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The Food and Drug Administration's Financial Disclosure System for Special Government Employees: Progress and Problems. FPCD-76-99; B-103987. January 24, 1977. 32 pp. + appendices (20 pp.).

Report to the Congress; by Elmer B. Staats, Comptroller General.

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Authority: 5 U.S.C. 2105(a). 18 U.S.C. 201-18. 45 C.F.R. 73.735. Executive Order 11222.

A review was conducted of the Food and Drug Administration's (FDA's) financial disclosure system for special Government employees (SGEs), which is designed to protect against conflicts of interest. Files of 906 SGEs were reviewed to determine whether all confidential statements of employment and financial interests were filed and reviewed in a timely manner and properly filed and adequately reviewed. The evaluation of the financial disclosure system also concerned FDA's: (1) policy for making conflict-of-interest determinations; (2) procedures to prevent SGEs serving on committees from participating in restricted activities; and (3) system to publicly disclose potentially controversial cases. Findings/Conclusions: Some statements were not filed or were untimely filed. FDA officials did not always have required information for making conflict-of-interest determinations and determinations were not always documented. Generally, restrictions placed on the activities of consultants were not applied to the activities of non-product-oriented advisory committee members. In many cases, potential conflict-of-interest situations were not publicly disclosed, and there were inconsistencies in the nature and format of information disclosed in memoranda. Recommendations: The financial disclosure system should be improved by: (1) clearly stating policy and developing procedures for SGEs working in non-product-oriented capacities representing special interests; (2) improving the form used to collect financial disclosure information and procedures for reviewing the statements; and (3) developing procedures specifying what information should be contained in public disclosure memoranda. The policy guidance should be submitted to the Office of the Secretary of the

Department of Health, Education, and Welfare and to the Civil Service Commission for approval. (SW)

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

The Food And Drug Administration's Financial Disclosure System For Special Government Employees: Progress And Problems

The Food and Drug Administration of the Department of Health, Education, and Welfare has progressed considerably in the past year in developing its system for special Government employees to protect against conflicts of interest. These employees are hired as temporary staff to provide specialized advice.

GAO recommends that the Food and Drug Administration finalize development of policy and supporting procedures. Various errors and inconsistencies in the case files resulted from the lack of definitive policy.

GAO also recommends (1) procedures to make sure that special Government employees do not participate in restricted matters and (2) improvements in the system to publicly reveal controversial interests.

FPCD-76-99

JAN. 24, 1977

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-103987

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses progress and problems in the development of the Food and Drug Administration's financial disclosure system for special Government employees. Although we have issued a series of reports on financial disclosure systems for regular employees, this is our first covering special Government employees.

We made this review at the request of the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce. Our authority is the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

As instructed by the Chairman, we did not obtain formal comments. However, we discussed the report with the Associate Commissioner for Administration and other agency staffs in the Food and Drug Administration responsible for the financial disclosure system. We also discussed the report with officials in the Office of the General Counsel, Department of Health, Education, and Welfare. Their comments, where appropriate, were considered in this report.

We are sending copies of this report to the Director, Office of Management and Budget; and the Secretary, Health, Education, and Welfare; the Commissioner, Food and Drug Administration; and other interested parties.

Comptroller General
of the United States

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ABBREVIATIONS

CSC	Civil Service Commission
FDA	Food and Drug Administration
HEW	Department of Health, Education, and Welfare
PRDC	Public Records and Documentation Center
SGEs	special Government employees

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

THE FOOD AND DRUG ADMINISTRATION'S FINANCIAL DISCLOSURE SYSTEM FOR SPECIAL GOVERNMENT EMPLOYEES: PROGRESS AND PROBLEMS

D I G E S T

The Food and Drug Administration, an organization within the Department of Health, Education, and Welfare (HEW), is a principal consumer protection and regulatory agency of the Government, charged with enforcing Federal laws involving food, drugs, medical devices, and cosmetics. Special Government employees augment the agency's regular full-time staff, providing technical knowledge essential to the agency. To maintain public confidence in Food and Drug Administration decisions these employees must adhere to the highest ethical standards. (See pp. 2 and 28.)

How do conflict-of-interest statutes for special Government employees apply to the Food and Drug Administration? Problems in answering this question have hindered the agency's development of policy to protect against special Government employee conflicts of interest. (See pp. 13 and 15.) The agency thinks it has finally answered this question (see p. 15) but it needs to develop its policy further and submit it to HEW and the Civil Service Commission for approval. It also needs to develop supporting procedures. (See p. 18.)

--In January 1976, the agency issued, in draft, policy to be used on a pilot basis. Before then, conflict-of-interest issues were resolved case by case. Revised policy was issued in October 1976 based in part on GAO's review. (See pp. 10 and 15.)

--GAO found numerous errors and inconsistencies in case files. (See ch. 5.) These were directly attributable to the lack of formal policy before January 1976 and to the fact that the policy issued at the time was in draft to be used on a pilot basis. See pp. 23 and 28.)

--GAO did not find any cases involving actual conflicts of interest. But the scope of GAO's review was not sufficiently broad to enable GAO to find such cases should they exist. No comparison was made between specific financial interests and individual duties and responsibilities (See pp. 31 and 32.)

--The Food and Drug Administration believes that it is in the forefront of policy development for special Government employees. (See p. 13.) But GAO is still concerned because present guidance does not provide policy for all special Government employees. (See pp. 16 and 17.)

The Food and Drug Administration needs to develop procedures to make sure that special Government employees serving on committees do not participate in matters in which they are disqualified by employment or other financial interests. Based on tests made by GAO, the Food and Drug Administration officials charged with this responsibility did not always have required information. (See p. 19.)

The Food and Drug Administration further needs to formalize its system of public disclosure to make sure that potentially controversial interests held by special Government employees are described clearly and consistently. (See pp. 20 through 22.)

GAO recommends that the Secretary, HEW, actively assist the Food and Drug Administration in developing a policy to protect against conflicts of interest and to resolve difficult policy issues. (See p. 29.)

GAO also recommends that the Secretary, HEW, direct the Commissioner of the Food and Drug Administration to take steps to improve its system (see pp. 29 and 30) including:

--Completing system development which involves (1) developing policy to provide guidance for special Government employees not covered by present policy guidance, (2) submitting its policy guidance to HEW and the Civil Service Commission for approval, (3) developing specific procedures to make sure policy is implemented, and (4) improving the form used to collect financial disclosure information.

--Issuing guidelines clearly defining the responsibilities and organizational level of officials making the initial conflict-of-interest recommendation.

--Formalizing the system to make sure that special Government employees do not participate in agency matters in which they have financial interests and hence are disqualified.

--Developing written procedures setting forth what information should be contained in public disclosure memoranda and the format to be used, so the information will be presented clearly and understandably.

