FDA Guidance on Conflict of Interest for Advisory Committee Members, Consultants and Experts
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February 2000

Conflict of Interest

Complete Document

The FDA Waiver Criteria 2000 provides information on how the Agency manages conflict of interest issues related to special government employees (SGE) who serve as advisory committee members, consultants or experts to the Agency. FDA's conflict of interest program has been referred to as a model for other Executive Branch agencies to follow.

The FDA Waiver Criteria 2000 is a guidance document reflecting the Agency's current thinking. The criteria within this document do not translate to rigid decisions and each situation is evaluated within the context of myriad factors presented.

The section titled "Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants and Experts" provides background information on federal conflict of interest statutes and regulations and describes the process FDA follows when a waiver for conflict of interest is sought.

The Waiver Criteria Document:

- describes the kinds of waivers that FDA uses
- defines terms and concepts used in the Conflict of Interest guidance tables
- presents the Conflict of Interest guidance tables
- contains appendices with sample waivers and waiver checklists, appearance determinations and additional requirements under the Food and Drug Modernization Act (FDAMA) for FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research

Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants, and Experts

I. INTRODUCTION

This portion of the document provides background information on Federal conflict of interest statutes and regulations, provides principles and criteria for determining whether a conflict of interest exists and whether a waiver may be appropriate, and provides a description of Agency procedures for handling conflict of interest issues.

II. BACKGROUND

A. FDA's Use of Outside Experts

The Food and Drug Administration (FDA) is a science-based regulatory agency with responsibility for approximately 25 percent of the gross national product. FDA oversees foods, drugs, biologics, and medical devices that the American public uses every day. To carry out its mission, FDA's decisions need to be based on the highest scientific standards. As science becomes more specialized, it becomes more difficult for general scientists to keep up with the scientific advances in the many areas that FDA regulates. To a large extent, the critical science base exists at the major research institutions in the private sector.

To provide this critical science base, FDA has over 900 outside experts who provide FDA with essential expertise in highly specialized areas. Many of these experts serve as members of FDA advisory committees. Others consult with FDA on individual tasks.

B. The Potential for Conflict of Interest

While FDA has a great need for outside scientific advice, it is critical that the advice be free from conflict of interest and potential bias. If the advice FDA receives is biased or is seen as biased, it is of little value to the Agency.

The outside experts who serve FDA are often pre-eminent scientists in their field. They are typically active researchers on the cutting edge of science. As such, they and their organizations are often sought out by regulated industry to assist in product development. Indeed, studies have shown that academic biomedical research in the United States increasingly is supported by industry. For that reason, FDA's outside experts and the research centers where they work frequently have research grants from, and contracts with, regulated industry. This situation can give rise to potential conflicts of interest or appearances of a lack of impartiality.

C. Minimizing Concern About Conflict of Interest

Federal statutes enacted by Congress create conflict of interest rules applicable to all Federal employees, including special Government employees (SGEs) serving on advisory committees. Regulations issued by the Office of Government Ethics (OGE) and the Department of Health and Human Services (HHS) create additional standards of ethical conduct and provide interpretive guidance concerning the Federal conflict of interest statutes. The Designated Agency Ethics Official (DAEO) of HHS has been designated by the Secretary of HHS to coordinate and manage the Department's ethics program. The DAEO, and the DAEO's staff in the Office of the General Counsel/Ethics Division, provide legal guidance concerning the Federal

conflict of interest statues and regulations and provide guidance, as needed, regarding the application of those legal authorities in specific cases. The DAEO has delegated to the FDA Deputy Ethics Counselor and the FDA Ethics Staff authority to perform many of the functions of administering the FDA ethics program. Within FDA, the Commissioner of Food and Drugs has the final authority, subject to legal review by the DAEO for HHS, to make determinations in matters, such as the issuing of conflict of interest waivers, where Federal law accords the agency authority to exercise discretion regarding and employee's participation in official matters.

