September 2008

FDA ADVISORY COMMITTEES

Process for Recruiting Members and Evaluating Potential Conflicts of Interest

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Highlights

Highlights of GAO-08-640, a report to congressional requesters

Why GAO Did This Study

The Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) has been criticized about how it recruits individuals to become members of its advisory committees and how it grants some determinations that allow members with conflicts of interest to participate in committee meetings. Advisory committee meetings can include both standing and temporary members. Temporary members only serve for a particular meeting. GAO was asked to examine FDA's advisory committee processes. GAO reported on (1) how FDA recruited individuals for membership and evaluated candidates for potential conflicts of interest, (2) barriers that were reported to recruiting qualified individuals to serve on committees, and (3) the proportion of standing and temporary members, and the frequency with which members with conflict of interest determinations participated in meetings.

GAO reviewed FDA advisory committee policies and analyzed meeting records for FDA's Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH). GAO also interviewed individuals familiar with FDA's committee member recruiting process. GAO did not examine the effects of changes in FDA's advisory committee processes resulting from the FDA Amendments Act of 2007 and 2007 FDA policy revisions as it was too soon to assess them.

To view the full product, including the scope and methodology, click on GAO-08-640. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Prior to the FDA Amendments Act of 2007, FDA employed several methods to recruit candidates for advisory committees and to evaluate candidates by prescreening them for potential conflicts of interest. FDA recruited candidates by announcing vacancies in the *Federal Register*, distributing recruitment brochures at advisory committee meetings and national meetings, word-of-mouth or asking current advisory committee members, and posting recruitment and conflict of interest information on FDA's Web site. To evaluate advisory committee candidates for conflicts of interest, FDA reviewed the candidates' curricula vitae and usually conducted a prescreening interview. FDA employed many of the same recruitment and evaluation practices used by organizations previously identified by GAO as employing methods that could ensure an independent and balanced advisory committee.

FDA faced barriers to recruiting qualified advisory committee candidates, particularly those without potential conflicts of interest, according to FDA officials and former FDA advisory committee members. However, GAO found that the agency may have been able to mitigate these barriers by expanding its outreach efforts. FDA staff and former FDA advisory committee members GAO interviewed generally agreed that individuals with the expertise FDA sought for its advisory committees were the same leading experts that industry sought to conduct research. In addition, word-of-mouth—the advisory committee member recruitment method FDA officials generally agreed was most effective—was limited in the number of candidate nominations it could generate. The FDA Amendments Act of 2007 modifies FDA's process for prescreening candidates for committee membership.

Standing and temporary members were 58 and 42 percent, respectively, of the 1,218 participants in the 83 advisory committee meetings held by CBER, CDER, and CDRH in 2004 and 2006 that GAO reviewed. FDA may permit an advisory committee member who has a conflict of interest, or an appearance of a conflict, and whose expertise is needed to participate in an advisory committee meeting under certain circumstances by granting a conflict of interest determination. More than half of the meetings had at least one standing or temporary member with at least one conflict of interest determination. The 200 members found to have at least one conflict of interest determination represented about 16 percent of all 83 meetings' participants. The FDA Amendments Act of 2007 limits the number of certain conflict of interest determinations that FDA can grant and FDA's conflict of interest policy revisions limit the amount of the disqualifying financial interests.

In its comments on a draft of this report, HHS noted that on August 4, 2008, after GAO provided the draft report for its review, FDA issued four final guidance documents concerning management of its advisory committees. HHS also provided additional clarifications about aspects of FDA's advisory committees. GAO revised the report to cite the final guidances and to incorporate HHS's clarifications where appropriate.