This review was requested by the Chairman, Oversight and Investigations Subcommittee, Committee on Interstate and Foreign Commerce. The primary concerns were:

--The effectiveness of the Food and Drug Administration's financial disclosure system for special Government employees.

--Whether financial disclosure statements are promptly filed by the special Government employees and reviewed by the agency.

--Whether special Government employees appear to have financial conflicts of interest which could affect the quality and objectivity of their work for the agency. (See p. 31.)

GAO was asked by the requestor not to obtain formal comments. However, GAO discussed the report with the Associate Commissioner for Administration and other agency staff in the Food and Drug Administration responsible for the financial disclosure system. GAO also discussed the report with officials in the Office of the General Counsel, Department of Health, Education, and Welfare. Their comments, where appropriate, were considered in drafting the report.

This is GAO's first report on financial disclosure for special Government employees and one in a series of reports on financial disclosure systems in the Government. (See app. I.)

CHAPTER 1

INTRODUCTION

This is our second report on the Food and Drug Administration's (FDA's) financial disclosure system. In the earlier report entitled "Financial Disclosure System for Employees of the Food and Drug Administration Needs Tightening" (FPCD-76-21, Jan. 19, 1976), we discussed FDA's financial disclosure system for regular employees. This report discusses the system for protecting against conflict of interest for special Government employees (SGEs) and the actions which are needed to strengthen this system.

As of May 31, 1976, FDA had 810 SGEs. Approximately 480 of these were voting members of public advisory committees and another 37 were nonvoting consumer and industry representatives to these committees. The majority of the remaining SGEs were consultants and experts to committees.

Most SGEs in FDA are principally employed by universities and hospitals. Other employers are foundations and Government agencies. Industry representatives come almost exclusively from FDA-regulated industries.

The term "special Government employee" has been broadly defined in 18 U.S.C., section 202 (a), as an officer or employee of the Government who is retained, designated, appointed, or employed to perform, with or without compensation, temporary duties either on a full-time or intermittent basis for a period of not more than 130 days during any period of 365 consecutive days. This does not mean, however, that every person who performs temporary duties with a Government agency must be an SGE. The term SGE is limited to those persons who have an employee-employer relationship with the agency concerned (See 5 U.S.C. 2105(a)).

There is no specific statutory requirement that members of public advisory committees be appointed as SGEs. 1/ Where a member's temporary duties on a public advisory committee result in an employee-employer relationship, however, appointment as an SGE would be required. If a member serves strictly in a representative capacity, as in the case of FDA's consumer and industry representatives, there is no requirement to appoint that member as an SGE. 2/ However, an agency, at its discretion, may

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1/Federal Advisory Committee Act, 5 U.S.C., appendix I.

2/Federal Personnel Manual, chapter 735, appendix C, pages 735-C-4 and 5.

require that members serving in a representative capacity be SGEs, thus making them subject to the conflict-of-interest laws.

FDA's MISSION

FDA, a constituent agency of the Department of Health, Education, and Welfare (HEW), is a principal consumer protection agency of the Federal Government enforcing the Federal Food, Drug, and Cosmetic Act and other related laws.

FDA's major task is to prevent adulteration or misbranding of foods, drugs, medical devices, and cosmetics. It is likewise concerned with the safety of a host of chemical products, biological products, and electronic equipment which emits radiation. In pursuing these activities, FDA must be responsive to many groups and individuals who are concerned with the health needs of the Nation.

SGE's ROLE

FDA believes that it is not possible to maintain in-house all the many kinds of scientific talent required for intermittent, but high priority work. Thus, the regular full-time FDA staff is augmented by SGEs who are individuals with knowledge and judgment in a specific field and qualified by training and experience to evaluate information and interpret its significance under various circumstances. Each is expected to be a leader in his profession and fully conversant with the most advanced expression of its scientific basis, clinical or technical applications, and societal implications. These individuals represent the diversity of judgment, outlook, and background which FDA believes essential to balanced and effective programs. FDA has taken the position that without the use of SGEs it could not discharge its scientific and regulatory responsibilities at the level which the safety and health of the public warrants.

Most SGEs are members of public advisory committees or serve as consultants and experts to these committees. All voting members and many nonvoting members on these committees are SGEs.

Public advisory committees assist FDA by holding public hearings, reviewing and making recommendations on matters pending before FDA. These committees supplement the knowledge and judgment which is generated internally in FDA and can be brought to bear on the broad range of areas in which FDA is responsible. According to FDA, these committees are

strictly advisory and have no direct operating or administrative authority.

FDA had 60 public advisory committees at the time of our review. The number of committees changes from time to time; one new committee was established in each of the last 2 years. Most committees have a limited life, functioning from 2 to 6 years or until their mission is completed. These committees meet formally from 1 to 12 times a year.

Voting committee members generally do not represent any particular interest group or organization. Nonvoting consumer and industry members, however, serve in a liaison function with those whom they represent. Voting committee members have a greater capacity to influence agency decisions than nonvoting members. Their position on issues is a matter of record and is expected to be arrived at objectively and independently, totally free from bias motivated by an affiliation with a particular interest.

Consumer liaison members are nominated and selected by consumer organizations and other interested consumers. Industry members are selected by industry associations. It is the responsibility of these members to represent the consumer and industry interests fairly in all deliberations; they must exercise restraint and not engage in unseemly advocacy or attempt to exert undue influence over the other members of the advisory committee. The need for consumer and industry representation is determined on a committee by committee basis and, in most cases where one interest is present, so is the other.

Most industry representatives are not SGEs and, therefore, are not subject to SGE conflict-of-interest regulations and do not file financial disclosure statements. FDA does not require either consumer or industry representatives to become SGEs. To attend closed committee meetings, consumer representatives must be SGEs whereas industry representatives may not attend meetings closed for the purpose of discussing trade secrets even if they are SGEs.

CONFLICT-OF-INTEREST PROBLEMS

Many of the characteristics which make SGEs desirable (wide experience, an active role in the development and advancement of new products and techniques, a close relationship with other Federal agencies as well as with the non-Federal community) create problems in terms of conflict of interest which are far greater than for regular employees.

--Regular employees customarily derive most if not all of their income from FDA employment. SGEs normally have other employers as well as outside financial interests, and the income derived from FDA is often minor in relation to that derived from other sources. Some SGEs serve without compensation. Compensated SGEs received an average of $1,558 in 1975 ranging from a low of $64 to slightly under the maximum allowable of $16,744.

--While it is possible to eliminate conflicts for regular employees by such actions as job reassignment and divestiture of controversial interests, such solutions are often not appropriate for SGEs. FDA is generally not the primary employer; the maximum tenure in any one assignment is 130 days a year for a period of up to 4 years.