FDA has authority to allow an advisory committee member or outside expert to participate in the review of a new therapy notwithstanding an otherwise disqualifying financial interest provided that FDA complies with applicable legal standards. FDA may provide for this participation by granting a conflict of interest waiver for the expert. The decision to grant a waiver is subject to scrutiny and review by different parties: (1) the FDA Division or Office responsible for deciding on the safety and efficacy of the therapy, (2) the Center component that oversees the relevant advisory committee, and (3) FDA's Ethics Staff. These three evaluations occur before the request reaches the deciding official in FDA. In some situations, legal counsel in the OGC Ethics Division of the Department of Health and Human Services and the Office of Government Ethics is sought prior to a decision.

Decisions on ethical issues associated with the use of outside experts are made in accordance with appropriate legal advice and vetted by at least four (and as many as six) levels. These multiple, independent and sometimes redundant reviews, taken together, ensure FDA, the medical community, industry, consumer and patient groups and the American public that advisory committee recommendations are based on the best possible science and are free from bias. Further, advisory committee members provide scientific advice in a public forum where their advice is open to public scrutiny and is balanced by advice from other knowledgeable experts.

III. HISTORICAL OVERVIEW

For years, the Federal Government has attempted to balance the need for outside expertise in advisory committees with protecting against potential conflicts of interest. Federal criminal law prohibits a Federal employee from participating personally and substantively in an official capacity in any particular matter in which he has a direct or imputed financial interest if the particular matter will have a direct and predictable effect on that interest (18 U.S.C. 208(a)). The impact of this prohibition on advisory committees became an issue that the Federal government sought to resolve in the late1980's.

A. The President's Commission on Federal Ethics Law Reform

In 1989, the President's Commission on Federal Ethics Law Reform (the Commission) addressed the conflict of interest issues associated with advisory committee members and published a detailed report of its findings and recommendations. The Commission found that most criminal conflict of interest laws make special allowances for advisory committee members. However, section 208(a) (18 U.S.C. 208(a)) (described above) prohibits taking action affecting a personal financial interest and did not include any exemption for special Government employees (including advisory committee members). The Commission recognized the need for ethical restraints on advisory committee members but believed "the government is needlessly handicapped in obtaining advice and information from individuals with expertise located in the private sector."[2]

The Commission concluded that the usual remedies for potential conflict of interest fell short of meeting the government's needs. The Commission found that experts in a given area typically may have significant employment and other financial interests related to that very same area. Few experts would choose to divest themselves of assets or jobs to assume temporary, often unpaid positions on an advisory committee. Further, recusal would generally be an unworkable remedy

because it would deprive the committee of the conflicted person's expertise. The Commission also found that existing requirements for disqualification or waiver did not solve the problem because they had "the effect of eliminating a class of talented and skilled individuals from providing advice to the government."[3]

The Commission stated that advisory committees convened under the Federal Advisory Committee Act (FACA) warrant a different approach than the standard conflict of interest treatment in 18 U.S.C. 208. According to the Commission, FACA itself includes alternative safeguards that help protect the public's interest in the integrity of advisory committee deliberations. First, FACA includes a requirement that the membership of advisory committees be fairly balanced with respect to the issues under consideration. Furthermore, FACA requires advisory committees to hold public meetings, except in unusual circumstances. As such, deliberations of a FACA advisory committee are open to the most exacting public scrutiny. Finally, the recommendations of an advisory committee are not, in themselves, binding. Advisory committee recommendations are "presented publicly to another government official who can judge independently the degree to which recommendations" might be influenced by the personal interest of the members.[4]

Finally, the Commission recommended legislation that would authorize the official who appoints the members of an advisory committee to determine, after a review of financial disclosure forms filed by the prospective member, that the need for the member's expertise outweighs the conflict of interest.[4]

B. The Ethics Reform Act of 1989

After the Commission's final report, Congress enacted the Ethics Reform Act of 1989 (Pub. L. 101-94). The Ethics Reform Act reflected the recommendations of the Commission by including a new conflict of interest provision in 18 U.S.C. 208. Under new section 208(b)(3), a special Government employee may participate in an advisory committee under FACA despite a potential conflict of interest if the official responsible for the employee's appointment, after reviewing the employee's financial disclosure statements, determines *that the need for the employee's services outweighs the potential conflict of interest* created by the employee's financial interest.

