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Linda Ann Sherman
Advisory Committee Oversight and Management Staff (HF-4)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees (Docket No. 02D-0049)

Dear Ms. Sherman:

We appreciate this opportunity to comment on the Food and Drug Administration's (FDA) recently proposed draft guidance on conflicts of interest.¹

Conflicts of interest are a source of increasing concern to members of Congress, federal agencies, academic associations, science journal editors, and others. We see this FDA guidance as an important effort by one federal agency to address persistent problems in the federal government's implementation of the Federal Advisory Committee Act (FACA) to ensure balance and integrity in the workings of FACA committees.

These comments are not informed by specific results from the FDA survey of advisory committee members. We requested a copy of the results several months ago but due to a mix up have not yet received them. We urge FDA to post the aggregated survey results on its web site so other agencies and the public might learn from the survey.

Summary

We applaud FDA for taking steps to disclose more information about conflicts of interest so the public may better evaluate the discussions and advice produced by FDA advisory committees. We support the proposed framework for describing the dollar-value significance of financial

¹The Center for Science in the Public Interest (CSPI) is a nonprofit consumer-advocacy organization that focuses on health and environmental issues. It is supported by over 800,000 subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI's Integrity in Science project advocates increased public disclosure of scientists' and research institutions' conflicts of interest as part of a broader effort to reduce inappropriate corporate influences on scientific research, oversight, and reporting. CSPI does not accept corporate or government support.

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relationships (range reporting). At the same time, we believe the draft guidance has significant shortcomings and needs strengthening in a number of ways:

1. FDA should make the reasoning supporting its guidance more transparent
2. FDA should expand upon its categorization of industry ties
3. The guidance should enunciate a presumption in favor of public disclosure and clearly articulate standards for determining exceptions to disclosure
4. FDA should apply the guidance to committees discussing general matters
5. FDA should incorporate e-government strategies in publicly disclosing conflict-of-interest information
6. FDA should identify alternatives to waivers for obtaining necessary expert advice

Disclosure means public disclosure

To avoid ambiguity in the use of the term “disclosure,” we make a distinction between potential advisory committee members’ reporting of conflict-of-interest information to a federal agency (“information collection”) and disclosure of that information by the agency or the individual to the public (“public disclosure” or “disclosure”).

1. FDA should make the reasoning supporting its guidance more transparent

In general, the guidance could do a better job of explaining the agency’s thinking behind its determinations. It should more clearly indicate how this guidance overlaps, supercedes, or otherwise relates to existing statutes, regulations, guidance (e.g., “FDA Guidance on Conflict of Interest for Advisory Committee Members, Consultants and Experts,” February 2000), and other determinations influencing FDA’s proposal.

For example, FDA should clearly define “conflict of interest” as used in the draft guidance. In addition, where FDA substantially relies on analyses by others, such as the Office of Government Ethics (OGE), the agency should provide the reasoning behind its interpretation of those analyses. We believe the public would benefit from a citation to the OGE analysis or, if such document is not publicly available, an objective summary of it. Without such explanation, it is impossible to evaluate FDA’s interpretation and proposed action. In short, given the array of existing regulations, policies, and agency statements, FDA should provide more assistance to the reader in defining the terms used, describing the precedents, and justifying the reasoning of its proposals.

2. FDA should expand upon its categorization of industry ties

The proposed guidance improves upon existing conflict-of-interest guidelines. The proposed use of ranges to report dollar amounts for consulting activities; stock interests; contracts and grants; and teaching, speaking, or writing will help the public better assess the work of individual advisors and committees as a whole. Reporting such details of members’ financial relationships

helps the public gauge the significance of an individual's relationships relative to his or her participation on the committee. The dollar amounts that define the ranges for reporting seem reasonable, however the agency should provide some explanation of its reasoning in establishing these thresholds.

3. The guidance should enunciate a presumption in favor of public disclosure and clearly articulate standards for determining exceptions to disclosure

The guidance does not emphasize transparency and the public's right to know about advisory committee members' relevant financial relationships. As currently written, the guidance only guarantees public access to the type and magnitude of the conflict of interest. The guidance should also specify the information that staff has discretion to disclose and the criteria to be used to determine when information should be withheld, if at all.

First, FDA should more clearly embrace the principle of the public's right to know. The Food and Drug Administration Modernization Act (FDAMA) states without equivocation or exception that "each member of a panel shall publicly disclose all conflicts of interest that a member may have with the work to be undertaken by the panel." 21 U.S.C. 355(n)(4) The statute clearly embraces the public's right to know specific relationships, financial or otherwise, that create conflicts of interest for committee members.

FDA notes that the Department of Justice's Office of Legal Counsel determined that FDA has discretion to tailor disclosures to achieve the statute's goal. We are concerned that this determination will be misconstrued to conclude that the agency may withhold information if it perceives disclosure to impede the agency's ability to obtain needed expertise.

Such a conclusion would be a misreading of the spirit and letter of applicable statute. FDA should publicly release the Office of Legal Council's opinion to enable the public to evaluate the agency's interpretation of the statute.

The section of the statute cited clearly grants the agency discretion to provide a waiver to address competing goals; the section does not, however, grant the agency discretion not to disclose. In fact, the section of the statute cited clearly states that a waiver must be accompanied by disclosure of the conflict of interest. 21 U.S.C. 355(n)(4) reads as follows:

Each 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 of a panel may vote on any matter where the member or 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.* (emphases added)

Nowhere does the section grant FDA authority to withhold information regarding conflicts of interest in order to obtain needed expertise.