FDA has recognized that often a highly qualified person cannot be found who is totally free from non-Federal employment or private financial interests that present potential for conflict of interest. Its Staff Manual Guide (FDA 2111.1) issued in July 1975, states:

> "It will not always be possible for FDA to obtain the services of a competent consultant, expert, or committee member who does not have some sort of relationship with regulated industry. In addition, a group of consultants to FDA may of necessity be composed largely or wholly of persons representing a common class, group, or interest whose regular employers might benefit or appear to benefit from the actions of the group. However, in many cases, only in such groups can the necessary expertise needed by FDA be obtained."

FDA is concerned about this problem and its implications in terms of the continued use of SGEs. FDA firmly believes that the conflict-of-interest statutes were not intended to deny the Federal Government access to the highest quality scientific and medical advice. The Congress has demonstrated its concern over this possible inaccessibility by making the conflict-of-interest prohibitions less stringent for SGEs than for regular employees.

CHAPTER 2

STATUTORY PROHIBITIONS AND THE DEPARTMENT'S FINANCIAL DISCLOSURE REQUIREMENTS

STATUTORY PROHIBITIONS

Before 1962 the Federal conflict-of-interest laws applied equally to full-time and part-time employees. In 1962 the Congress recognized that the restraints placed on part-time employees were unduly restrictive and hindered the Government in obtaining expert advice. The Senate Judiciary Committee report on a bill to amend the conflict-of-interest statutes stated:

> "In considering the application of present law in relation to the Government's utilization of temporary or intermittent consultants and advisers, it must be emphasized that most of the existing conflict-of-interest statutes were enacted in the 19th century--that is, at a time when persons outside the Government rarely served it in this way. The laws were therefore directed at activities of regular Government employees, and their present impact on the occasionally needed experts--those whose main work is performed outside the Government--is unduly severe. This harsh impact constitutes an appreciable deterrent to the Government's obtaining needed part-time services."
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> "At this date it is no longer open to question that many, if not most of the departments and agencies find it necessary for the optimum performance of their tasks to make use of the skill, talent, and experience of leaders in the sciences, business, and the professions whose regular work is conducted in private spheres. Today's Government requires the part-time services of thousands of such persons to deal with problems of increasing complexity and scope. It can scarcely be questioned that a satisfactory means must be found of facilitating the employment of these individuals by the departments and agencies, as needed, without relaxing basic ethical standards or permitting actual conflicts of interest."

The resulting legislation, a criminal statute (18 U.S.C. 201-218), established the category of "special Government employee" and required generally less stringent restrictions on these employees than those applicable to regular Government employees. For example, 18 U.S.C. 209, which prohibits a regular employee's receipt of pay from private sources in certain circumstances, specifically excludes SGEs from its coverage.

The most pertinent restrictions placed on SGEs are set forth in sections 203, 205, 207, and 208 of 18 U.S.C. Sections 203 and 205 contain prohibitions affecting the activities of SGEs in their private capacities. Section 207 contains prohibitions affecting the activities of SGEs after their Government employment is ended.

Section 208 prohibits an SGE, in the course of his official duties, from participating personally and substantially in a particular matter in which, to his knowledge, he, his spouse, minor child, partner, or a profit or nonprofit enterprise with which he is connected has a financial interest. Under 208(b) an agency may grant an SGE an ad hoc exemption from this prohibition if the interest is deemed not so substantial as to affect the integrity of his service. An agency may also waive certain financial interests by a general rule or regulation which are considered too remote or too inconsequential to affect the integrity of an SGE's services. Our review focused primarily on section 208 provisions.

While the Congress lessened the restrictions placed on SGEs, it emphasized the need for greater administrative supervision. In commenting on the proposed 1962 legislation, the chairman of the cognizant Senate Subcommittee stated:

> "* * * we have created a "special Government employee" for whom the restraints * * * have been relaxed under the bill. This was done to permit the Government to be able to bring advisers and consultants in temporarily--a problem which under present law is difficult, as the report indicates.
>
> "I wish to emphasize that there will have to be close administrative regulation of this provision. Among the regulations should be current statements of their financial interests, a continuous scrutiny of the role and the need for the individual in the agency, and of the appearance of these employees on behalf of non-Government organizations and enterprises.

"These individual views of mine are in the nature of a warning and a caution to the executive branch to be more alert and to be more vigilant where we have relaxed this conflict-of-interest provision."

EXECUTIVE ORDER

In 1963, the President recognized the need for employing highly skilled persons on a temporary basis, but he was also acutely aware of the potential for conflict of interest. In a memorandum 1/ to the heads of executive departments and agencies, the President stated:

"The temporary or intermittent adviser or consultant and the department or agency which employs him both must be alert to the possibility of conflict. It is, of course, incumbent upon the adviser or consultant to familiarize himself with the laws and regulations which are applicable to him. The responsibility of the department or agency is equally great. It is important that it oversee his activities in order to insure that the public interest is protected from improper conduct on his part and that he will not, through ignorance or inadvertence embarrass the Government or himself. It must assist him to understand the pertinent laws and regulations. It must obtain from him such information concerning his financial interests as is necessary to disclose possible conflicts. It must take measures to avoid the use of his services in any situation in which a violation of law or regulation is likely to occur. And it must take prompt and proper disciplinary or remedial action when a violation, whether intentional or innocent, is detected."

In 1965, the President issued Executive Order 11222, part III of which prescribed standards of ethical conduct for SGEs. This order states that SGEs must refrain from any use of public office which is motivated by or gives the appearance of being motivated by the desire for private gain for himself or other persons, particularly those with whom he has family business, or financial ties. It also directed the Civil

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1/This memorandum was revoked by Executive Order 11222. However, the substance of the memorandum is still contained in the Federal Personnel Manual, Chapter 735, Appendix C.

Service Commission (CSC) to establish implementing regulations and to approve standards of conduct established by each agency. In November 1965, CSC issued instructions requiring each agency to prepare standards of employee conduct and to establish a system for reviewing employee financial disclosure statements.

DEPARTMENT'S REGULATION

Pursuant to the Executive order and CSC's implementing instructions, in March 1966, HEW issued a regulation (45 C.F.R. 73.735) governing employees' responsibilities and conduct. Only Subpart L of the regulation applies to SGEs. It states that an SGE must conduct himself according to ethical behavior of the highest order and prescribes standards for adherence.

SGEs are required by this regulation to submit a statement which reports (1) all other employment and (2) the financial interests which relate either directly, or indirectly, to his duties and responsibilities. These statements are required at the time of employment and are to be kept current throughout the period of employment.

In 1972, the Department issued supplemental regulations (45 C.F.R. 73a.735) providing interpretive definitions to the Department's regulation and additional requirements for FDA's regular employees. It stated that since FDA is a unique consumer protection and regulatory agency within the Department, the Department's regulation needed further supplementation to reflect this role. The Department has not issued supplemental regulations covering SGEs.

The Assistant General Counsel, Business and Administrative Law Division, Office of the General Counsel, was designated the Department's ethics counselor to give advice and administer regulations governing SGE's responsibility and conduct. If the ethics counselor cannot resolve a conflict, pertinent information is forwarded to the Secretary of HEW, for his consideration.