Thus, under the Ethics Reform Act, Agencies must balance the need for scientific expertise with the need to protect against the possibility that the member will be in a position to affect his financial interests.

IV. CURRENT FEDERAL REGULATIONS IMPLEMENTING 18 U.S.C. 208

In December 1996, the Office of Government Ethics (OGE) issued final regulations (5 CFR part 2640) that interpret and implement 18 U.S.C. 208 (61 FR 66829, December 18, 1996). The regulations: (1) provide guidance to agencies on the factors to consider when handling conflicts of interest and granting waivers for all Federal employees (including outside experts), (2) provide interpretive guidance concerning the conflict of interest laws, and (3) authorize certain exemptions to the conflict of interest prohibition.

A. General Conflict of Interest Prohibition

As explained in the OGE regulations, unless granted a waiver, a Federal employee may not personally and substantially participate in an official capacity in any particular matter which, to his knowledge, he or any other person (whose interests are imputed to the employee under 18 U.S.C. 208) has a financial interest if the particular matter will have a direct and predictable effect on that interest (5 CFR 2640.103(a)).

The regulations explain several concepts that assist Agencies in implementing the requirements. These include:

- *Definition of Financial Interest*

  Financial interest, a term of art under section 208 and 5 CFR part 2640, is

defined in the regulations as the potential for gain or loss as a result of governmental action on the particular matter. The regulation makes clear that the phrase also includes a salary, job offer, indebtedness, and similar interests. (5 CFR 2640.103(b))

- *Particular Matters*

  There are two types of particular matters: particular matters involving specific parties, which typically involve a specific proceeding affecting the legal rights of the parties (e.g., a sponsor presenting a pending application to an advisory committee) (5 CFR 2640.102(l)); and particular matters of general applicability (e.g., FDA seeking advisory committee input on a guidance document) (5 CFR 2640.102(m)).

- *Other Persons Who May Present Conflict of Interest Issues*

  Under 18 U.S.C. 208, the financial interests of other persons and organizations are imputed to the employee and may disqualify an employee to the same extent as the employee's own interests. Such other persons and organizations include: the employee's spouse, minor child, or general partner; an organization or entity for which the employee serves as officer, director, trustee, general partner, or employee; and a person with whom the employee is negotiating for, or has an arrangement concerning, prospective employment.

- *Direct and Predictable Effect*

  Under 18 U.S.C. 208, a conflict of interest arises when the employee participates in an official matter and there is a direct and predictable link between the matters in which the Federal employee participates and the employee's financial interests. The link cannot be contingent and dependent on other events.

B. Waivers for Conflict of Interest Under the Implementing Regulations

18 U.S.C. 208(b) permits the government to waive the disqualification requirement of section 208(a) and authorize an employee, under certain circumstances, to participate in particular matters notwithstanding an otherwise disqualifying financial interest. The statute provides for three types of such authorizations: (b)(1) waivers (waivers under 18 U.S.C. 208(b)(1)); (b)(2) exemptions (exemptions under 18 U.S.C. 208(b)(2)); and (b)(3) waivers (waivers under 18 U.S.C. 208(b)(3)).

1. *(b)(1) Waivers*

   Under 18 U.S.C. 208 (b)(1), FDA may grant a (b)(1) waiver to any employee appointed by FDA when it determines that *the disqualifying financial interest is not so substantial that it is likely to affect the integrity of an employee's services* to the government.

   The granting official may consider several factors in making this determination, including: the type of interest creating the disqualification; the identity of the person whose financial interest is at issue; the dollar value of the disqualifying financial interest including its value in relationship to the individual's overall assets; the nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion; the sensitivity of the matter; and the need for the employee's services in the particular matter (5 CFR 2640.301(b)).

   The OGE regulations (5 CFR 2640.301(a)) describe the procedures for granting a (b)(1) waiver, including:

   - The disqualifying interest and the circumstances of the particular matter or matters must be fully disclosed to the government official responsible for appointing the employee to his position (or other official when authority to issue waivers has been delegated).