Further, full public disclosure was also the intent of the law. In 1989, a presidential commission proposed that Congress allow agencies to waive conflict-of-interest requirements if the agency determines that the need for the individual's participation outweighs the risks. Based on the Commission's recommendation, Congress adopted such a provision. The Commission's intent, as written in its published report, was that "public disclosure would be required of not only the waiver, but also the information on the individual's financial disclosure form describing the financial interest(s) that necessitated the waiver." ("To Serve With Honor: Report of the President's Commission on Ethics in Government," 1989, p. 31) The agency's need for expert input does not remove the public disclosure requirement.

21 U.S.C. 355(n)(4) requires, as noted above, and FDA committees operate *de facto*, with two standards for dealing with conflicts of interest, one that defines relationships requiring waivers or exclusions and another that defines relationships that are tolerable if publicly disclosed ("Each member shall publicly disclose all conflicts of interest..."). The statute does not conceive of conflicts of interest that are tolerable but not disclosed. The draft guidance raises concern that such a category would be created. To resolve this problem, the guidance should clearly direct staff to err on the side of public disclosure.

To illustrate this point, imagine a hypothetical situation in which a member of a drug advisory committee consults for and holds stock in a non-related drug company. The value of that consulting contract is \$4,000. We believe that this financial tie represents a relevant conflict of interest because the member's industry-favorable activity on the committee could lead to increased funding from drug companies in the future. Even though this relationship would not trigger a waiver or an exclusion, it should still be disclosed to the public.

Second, if the agency is to restrict disclosure (i.e., withhold portions of the information included in an individual's reported financial information), then FDA should justify and provide clear criteria for withholding information. Beyond a narrow construction of the type and magnitude of a conflict, the guidance is silent on whether staff should disclose or, alternatively, withhold additional information. Has FDA determined that foreseeable harm will come with disclosure of information beyond that indicated in Table 1 (e.g., the name of the company for whom the individual consulted, the source of research funding)? Alternatively, does staff have discretion to disclose further information, such as the names of companies whose stock is owned and names of consulting clients? The guidance indicates that names of competitors would be withheld. Should FDA staff (and the public) infer that FDA will disclose identifying information in the context of other types of conflict?

Third, the guidance creates, perhaps unintentionally, a *de facto* standard for triggering public disclosure that arbitrarily allows the agency to withhold information beyond that which the

guidance describes. As written, the guidance allows the agency to withhold information about conflicts of interest unless it determines that “no foreseeable harm” will come from disclosure. The guidance, however, is silent in guiding FDA staff in determining whether a foreseeable harm exists; whose interests should be considered in determining harm; and whether that harm is sufficiently significant to block disclosure.

As written, the draft guidance appears to open the door to inappropriate balance tests in determining whether foreseeable harm exists. The agency should not start from the assumption that the agency’s interest in attracting members to serve on the committee or the individual right of privacy supercedes the public interest in transparency and accountability. Rather, the final guidance should adopt the principles embodied in the Freedom of Information Act and presume the public has an interest in reasonably assessing the selection, conduct, and statements of federal advisory committee members. Those who would withhold information from the public (due to legitimate concerns for individual privacy or agency deliberative processes) have the burden to justify such nondisclosure.

4. The guidance should apply to committees discussing general matters

It would be a mistake to exclude committees dealing with general matters from the guidance, as the current proposal does. FDA claims that general matters create fewer risks from conflicts of interest and thus the public requires less information about them. We disagree with that assertion. General-matter committees deal with broad questions of policy, which can have far-reaching and significant impact on economically interested parties. Those committees should be subject to the same standards of transparency, integrity, and accountability as are specific-matter committees.

5. FDA should incorporate e-government strategies in disseminating conflict-of-interest information to the public

FDA should provide public access to conflict-of-interest information in ways the public can easily find, access, and use. With increased government endorsement of the Internet as a reliable, inexpensive, and accessible means of disseminating information, FDA’s current practice of providing conflict-of-interest statements in committee transcripts is inadequate, outdated, and obfuscatory. The 1996 amendments to the Freedom of Information Act, commonly referred to as E-FOIA, require agencies to provide information to the public in an affirmative manner. Further, a recent survey for the Center for Excellence in Government found that the public increasingly views the Internet as a tool to strengthen government accountability. (Council for Excellence in Government, “E-Government: To Connect, Protect, and Serve Us,” February 2002)

In addition to including conflict-of-interest information at FACA committee meetings, the agency should publicly disclose specifics about the scope and magnitude of conflicts of interest:

- On the agency web site where the agency posts committee rosters, transcripts, and minutes.
- Through the central FACA information repository, the Committee Management Secretariat's FACA Database (www.facadatabase.gov), operated by the General Services Administration.
- In all paper versions of committee rosters, transcripts, and minutes.

6. FDA should identify alternatives to waivers for obtaining necessary expert advice

The waiver of a conflict of interest should not be regarded as the sole remedy for obtaining expertise where a conflict is unavoidable. Another strategy might be limited service to the committee in the form of testimony on specific questions or issues. In this way, the agency would be able to obtain needed advice while limiting the risk that individuals with conflicts of influence would unduly influence the committee's work. FDA staff should consider this and other ways of isolating expert advice from broader committee deliberations. However, individuals who provide limited service should also be subject to the same conflict-of-interest process and policies (e.g., public disclosure) as full committee members.

We appreciate the opportunity to comment on the draft guidance. We would be pleased to discuss these issues with you further.

Sincerely,


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