FDA's Associate and Deputy Associate Commissioner for Administration and the Director, Policy Management Staff, are responsible for making a conflict-of-interest determination based on statements submitted by SGEs on employment and financial interests which must be filed (1) prior to initial appointment and (2) annually prior to reappointment.

CHAPTER 3

SYSTEM TO PROTECT AGAINST

CONFLICT OF INTEREST FOR SGEs

HOW SGEs ARE APPOINTED

FDA advertises in the Federal Register for (1) position openings resulting from the establishment of new committees and (2) vacancies which are to occur during the next 12 months for existing committees. These notices state the function of the committees, qualifications required, and term of the office. For nominations submitted, a summary of the candidate's qualifications is required and, except for industry representatives, a statement that the individual appears to have no conflict of interest that would preclude committee membership. Industry representatives are selected by industry associations.

Most committee openings are presently being filled from responses to Federal Register notices. Occasionally, nominations are solicited from committee members already appointed and by mass mailings to various professional and scientific groups.

The sequence of steps followed before the initial appointment of an SGE are:

1. An official in the sponsoring bureau/office (usually an executive secretary) contacts the prospective SGE to determine his interest, availability, suitability, and possible conflicts of interest.

2. The committee management officer of the sponsoring office forwards the necessary appointment forms, including the FD-2637, "Confidential Statement of Employment and Financial Interest," to the nominee.

3. An official in the sponsoring bureau/office reviews the appointment forms and initially states in writing whether a conflict of interest exists.

4. The Director, Policy Management Staff, reviews the appointment forms, including the "Confidential Statement of Employment and Financial Interest," and makes the final determination whether a conflict exists.

At any point during the process, the prospective member can be eliminated from further consideration for any of a number of reasons, one being that a conflict of interest has been identified which cannot be resolved. If a conflict is not considered serious, it will normally be resolved by restricting the SGE's participation in FDA activities which may relate to this interest.

POLICY FOR MAKING CONFLICT-OF-INTEREST DETERMINATIONS

In January 1976, FDA issued in draft a staff manual guide in an initial effort to formalize policy and criteria for dealing with SGE conflict-of-interest situations. Most of the SGEs active at the time of our review had been appointed before this policy guidance was formalized. Formerly, FDA had been rendering case by case judgments based solely on the Federal conflict-of-interest statutes and Subpart L of the Department's regulation. Because of FDA's sophisticated programs and extensive use of SGEs, these general guidelines were proven inadequate in resolving conflict-of-interest matters on a uniform and equitable basis.

This guide was issued in draft to be used on a pilot basis because FDA wanted experience with the policy before making it final. The guide described the specific application of the Federal statutes to FDA situations and set forth restrictions on an SGE's participation in FDA activities based on past or existing interests. It also described certain restrictions on outside activities and interests during and after FDA employment.

Substantial interests which would normally preclude employment fell in three categories: financial assets, consultant relationships, and research grants and contracts. The limits specified below applied only to interests involving "products" in the industry "regulated by the particular bureau/office" with which the SGE was being considered for employment.

Category of interest	Limit
Financial assets	$10,000 present market value
Consultant fees	$1,000 in past year with regulated firms
Research grants and contracts	$5,000 from one firm or total of $25,000 from all regulated firms in the past year

Interests below the limits set forth above would not allow unrestricted participation by SGEs in FDA matters. The following is a summary of restrictions on an SGE's participation based on past or existing interests.

Category of interest	Situation	Restrictions
Financial assets	Advisory committee member who holds less than $2,000 in assets in any one regulated firm	None
	Expert or consultant who holds less than $2,000 in assets in any regulated firm	(a)
	Assets of more than $2,000 in any one regulated firm but less than $10,000 in all regulated firms	(a)
	$10,000 in assets in regulated firms	(b)
Consultant fees	None in past 12 months	None
	Less than $1,000 remuneration in past 12 months	(a)
	Greater than $1,000 remuneration in past 12 months	(b)
	Consulted on matter now pending before FDA	(a)
Research grants and contracts	None in past 12 months	None
	Less than $5,000 from one firm or $25,000 from all firms in past 12 months	(a)
	Greater than $5,000 from one firm or $25,000 from all firms in past 12 months	(b)
Investigator	Past or present investigation on an application currently pending before the agency	(c)

Category of interest	Situation	Restrictions
Investigator	Application not pending, but individual is prominently identified with a particular point of view regarding a problem	(c)

a/Restricted from participating in regulatory matters or providing advice on products involving firms in which he has financial interest or firms producing closely competing products. Restrictions are to be made a matter of record on the HEW-410, "Supplemental Information--Expert or Consultant."

b/Conflict-of-Interest Review Board must approve employment and determine degree of participation. (Public disclosure of these cases is currently being used in lieu of a review board.)

c/Restricted from participating in regulatory matters or providing advice regarding the application or problem with which he has an association.

Limitations are also placed on new interests acquired during employment. All increases in financial interests relating to the employing bureau/office must be approved by FDA except for increases in financial assets of $1,000 or less.

The "Confidential Statement of Employment and Financial Interests" is used to collect information on past and present employment relationships such as consultancy or through grants, contracts, and research activities to determine what ties exist with FDA-regulated industry as well as other Federal agencies. Also, information is required concerning promotion and advertising activities and financial interests in products FDA regulates. Neither appointment nor reappointment actions should be processed by the Personnel Office without this form complete with a conflict-of-interest determination by the Director, Policy Management Staff.

PUBLIC DISCLOSURE OF CONTROVERSIAL CASES

An SGE's financial interests should be made a matter of public record when they exceed the criteria stated in the staff manual guide, are not explicitly covered by the guide, or involve waivers or special restrictions. The facts and issues surrounding these potentially controversial situations are described in a memorandum available for review in FDA's

Public Records and Documentation Center (PRDC). The memorandum is commonly referred to in FDA as a PRDC memorandum. It is also known as a four-way memorandum because four signatures are required to formalize the memorandum: (1) the prospective SGEs, (2) a responsible line official in the sponsoring bureau/office, (3) the Assistant General Counsel, and (4) the Associate Commissioner for Administration. These memoranda are renewed only when a change occurs in an SGE's employment or financial interests.

FDA believes that public disclosure is the best way to deal with situations involving SGEs which may have the appearance of a conflict of interest, particularly since options which are available in the case of regular employees, such as job reassignment or a divesting of interests are not appropriate. FDA policy is to avoid hiring individuals with interests that would require issuing a PRDC memorandum, if possible. FDA contends that there are situations where available manpower in a specific scientific discipline is limited to a few individuals who have needed qualifications. On reappointments, public disclosure is often the only alternative to terminating the individual in resolving cases involving the appearance of conflicts of interest.

