



Dear Advisory Committee Member,

Recently, issues related to financial conflict of interest have attracted a great deal of attention both in the academic world and in the media. As an FDA advisory committee member, you are aware of the complex screening process for conflicts of interest that FDA completes prior to every Committee meeting.

Since the mid-1990's, FDA has not publicly disclosed details about any of the financial or research interests of its members. Recently, some of FDA's stakeholders have expressed concern about FDA's current disclosure policy.

Today's scientific community has re-examined the issue of financial disclosure and many organizations, e.g., journals and professional societies, have instituted new measures to provide more information about financial relationships. In light of new disclosure practices in other settings and requests from our stakeholders, FDA is reviewing its current practices.

As an advisory committee member, your opinion on this sensitive topic is very important to us. FDA has developed a questionnaire designed to help us assess your views and your input is critical to any policy changes we may choose to make.

Please complete the attached multiple choice questionnaire. Your response is required by close of business Monday, September 10, 2001. If this message reaches you later than the 10th of September, please proceed to complete the questionnaire and return it immediately, because the Agency expects to achieve a 100% response rate. **When you have completed your questionnaire, please send the document with your responses via email to Dr. Linda Ann Sherman ([ls Sherman@oc.fda.gov](mailto:ls Sherman@oc.fda.gov)). Alternatively, you may fax your response to 301-827-0199.** If you have any questions, please contact Dr. Linda Ann Sherman either by email or telephone at 301-827-3306.

Thank you for your cooperation.

Sincerely,

Linda A. Suydam, D.P.A.  
Senior Associate Commissioner

Enclosures

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# SGE Questionnaire

**Directions:** Please read through the entire questionnaire before answering. Next, recognizing that no survey is ideal, please select ONE BEST answer that fits your view.

Record your responses at the conclusion of each question in the space provided. Save the document with the completed responses for your records. Copy your questionnaire including your responses and email it to [lsherman@oc.fda.gov](mailto:lsherman@oc.fda.gov).

If you have limited email capabilities, you may fax your answers to 301-827-0199.

Due Date: Monday, September 10, 2001.

## **Demographics:**

1. I serve on an Advisory Committee associated with :
  - a) Center for Biologics Evaluation and Research
  - b) Center for Devices and Radiological Health
  - c) Center for Drug Evaluation and Research
  - d) Center for Food Safety and Applied Nutrition
  - e) Center for Veterinary Medicine
  - f) National Center for Toxicological Research (Science Advisory Board or Ranch Hands)
  - g) Office of the Commissioner (Science Board)

**Best Single Answer for Question 1:** \_\_\_\_\_

2. I am a
  - a) Consumer Representative
  - b) Industry Representative
  - c) Patient Representative
  - d) Clinical/Scientific Member

**Best Single Answer for Question 2:** \_\_\_\_\_

Please continue on the next page

3. Length of service to the Food and Drug Administration as a special Government employee (SGE)
- a) Less than one year
  - b) One to four years
  - c) Greater than four years

**Best Single Answer for Question 3:** \_\_\_\_\_

4. What percentage of your total annual income is derived from relationships (such as stock, consulting, speaking, etc.) with regulated (pharmaceutical, device, food) industry?
- a) None
  - b) Greater than zero but less than or equal 10 percent
  - c) 11 -25 percent
  - d) 26-50 percent
  - e) 51-75 percent
  - f) 76-100 percent

**Best Single Answer for Question 4:** \_\_\_\_\_

**My views regarding Financial Disclosure:**

5. In my opinion, the statement of Conflict of Interest for Advisory Members and Consultants that is read into the record at the beginning of an Advisory Committee meeting (e.g., Current practice is to announce that John Doe has a waiver.)
- a) Provides adequate detail
  - b) Provides insufficient detail
  - c) Is unsatisfactory because the statement is vague and/or misleading

**Best Single Answer for Question 5:** \_\_\_\_\_

Please continue on the next page

6. My experience(s) in working with FDA regarding my own, my family's, and my employer's financial involvement, has been in general
- a) Acceptable
  - b) Acceptable, but uncomfortable, because it is intrusive on my privacy
  - c) Acceptable, but burdensome in terms of detail and redundancy
  - d) Unacceptable

