Qualifications for members of standing policy and technical advisory committees* require that committee members are subject to the same conflict of interest laws referred to in the bills.

> ***Key change from current law:*** new law's scope limited to FACA committees.
> ***Key differences between the bills:*** none.

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[4] "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].

Appointments to Advisory Committees. Both bills contain similar recruitment provisions requiring the Secretary to develop and implement effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient consumer groups. H.R. 2900 would require the Secretary to consult with several specific offices at FDA during this process; S. 1082 would not. Both bills specify that recruitment activities may include advertising at conferences, use of certain electronic media, and communications related to certain federal research grants. Current law requires the FDA Commissioner to post recruitment notices in the Federal Register (21 C.F.R. 14.82 (a), 14.84 (c)).

> ***Key change from current law:*** new recruitment mechanisms for advisory committee members; financial conflict exemptions discouraged.
> ***Key differences between the bills:*** H.R. 2900 requires consultation with specific FDA offices to develop a recruitment strategy; specifies that guest experts with financial interests are permitted.

Regarding advisory committee members' evaluation, both bills would require the Secretary to review the expertise and EGA financial disclosure of committee nominees so as to reduce the likelihood that any would require financial interest rule exceptions under 18 U.S.C. 208(b).

H.R. 2900 contains a section that would specifically permit the participation of a guest expert with financial interest if the Secretary determined that the guest had particular required expertise. The guest would not be permitted to participate in the committees' discussion or voting. S. 1082 contains no parallel provision. Current FDA regulations are similar to H.R. 2900, in that they permit advisory committees to confer with any person who may have information or views relevant to any matter pending before the committee (21 C.F.R. 14.31 (a)). They also permit the FDA Commissioner to appoint persons as special government employees to be consultants to an advisory committee. Consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee (21 C.F.R. 14.31 (e)).

Granting and Disclosure of Waivers. Both bills would require each member of an advisory committee to disclose financial interests to the Secretary prior to a meeting on a particular matter. The SAP currently requires that each member of a panel publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel.

> ***Key change from current law:*** new waiver and related public disclosure requirements.
> ***Key differences between the bills:*** H.R. 2900 limits waivers to one per meeting.

The bills would prohibit an advisory committee member from voting on any matter considered by the committee if the member has a financial interest that could be affected by advice the committee gives to the HHS Secretary. This restriction would be modified by an exemption and a waiver. Under the terms of the exemption (like the exemption already present in the AAFPI), the member would be allowed to vote if the interest was exempted by the Director of the Office of Government Ethics as too remote or inconsequential to affect the member's service. The

waiver could be grated by the HHS Secretary if necessary to afford the advisory committee with essential expertise, but would not available if the committee members' own scientific work was involved. The terms of the waiver (including its scientific work limitation) are similar to current law under SAP.

In accordance with its general provisions discouraging the use of waivers, H.R. 2900 would limit the number of waivers issued under the new provision described above to one per meeting. This limitation has been the subject of debate, particularly from groups advocating on behalf of individuals with rare diseases, where there may be few available scientific experts — even fewer who have no conflict of interest. S. 1082 contains no such limitation. The bills' new waiver would be available in addition to the two that are currently permissible under AAFPI.

Both bills would require the Secretary to disclose certain information on the FDA website in the event that he or she issued a waiver under AAFPI or the bill's provisions. The disclosed information would include the type, nature, and magnitude of the pertinent financial interests and the reasons for the Secretary's action. The disclosure would be limited so as not to include information that is not subject to a Freedom of Information Act (FOIA) request. The Secretary would be required to make the disclosure not less than 15 days prior to an advisory committee meeting, or, in the event that the financial interests became known to the Secretary less than 30 days prior to the meeting, no later than the date of the meeting. Required disclosures would be included in the public record and transcript of each meeting. Current law has no parallel provisions, although, FDA regulations generally favor disclosure, as specified above.

Annual Report. Both bills would require the Secretary to submit annual reports to relevant congressional committees describing advisory committee vacancies, nominees, and the number of nominees willing to serve; the number of conflict-related disclosures per meeting and the percentage of members who did not require such disclosures; the number of times required disclosures occurred less than 30 days in advance of meetings; and how the Secretary plans to reduce the number of vacancies on advisory committees and increase the number of nominations, including those of academicians or practitioners. Current law contains no parallel provisions.

Key change from current law: annual reports required regarding advisory committee membership, conflict of interest waivers.
Key differences between the bills: none.

Periodic Review of Guidance. Both bills would require the Secretary to review and update FDA conflict of interest guidance not less than once every five years. Current law contains no parallel provisions.

Key change from current law: guidance update required every 5 years.
Key differences between the bills: none.

Conforming Amendment. Both bills delete the provision in the SAP that provides that "[e]ach member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member

Key change from current law: FFDCA amended to conform to H.R. 2900 and S. 1082.
Key differences between the bills: none.

of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved." As specified above, language with a similar effect would be inserted elsewhere, where it would apply to all advisory panels, rather that just those concerning drugs and biologics.