FDA has established a Conflict of Interest Review Board which, in the future, will rule on cases having the appearance of a conflict as well as review and make recommendations to the Commissioner of FDA on policy matters relating to SGE conflicts of interest.

PROBLEMS IN POLICY DEVELOPMENT

FDA believes it is in the forefront of policy development relating to the use of SGEs and that this guidance represents a pioneering effort within the Federal Government. According to FDA, however, the development of conflict-of-interest regulations and guidelines for SGEs has been exceedingly difficult for the following reasons.

--The present wording of the statutes creates problems for FDA in a number of areas. For example, there is no adequate definition as to what constitutes "personal and substantial" participation, "acting as an agent," and what should be considered "too remote and inconsequential." FDA believes the statutes did not anticipate the need to use a large number of SGEs which must be drawn from a limited labor supply in the scientific and academic community.

--FDA has not found any court precedents in the conflict-of-interest area involving SGEs which might serve as a guide in developing policy.

--Many emerging interpretations of the statutes conflict with each other and it is difficult to determine which viewpoint should be used in developing policy.

CHAPTER 4

IMPROVEMENTS NEEDED IN SYSTEM

Since a large proportion of SGEs employed by FDA have other employers and financial interests, it is essential that FDA have a sound policy on which to base conflict-of-interest determinations which provides guidance for all groups under all working conditions and is supported by formalized procedures. For this policy to be of maximum benefit, the system to protect against conflict of interest should make certain that SGEs do not participate in activities which, according to this policy, would disqualify them. Potentially controversial cases should be described clearly and consistently in public disclosure memoranda. This chapter discusses problems with FDA's policy guidance and the improvements we believe are needed to make the system more effective.

PROBLEMS WITH POLICY GUIDANCE

Our review revealed various errors and points of confusion in the January 1976 draft staff manual guide which required clarification by agency officials. In analyzing the draft guidance, we were also concerned whether all relevant issues had been fully considered. Most of these concerns centered on the SGE's employment ties with FDA-regulated industry; employer's financial interests; total involvement with FDA-regulated industry; and the extent that all SGEs were covered by the policy guidance.

In October 1976, FDA revised its policy guidance (see app. II) based on 9 months of operating experience with formalized policy guidance. FDA believes that in drafting this guide it has satisfactorily resolved the meaning of the statutes as they relate to FDA employment. FDA made some changes based on the concerns we expressed. This policy has not been submitted to the Department or CSC for approval. The new policy guidance:

--Limits investments, employment, grants, and contracts in a single firm to $5,000 before requiring public disclosure and clarified that in all cases these limits apply only to firms involved with products regulated by the employing bureau/office. A combination of investments and employment relationships in a single firm may also warrant public disclosure even though no single interest exceeds $5,000.

--States that the criteria is not rigid and may be modified to fit individual situations. For example, where an SGE's university receives funds principally from a firm involved with products regulated by the employing bureau/office, a restriction on an SGE's participation may be necessary.

--Clarifies the circumstances under which an SGE's participation in FDA activities are to be restricted and where public disclosure is required.

While we believe this revised guidance significantly advanced policy development, we still have some concerns. Our primary concern is that the guidance does not provide policy for certain groups of SGEs.

--The guidance is directed at SGEs who deal with products which can be associated with specific firms. But about 60 SGEs are members of (1) the National Advisory Food and Drug Committee, (2) the Science Advisory Board, and (3) the Medical Radiation Advisory Committee which do not, or only sometimes, deal with products. In addition, many of FDA's approximately 290 consultants and experts work in areas which transcend any single class of products.

--The guidance does not address what the policy is for nonvoting industry and consumer representatives to public advisory committees who, at their election, may become SGEs. These representatives number about 65 (37 of which are SGEs) but collectively hold about 75 positions. One industry representative holds a position on six panels and another holds a position on four panels. FDA told us that pending a decision as to whether it will continue using these representatives, no new representatives were being appointed. FDA also said that conflict-of-interest determinations on reappointments will be made on a case by case basis.

--The guidance does not address situations where voting members of committees are selected from FDA-regulated industry. For example, the seven members on the Board of Tea Experts are associated with the tea industry because the legislation establishing this board requires that they be experts in their field. The Technical Electronic Product Radiation Safety Standards Committee requires that 5 of its 15 committee members be selected from the affected industries.

Because the written policy guidance has not been clear for these groups of employees, the practices found in reviewing SGE's case files were inconsistent. Generally, restrictions were not placed on the activities of non-product-oriented advisory committee members regardless of their financial interests, whereas consultants were restricted from participating in all matters in which they had employment or other financial interests. The rationale for these decisions was not contained in the case files.

We believe it is simply not sufficient to place limitations only on an SGE's employment and financial interests with firms involved with products the employing bureau/office regulates. Certain diversified firms are involved with products which, to varying degrees, are regulated by more than one FDA bureau/office. Appointing many individuals with considerable financial interests related to FDA activities increases the probability that a conflict-of-interest situation may occur. Public confidence in FDA's decisions could be affected adversely if many SGEs are perceived to have significant financial interests related to FDA activities.

We believe that FDA's policy should be clearly stated for SGEs working in non-product-oriented capacities or representing special interests either in a voting or nonvoting role. Further, we believe that FDA's practices in excluding SGEs from activities in which they have employment or financial interests should be consistent. In any event, the rationale for the exclusions or nonexclusions should be made clear in their files, to the extent it is not covered in policy guidance.

Revisions needed in form used to collect financial disclosure information

The "Confidential Statement of Employment and Financial Interest" does not provide FDA with the information needed to apply policy guidance. FDA said they were revising the form which might, among other things, require information on the dollar value of stock holdings, research grants and contracts; consultancy earnings and time periods; and details of past and present involvements in petitions before the agency. FDA officials told us that they had been obtaining supplementary data needed to conduct the conflict-of-interest review, in accordance with staff manual guide criteria, without the use of any standardized document or procedure since December 1975.

In addition to not requesting all needed information, various other modifications and revisions to this form would make it more responsive to FDA's needs.

--Clarification is needed concerning how much change can occur in each category of employment or financial interests before it must be reported and approved by FDA.

--All financial interests in firms or organizations should be reported, regardless of whether they involve FDA-regulated products, rather than requesting that the employee list only organizations which produce or market products regulated by FDA. In this way FDA would assume more responsibility for identifying potential conflict-of-interest situations.

FDA officials stated that they had not revised this form pending approval of policy. Once this is done, FDA will then be in a position to decide the format for gathering the information needed to implement the policy.

Policy needed concerning organizational level and responsibilities of reviewing officials

Formalized procedures are needed for reviewing the "Confidential Statement of Employment and Financial Interest" to assure that FDA's policy on conflict of interest is completely and accurately implemented. These procedures would be particularly useful for individuals in bureaus or regional offices who do this work infrequently and need help in understanding what is expected to satisfy the policy guidance.