**Best Single Answer for Question 6:** \_\_\_\_\_

7. I have read and generally understand the written materials on ethics matters including 18 U.S.C. 208 (the regulation that deals with matters related to financial conflicts of interest), Standards of Ethical Conduct for Employees of the Executive Branch, and the Emoluments Clause of the U.S. Constitution.
- a) Yes
  - b) No
  - c) Not sure I really understand all the requirements on governmental ethics matters as they pertain to FDA

**Best Single Answer for Question 7:** \_\_\_\_\_

8. Overall, I believe that it would add more credibility to the advisory committee process if more detailed information about my financial interests were revealed to the public at the beginning of an advisory committee meeting.
- a) Yes
  - b) No

**Best Single Answer for Question 8:** \_\_\_\_\_

9. When waivers are announced at the beginning of an Advisory Committee meeting, I believe that it would be in my best interest to reveal more detailed financial information to the public.
- a) Yes
  - b) No

**Best Single Answer for Question 9:** \_\_\_\_\_

Please continue on the next page

10. When waivers are announced at the beginning of an Advisory Committee meeting, I believe that it would be in the best interest of the Agency's stakeholders (including the consumer, industry, press) to reveal more detailed about the SGE's financial information to the public.

- a) Yes
- b) No

**Best Single Answer for Question 10:** \_\_\_\_\_

11. If the Agency decided to reveal more detailed information about my financial interests, those of my family and employer, I would

- a) Be willing to do whatever was required
- b) Would act depending on how much detailed information is required
- c) Consider resigning
- d) Have to resign

**Best Single Answer for Question 11:** \_\_\_\_\_

Please continue on the next page

**Disclosure of Information - Level of Increasing Detail:**  
(Please Note: the current practice is to disclose only that a waiver or appearance determination has been granted. No details of the interest are disclosed. The following questions ask you to select a choice of what you are willing to make public with regard to your financial interests. The choices are listed in order of increasing levels of disclosure.)

12. With regard to **stock holdings**, I would agree to the following disclosure statement for release to the public when the holdings are related to the issue before the committee:

- a) Continue current practice (i.e., announcement of the existence of a waiver, but no details are disclosed)
- b) Acknowledge stock holdings (e.g., I own stock in an affected firm.)
- c) Acknowledge stock holdings and name the specific company (e.g., I own stock in ABC Company )
- d) Name the specific company and a range of dollar amounts of stock owned (e.g., I own stock in ABC Company worth \$10,000 – \$25,000)
- e) Name the specific company and the approximate dollar amount of stock owned (e.g., I own stock in ABC Company worth approximately \$14,500)

**Best Single Answer for Question 12:** \_\_\_\_\_

Please continue on the next page

13. With regard to **consulting** activities related to the sponsor or competing firm(s) of the subject at issue, I would agree to the following disclosure statement for release to the public:
- a) Continue current practice (i.e., announcement of the existence of a waiver, but no details are disclosed)
  - b) Acknowledge consulting arrangement (e.g., I consult with an affected firm.)
  - c) Acknowledge consulting arrangement and name the specific company including description of the work and duration of the employment (e.g., I consult with ABC Company on its New Product Development Plan and consult twice yearly.)
  - d) Name the company for the consulting work, give a description of the work, the duration of the employment, and compensation range (e.g., I consult with ABC Company on its New Product Development Plan, consult twice yearly and I receive approximately \$8,000 -10,000 for service.)
  - e) Name the company for the consulting work, give a description of the work, the duration of the employment, and approximate fee amount (e.g., I consult with ABC Company on its New Product Development Plan, consult twice yearly and receive \$10,500 for service.)

**Best Single Answer for Question 13:** \_\_\_\_\_

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14. With regard to University **contract and grants** related to the sponsor or competing firm(s) of the subject at issue, I would agree to the following disclosure statement for release to the public:
- a) Continue current practice (i.e., announcement of the existence of a waiver, but no details are disclosed)
  - b) Acknowledge the university has a grant (e.g., My University has a grant from an affected firm)
  - c) Acknowledge the university has a grant with the name of the company, the product being studied, the SGE's role and the duration of the grant (e.g., My University has a grant from an XYZ company for a clinical trial on product 123. The grant runs for three years and I do/do not receive salary support.)
  - d) Name the company granting the contract, the product being studied, the SGE's role, the duration of the grant and a range of the dollar amount issued for the work (e.g., My University has a grant from an XYZ company for a clinical trial on a product. The grant is in the range of \$100,000 - \$300,000 per year. The grant runs for three years and I do/do not receive salary support.)
  - e) Name the company granting the contract, the product being studied, the SGE's role, the duration of the grant and the approximate dollar issued for the work (e.g., My University has a grant from an XYZ company for a clinical trial on product 123. The grant is for \$250,000 per year. The grant runs for three years and I do/do not receive salary support.)

