U.S. Food and Drug Administration

Draft Guidance [1]

on

Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees

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U.S. Department of Health and Human Services
Food and Drug Administration
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Special Government Employee Conflict of Interest Disclosures

Draft Guidance
on
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I. INTRODUCTION

This guidance document provides information on the type and amount of information that will be disclosed to the public when a special Government employee (SGE) is granted a waiver for a conflict of interest with the topic to be discussed by the advisory committee that the SGE is attending. This guidance applies only to those advisory committee meetings at which a particular matter relating to a particular product is discussed (product specific advisory committee meeting). The guidance applies whether the waiver was granted under the terms of 18 U.S.C. § 208 or 21 U.S.C. § 355(n)(4).

This guidance does not apply to advisory committee meetings that provide advice on topics of general applicability even if SGEs on the committee have received general matters waivers covering their participation on the committee.

II. SUMMARY OF THE GUIDANCE

FDA is establishing a new policy whereby information relating to the nature and magnitude of the conflict of interest that has been waived for an SGE's participation on a product specific advisory committee will be disclosed to the public prior to the advisory committee. The disclosure will be made by the SGEs in the form of a declaration to be read into the record. Information to be disclosed will adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the SGE will make. A table is provided showing in detail the types of information that should be disclosed.

III. STATUTORY BACKGROUND

FDA collects financial interest information from SGEs prior to their participation on product specific advisory committees in order to determine whether the SGEs have any financial interests that pose conflicts of interest for the SGEs.[2] In making the determination of whether a certain financial interest poses a conflict, FDA applies the terms of two separate statutes, 18 U.S.C. § 208, and 21 U.S.C. § 505(n). Under both statutes, FDA may grant a waiver of any conflict of interest providing certain criteria are met. In addition, both sections provide for public disclosure of financial interest information when a waiver has been granted. See 18 U.S.C. § 208(d)(l) and 21 U.S.C. § 355(n)(4).

Section 208 provides that a copy of any waiver determination shall be made available to the public upon request. The section goes on to provide that an agency may withhold from disclosure information that would be exempt under the Freedom of Information Act, 5 U.S.C. § 552(b). Under this provision, all of the information concerning conflicts of interest may be withheld as exempt pursuant to 5 U.S.C. § 552(b)(3) because another statute, the Ethics in Government Act, prohibits release of the information. See 5 U.S.C. App. 4, § 107(a)(l). Nevertheless, in order to provide meaningful disclosure of conflict of interest information, the Office of Government Ethics has concluded that, under section 208, agencies have discretion to disclose information concerning the waived conflict of interest absent a foreseeable harm to be caused by disclosure.

Similarly, section 355 provides that before participating on a drug or biologic product approval or exemption advisory committee, SGEs must disclose "all conflicts of interest that the [SGE] may have with the work to be undertaken by the [advisory committee]." 21 U.S.C. § 355(n)(4).

The Office of Legal Counsel, United States Department of Justice (OLC) has concluded that in order to satisfy this disclosure requirement, SGEs are required to disclose information sufficient to adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the SGE will make. OLC also concluded that FDA may exercise its discretion in making this disclosure to avoid making the disclosure requirement so intrusive or onerous as to make SGEs unwilling to serve on advisory committees.

IV. FDA SURVEY OF ALL SGES

In order to **assess** what information could be disclosed pursuant to these statutes, FDA sent a survey to all advisory committee members. That survey asked in great detail whether the SGEs would support disclosure of specific details concerning specific conflicts of interest. 'A copy of the survey and its tabulated results can be obtained by electronic request to lsherman@oc.fda.gov.

The result of that survey showed that, in general, SGEs were willing to tolerate greater disclosure of the financial interests than has been disclosed in the past. Based on these results, FDA has concluded that no foreseeable harm will result from disclosing both the nature and dollar range of any financial interest that gives rise to a conflict for which a waiver was granted.

V. SUBSTANCE OF THE GUIDANCE

Based on the provisions of the applicable statutes and on the results of the factual survey conducted by FDA, FDA has concluded that the information contained in Table 1 should be disclosed.

The disclosure will identify whether the interest is related to the sponsor or competitor that markets a product competing with the product at issue (without naming the competitor) and whether the SGE worked on the competing product or not.

Table 1. Information to be Disclosed Concerning SGE Conflicts of Interest Waivers

Type of Interest	Magnitude
Stock	Identify whether stock is valued at: a. less than $5,001; b. from $5,001 to $25,000; c. from $25,001 to $50,000; d. from $50,001 to $100,000; or e. greater than $100,000.
Employment of SGE or Spouse	Identify whether employment involves the sponsor's produ a competing product or an unrelated product.
Consulting	Identify whether consulting fees earned within the last yea are:

a. less than $10,001; b. from $10,001 to $50,000; o c. greater than $50,000.	r
Contracts and Grants (This may include contracts and grants imputed to the SGE through his/her employer)	Identify whether contract or grant is: a. less than $100,000 per year; b. between $100,001 and $300,000 per year; or c. greater than $300,000 per year.
Patents/Royalties/ Trademarks	If patent is licensed and royalties exist, SGE, as a rule will excluded from participation.
Expert Witness	SGE will, as a general rule, be excluded from participation
Teaching Speaking or Writing	Identify whether fees earned within the last year are: a. less than $5,001; b. from $5,001 to $10,000; or c. greater than $10,000

SGEs will be asked to execute a consent instructing FDA to disclose the information on the SGE's behalf. Participation will be contingent upon disclosure. Based on the longstanding interest for this information, FDA will disclose the information at the beginning of the advisory committee meeting to which it applies by reading the information into the record at the beginning of the meeting.

'FDA has determined that this guidance is a Level 1 guidance document as defined by 21 C.F. R. § 10.15(c). Therefore, FDA is publishing this document in draft format and will be accepting comments prior to putting it in final form.

[2]The information collection is authorized by section 107 of the Ethics in Government Act, 5 U. S. C. App. 4, § 107. Information is collected on FDA Form 3410 that has *received specific by OMB pursuant to the Paperwork Reduction Act of 1995, Pub. L. 104-13, May 22, 1995, 109 Stat. 164 (codified at 44 U.S.C. §§3501-3520) and by the Office of Government Ethics.*