The responsibilities of the official making the initial conflict of interest recommendation also need to be set forth in writing, along with his position in the organization. The Director, Policy Management Staff, told us that, in his opinion, this recommendation should be made at the bureau Deputy Director level or above. In two bureaus the official making this recommendation was at the Deputy Director level, but in the other four bureaus this official was the Committee Management Officer, the Executive Officer, an Assistant Director, and a Division Director.

FDA officials agreed that these written procedures would be helpful. However, the development of such procedures would follow approval of policy and revision of the statement.

PROCEDURES AND PRACTICES TO PREVENT COMMITTEE MEMBERS FROM PARTICIPATING IN PROHIBITED MATTERS NEED IMPROVEMENT

The responsibility for making sure that committee members do not participate in matters in which they have employment or other financial interests and are to be disqualified rests with the executive secretary of each committee. We were told that the executive secretaries were expected to know what each member of their committees was prohibited from participating in. The tests disclosed instances where executive secretaries did not have all the information needed to carry out this responsibility.

We talked to four executive secretaries, who stated that they check the HEW-410 "Supplemental Information--Expert or Consultant" listing of prohibited firms against the agenda of the meetings to determine whether matters involving the restricted companies are coming before the committee. In cases where the agenda only lists products, it is the responsibility of the executive secretary to relate these products to specific firms involved with them. These officials said that generally the minutes of the committee meetings stated who was disqualified, and in some cases gave the reason, but that there was no standard format used between committees or bureaus.

Three executive secretaries who preside over seven committees stated that since these committees came into existence they collectively could remember only eight occasions in which members of these committees had been disqualified from participating in a meeting. The other executive secretary, who is responsible for three committees, stated that there had never been a case where a member on any of these committees was disqualified from a meeting.

On May 31, 1976, a total of 88 members was on these 10 committees. We matched the restrictions which should have been placed on 80 individuals (based on the conflict-of-interest review) with the information in the hands of these executive secretaries. The executive secretaries did not have complete information on restrictions for 11 members and had no information for 1 member.

We believe that procedures need to be established to make sure that the executive secretaries have ready access to complete and current information on prohibited interest for members of their committees.

SYSTEM OF PUBLIC DISCLOSURE NEEDS TO BE FORMALIZED

PRDC memoranda make public the facts and issues surrounding potentially controversial situations. There are approximately 680 SGEs with one or more employment or financial interests. FDA told us that in using the criteria set forth in the January 1976 draft staff manual guide they determined that certain information on 43 SGEs should be publicly disclosed. As of August 31, 1976, 38 memoranda were on file in FDA's Public Records and Documentation Center, 3 were in process, and 2 more were finalized but were not on file. Most of these memoranda covered reappointments (only 6 cover initial appointments) and were processed in the last year.

FDA has not developed written procedures setting forth what information PRDC memoranda should include and in what format. FDA officials told us that many practices had changed since this system became effective early in 1975.

Inconsistencies in the nature and format of the information presented in the memoranda, in our opinion, diminished their effectiveness.

--In about one-half of the cases, the dollar amount of the employment or financial interest was not stated or the time frame (when applicable) relating to the interest was not indicated.

--In about 80 percent of the cases, the memoranda did not state either the committee's function in relation to the financial interest or whether this interest is [illegible]n a matter which comes before the employing committee.

--In about 40 percent of the cases neither the function of the committee was discussed nor was any mention made as to whether the interest would be of concern to it.

In many instances, public disclosure of matters described in the PRDC memoranda was not required.

--In certain cases there was no indication that the interests (financial assets, consultantships, grants and contracts) involved products in the industry regulated by the employing bureau or

office. In some cases, the statement was made that neither the company nor product came before the SGE's committee. According to the staff manual guide criteria, only interests in the employing bureau/office, above a specified dollar limit, require public disclosure.

--In some cases involving contracts and grants, the SGE's university was the recipient and it appeared that they were controlled by members of the faculty other than the SGE. The staff manual guide states that these interests are "too remote to affect the integrity of the employee's services."

--Based on the dollar criteria set forth in the staff manual guide, public disclosure was not required for 4 of the 11 SGEs having stock interests disclosed in these memoranda. Public disclosure was also not required based on dollar criteria in two cases involving contracts and grants.

On the other hand, we found that certain financial interests were up to 12 times the criteria limits and potential conflict-of-interest situations were not publicly disclosed.

--In one case the final conflict-of-interest determination was made on the condition that certain items were to be disclosed in a PRDC memorandum. This memorandum was not completed and FDA officials could not explain why.

--In another case an SGE reported that he was involved with two research grants totaling $500,000 from FDA-regulated firms. He was prohibited from participating in activities relating to these companies because this research related to the work he was doing for FDA. However, this situation was not publicly disclosed in a PRDC memorandum. FDA officials advised us that a PRDC memorandum would be completed if this indivdual was reappointed.

We also found that there was no procedure to make sure that all finalized PRDC memoranda were available for public review. Further, there was no requirement that the memoranda on file be renewed upon the receipt of updated statements.

We found that two of the finalized memoranda were apparently lost after being sent to the Public Records and Documentation Center. Of the memoranda on file, five were

more than 1 year old and there was no indication in the file as to whether the information was still current.

FDA officials advised us that PRDC memoranda were updated only when there was a change in the financial information on file. In the absence of a change, they are to remain on file indefinitely with no notation being made on the memoranda that the information is still current.

Conclusion

FDA needs to formalize its procedures to make sure that the facts surrounding potentially controversial cases are presented in a clear and consistent manner.

The memoranda should:

--State why FDA believes the interest is being made a matter of public record.

--Indicate the relationship between the interest and the work done by the SGE.

--Provide other relevant data, such as the dollar amount of the interest and the period applicable to the interest, if appropriate.

--Follow a consistent format for presenting the information.

--If more than 1 year old, indicate through periodic notations that the information is still current.

We believe that the matters made public in these memoranda should be consistent with FDA policy. Further, the trigger mechanism for the preparation of these memoranda should be consistently applied. Describing interests far below the dollar criteria required by FDA policy gives a misleading impression as to what the criteria is and what interests are routinely made public based on this criteria.

CHAPTER 5

REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

We reviewed case files covering a total of 906 SGEs who were active as of May 31, 1976, or were appointed or reappointed between May 31 and July 31, 1976. Generally, we found that financial disclosure statements were being filed by SGEs and reviewed by FDA in a timely manner and in accordance with FDA policy. As discussed below, however, we found cases where (1) statements were missing, (2) conflict-of-interest determinations were tardy, (3) financial disclosure information was not current at the time of appointment, and (4) required information was either not recorded or unclear.

On a selected basis, we reviewed several of these files in greater detail to gain a better overall perspective as to the effectiveness of FDA's system. This aspect of our review showed (1) that conflict-of-interest determinations were not always documented and (2) inconsistencies in the restrictions placed on the activities of SGEs. As discussed in chapter 4, we found two cases which, according to FDA criteria, should have been publicly disclosed but which were not. The majority of the errors we found occurred before FDA formalized its policy guidance in January 1976.