**Best Single Answer for Question 14:** \_\_\_\_\_

Please continue on the next page

15. With regard to **patents and royalties** related to the sponsor or competing firm(s) of the subject at issue, I would agree to the following disclosure statement for release to the public:
- a) Continue current practice (i.e., announcement of the existence of a waiver, but no details are disclosed)
  - b) Acknowledge the interest in a product (e.g., I have an interest in a product that is related to the product at issue before the Committee.)
  - c) Acknowledge that a patent exists and the sponsor which pays royalties (e.g., I have a patent for LMN and receive royalties from ABC Company.)
  - d) Identifies that a patent exists, the sponsor that pays royalties and the range of fees collected (e.g., I have a patent for LMN and receive royalties in the range of \$0 to \$5000 per year from ABC Company.)
  - e) Identifies that a patent exists, the sponsor that pays royalties and the approximate amount of royalties paid (e.g., I have patent for LMN and receive royalties of \$50,000 per year from ABC Company.)

**Best Single Answer for Question 15:** \_\_\_\_\_

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16. With regard to **expert witness testimony** related to the sponsor or competing firm(s) of the subject at issue, I would agree to the following disclosure statement for release to the public:

- a) Continue current practice (i.e., announcement of the existence of a waiver, but no details are disclosed)
- b) Acknowledge oral or written testimony related to a product at issue (e.g., I have testified or provided written testimony related to a product at issue before the Committee.)
- c) Acknowledge testimony given, the name of the company who paid for the service and the topic at issue (e.g., I have testified or provided written testimony on behalf XYZ company related to a product at issue before the Committee.)
- d) Identifies that oral or written testimony given, the name of the company who paid for the service, the topic at issue and a range of the dollar amount received (e.g., I have testified or provided written testimony on behalf XYZ company related to a product at issue before the Committee and receive between \$1000 - \$10,000 in fees.)
- e) Identifies that oral or written testimony given, the name of the company who paid for the service, the topic at issue and an approximate dollar amount paid for the service (e.g., I have testified or provided written testimony on behalf XYZ company related to a product at issue before the Committee and received \$7,500 in fees.)

**Best Single Answer for Question 16:** \_\_\_\_\_

Please continue on the next page

17. With regard to **teaching/speaking and writing** related to the sponsor or competing firm(s) of the subject at issue, I would agree to the following disclosure statement for release to the public:
- a) Continue current practice (i.e., announcement of the existence of a waiver, but no details are disclosed)
  - b) Acknowledge the acceptance of compensation for speaking on a topic related to a product at issue before the Committee. (e.g., I have accepted compensation for a speech on beta-blockers.)
  - c) Identifies topic of the speech and the name of the company that paid the honorarium (e.g., I have accepted compensation for a speech on beta-blockers and RST company paid the honorarium)
  - d) Identifies topic of the speech, the name of the company that paid the honorarium, and the range of the dollar amount received (e.g., I accepted compensation for a speech on beta-blockers on behalf of RST company and received an honorarium between \$1,000 – \$10,000)
  - e) Identifies topic of the speech, the name of the company that paid the honorarium, and the approximate dollar amount specified (e.g., I accepted compensation for a speech on beta-blockers on behalf of RST company and received an honorarium of \$2,500)

**Best Single Answer for Question 17:** \_\_\_\_\_

Please continue on the next page

18. Please feel free to use the space below and/or an additional sheet of paper, if you would like to share comments about issues related to conflicts of interest and/or this questionnaire.

FDA very much appreciates your cooperation in this questionnaire. Your answers will be kept entirely confidential. When the survey has been completely analyzed, you will receive a summary report. Thank you for participating in this study.

If you have any questions, please contact:  
Linda Ann Sherman, MD, MPA,  
Director of the Advisory Committee Oversight Staff  
Telephone 301-827-3306  
Fax: 301-827-0199  
Email [lsherman@oc.fda.gov](mailto:lsherman@oc.fda.gov)

Friday, September 07, 2001  
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