MISSING STATEMENTS

There was no "Confidential Statement of Employment and Financial Interest" in the file for five SGEs for any reappointment cycle since the SGEs were initially appointed between October 1972 and September 1973. All of these members were on the Medical Radiation Advisory Committee in the Bureau of Radiological Health which has a total of 13 members. Members of this committee are given appointments for the full period they are expected to serve rather than a series of 1-year appointments. The Director, Policy Management Staff, was not aware that appointments were being made beyond 1 year intervals and had not established a mechanism to alert him each year when it was time for the SGE to submit another financial disclosure statement. This official told us that such a procedure had been developed since we brought this problem to his attention.

TARDY CONFLICT-OF-INTEREST DETERMINATIONS

FDA policy requires all statements to be reviewed and a final conflict-of-interest determination made before an SGE's appointment. We found four cases, however, in which

the final conflict-of-interest determination was made after the beginning of the appointment period. In three of these cases, the period between the appointment and determination date was less than 1 week, but in one case it was 39 days. After we brought these cases to their attention, FDA officials stated they took action to assure that there would not be a recurrence of this problem.

FINANCIAL DISCLOSURE INFORMATION NOT CURRENT AT TIME OF APPOINTMENT

There is no maximum length of time which may elapse between the effective date of the information submitted (when the SGE dates the statement) and the start of the appointment period. The criteria informally applied by the Director, Policy Management Staff, is that this total period should not exceed 6 months. We found eight cases where this period was over 6 months, three of which were over 7 months. In an additional 44 cases, the timeframe from the date the statement was signed to the first review was between 4 and 6 months.

We believe that a policy needs to be established designating the maximum period of time permissible between the effective date of the financial disclosure information and the beginning of the appointment period. In cases where the statement is submitted by the SGE 6 months in advance of the start of his appointment, which is acceptable under present criteria, this data can be up to 18 months old before his appointment period ends and if reappointed, is required to submit a new statement.

REQUIRED INFORMATION EITHER NOT RECORDED OR UNCLEAR

Required information was not always recorded on the statements, including conflict-of-interest determinations.

--In six cases, the applicant had not dated the statement and there was no way to determine the effective date of the information.

--In eight cases, the first review official (responsible line office in the bureau/office) had not signed, dated, or indicated a conflict-of-interest recommendation on the statement.

--In three cases, the second review official (Director, Policy Management Staff) had not signed, dated, or indicated a conflict-of-interest determination on the statement.

--In ie case, no conflict-of-interest determination had been made either by the first or by the second review official. We found a total of 26 cases where this determination had not been indicated on the statement by the first review official and 14 lacking this determination by the second review official.

We found instances where the Director, Policy Management Staff, in making a conflict-of-interest determination, indicated "no conflict noted" even though the file contained a reference to restrictions placed on the SGE's activities; in some of these cases a PRDC memorandum was on file. In these cases the statements did not, by themselves, give an accurate picture of the extent to which the potential for conflict of interest was present.

CONFLICT-OF-INTEREST DETERMINATIONS NOT ALWAYS DOCUMENTED

We noted several cases where there was either insufficient information in the case file to support a conflict of interest determination or all relevant information on which to base this determination was not in the file.

--In two cases, supporting documents referred to on the statement were not in the file.

--In two cases, the information needed (i.e. the value of stocks when the number of shares is known) was not documented, although it was available from public sources.

--In some cases we had to obtain additional information from reviewing officials within the agency to find out the basis for the conflict-of-interest determinations.

In three cases a conflict-of-interest determination was made on an interim basis with the understanding that a final determination would be made upon receipt of additional information from the SGE. The information on which the interim determination was made was not adequate for a final determination and in one of these cases the SGE never supplied the additional information requested.

In other cases we found that no conflict-of-interest determinations had been made on revised statements. In one case the SGE submitted a revised statement to inform the agency that he was doing clinical work involving several new drugs. In two cases SGEs reported that they had

increased their financial interests in FDA-regulated industry. FDA officials informed us that these cases had occurred some time back and that all such cases were presently being reviewed.

These FDA officials stated that, as a general rule, they were not concerned about documenting the steps they had taken to clear SGEs for either appointment or reappointment if this served no other purpose than to document the fact that their actions were proper. In fact, the Director, Policy Management Staff, stated that he generally discouraged the official reviewing the statement from documenting the information developed in his review on such matters as dollar value of financial holdings.

We do not agree with this practice. We believe that the information in the files should be adequate to make sure that all cases have been properly reviewed and that conflict-of-interest determinations are made in accordance with FDA policy and criteria. A clear record of the actions taken to clear an SGE for conflict of interest may also prove useful to FDA when similar reviews are made yearly prior to reappointment.

INCONSISTENT TREATMENT OF RESTRICTIONS

FDA policy does not allow SGEs to participate in matters relating to specific firms in which they have financial interests, if these firms are involved with products regulated by the employing bureau/office and are above a prescribed dollar amount. We found some inconsistencies in the circumstances giving rise to restrictions being made a matter of record. Since it was not always clear from the SGE's case file what restrictions the reviewing officials intended should be placed on his activities, we had to rely on the accuracy of the HEW-410, "Supplemental Information--Expert or Consultant," in the personnel file in making our observations.

--Restrictions in several cases covered interests in FDA-regulated companies outside the employee's assigned bureau/office and in companies not regulated by FDA. For example, one SGE owned stock in 26 companies, some of which produce FDA-regulated products. According to FDA policy, no restrictions were required because his duties and responsibilities did not directly involve products or firms. Yet restrictions were placed on his activities relating to

the 26 companies, even those not involved with FDA-regulated products. FDA officials said they were not concerned that these practices were inconsistent with the policy as long as they were more conservative than required by policy.

--In cases involving members of the National Advisory Food and Drug Committee, we found that restrictions were not placed on their activities, even though they had interests with FDA-regulated industry. FDA officials stated that because members of this committee were involved with broad policy issues in a number of areas, which do not directly relate to products or firms, restrictions were not appropriate.

--In some cases companies sponsoring investigational new drugs and new drug applications are entered as restrictions and in other cases they are not. FDA officials stated that the policy guidance did not specifically cover these cases but, in their opinion, no restrictions were required for these companies.

--In one case a member of the Board of Tea Experts had financial involvement with the tea industry, but restrictions were not placed on his activities. FDA officials stated that based on the requirements of the legislation establishing this committee, they believed its members must come from the tea industry. They further pointed out that all tea testing is done blind and members of the broad do not have an opportunity to give preferential treatment to any of the teas tested.

We believe that FDA's practices concerning restrictions should be consistent and reflect agency policy. Placing more restrictions on SGEs than is necessary creates additional work for FDA officials responsible for making sure that they do not participate in prohibited activities.

CONCLUSIONS

Based on the errors and inconsistencies we found in reviewing SGE files, we believe that there is a need for more definitive policy guidance as well as written procedures to make sure that FDA policy is being completely and accurately carried out. These problems point up the need for better management control so that SGEs working for FDA are not involved in potential conflict-of-interest situations.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

FDA is responsible for protecting the Nation's consumers against impure and unsafe foods, drugs, cosmetics, and other potential hazards. FDA believes SGEs are essential to the effective accomplishment of its mission. To maintain public confidence in its decisions, it is essential that its SGEs adhere to the highest ethical standards.

But conflict-of-interest determinations relating to SGEs are, in many cases, difficult. FDA is most often a secondary employer. Many SGEs have employment or other financial relationships with FDA-regulated industry. Options available to eliminate potential conflicts of interest for regular employees, such as job reassignment or divestiture, in most cases, are not appropriate for SGEs. Also, FDA believes that the conflict-of-interest statutes are not always clear as they relate to SGEs. FDA has had problems interpreting certain key phrases and, in general, this has made the development of conflict-of-interest regulations and guidelines exceedingly difficult.

Before January 1976, FDA made case-by-case judgments concerning conflict of interests based on the Federal statutes and the Department's regulation. In January 1976, FDA issued draft policy guidance for SGEs to be used on a pilot basis until FDA gained experience with the policy in operation as well as resolve various legal issues. In October 1976, FDA revised its policy guidance based on 9 months of operating experience and concerns we expressed during our review. Most of the errors and inconsistencies found in reviewing SGEs' case files can be traced to the lack of formalized policy guidance prior to January 1976.

We believe that FDA's recent actions have increased the effectiveness of the system to protect against conflict-of-interest situations for SGEs. However, much remains to be done to complete system development and to integrate its components. Of primary importance is the need for FDA to submit its policy guidance to the Department and CSC for approval and develop implementing procedures. Until this is done, we believe that FDA cannot satisfactorily assure itself that all potential conflict-of-interest situations are being surfaced.

RECOMMENDATIONS

We recommend that, to improve the effectiveness of the FDA financial disclosure system for SGEs, the Secretary of HEW:

--Actively assist FDA in developing a policy to protect the Government against conflict-of-interest situations and resolving difficult policy issues with regard to the employment of SGEs. One avenue for doing this would be through the issuance of a supplemental regulation covering SGEs.

--Require the Commissioner of FDA to:

(a) Complete system development which involves (1) developing policy to provide guidance for special Government employees not covered by present policy guidance, (2) submitting its policy guidance to HEW and CSC for approval, (3) developing specific procedures to make sure policy is implemented, and (4) improving the form used to collect financial disclosure information.

(b) Issue specific guidelines clearly defining the responsibilities of the officials making the initial conflict-of-interest recommendation and the position this individual should be in the agency.

(c) Develop procedures to provide responsible officials with adequate information to make sure that SGEs do not participate in FDA matters in which they have financial interests and are disqualified.

(d) Develop written procedures setting forth what information should be included in public disclosure memoranda and the format to be used in order that the information be presented in a consistent and understandable manner.

(e) Improve procedures to make certain that all public disclosure memoranda are, in fact, received by the Public Records and Documentation Center and made available for public review. In cases where the information contained in these memoranda does not change in subsequent reappointment cycles, notations should be made periodically on these memoranda that the information is still current.

(f) Establish a policy designating the maximum period in which financial information can be submitted

before the beginning of an SGE's appointment period.

(g) Develop written procedures as to what information should be documented in an SGE's case file which served as the basis for the conflict-of-interest determination and the restrictions placed on an SGE's activities.

CHAPTER 7

SCOPE

We made our review primarily at FDA headquarters, Rockville, Maryland. It was made pursuant to a request from the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce. We were asked to consider whether:

--FDA has an effective financial disclosure system for SGEs.

--Financial disclosure statements are filed promptly by SGEs and reviewed by FDA in a timely manner.

--SGEs appear to have financial conflicts of interest which could affect the quality and objectivity of their work for FDA.

A principal objective was to evaluate FDA's system to surface and effectively deal with conflict-of-interest situations relating to an SGE's personal financial interests. This included FDA's (1) policy for making conflict-of-interest determinations and supporting procedures, (2) procedures and practices to prevent committee members from participating in restricted activities, and (3) system to publicly disclose potentially controversial cases.

We reviewed 906 SGE case files, 810 of which were active as of May 31, 1976, and another 96 covering initial appointments or reappointments of inactive SGEs between May 31 and July 31, 1976. These cases were reviewed to determine whether (1) all statements were filed, (2) the statements were filed and reviewed in a reasonable time frame, and (3) they were properly filed and adequately reviewed.

We also selected files where some type of problem appeared to exist; i.e., certain information seemed to be missing, the SGE had employment and financial interests in several categories, the case involved several complex issues not clearly covered by agency policy and criteria, or a PRDC memorandum was in the file. We reviewed these cases to gain a perspective on the effectiveness of the overall system.

We did not reveal any cases involving actual conflict of interest. However, we did not evaluate specific financial interests in relation to an individual's stated duties and

responsibilities nor did we talk with SGEs regarding their actual duties or financial interests. The confidentiality of employees who filed these statements was maintained at all time.

GAO REPORTS ON AGENCIES' FINANCIAL DISCLOSURE SYSTEM

Agency	Report title, number, and issue date
Federal Power Commission	Need for Improving the Regulation of the Natural Gas Industry and Management of Internal Operations, B-180228, 9/13/74.
Department of the Interior	Effectiveness of the Financial Disclosure System for Employees of the U.S. Geological Survey, FPCD-75-131, 3/3/75.
Civil Aeronautics Board	Effectiveness of the Financial Disclosure System for Civil Aeronautics Board Employees Needs Improvement, FPCD-76-6, 9/16/75.
Federal Maritime Commission	Improvements Needed In the Federal Maritime Commission's Financial Disclosure System For Employees, FPCD-76-16, 10/22/75.
U.S. Railway Association	Improvements Needed In Procurement and Financial Disclosure Activities of the U.S. Railway Association, RED-76-41, 11/5/75.
Department of the Interior	Department of the Interior Improves Its Financial Disclosure System For Employees, FPCD-75-167, 12/2/75.
Department of Health, Education, and Welfare	Financial Disclosure System for Employees of the Food and Drug Administration Needs Tightening, FPCD-76-21, 1/19/76.
Department of the Interior	Letter report to Congressman John Moss on U.S. Geological Survey Employees' Divestiture, FPCD-76-37, 2/2/76.

APPENDIX I

Agency	Report title, number, and issue date
Inter-American Foundation	Inter-American Foundation's Financial Disclosure System for Employees and its Procurement Practices, ID-76-69, 6/30/76
Department of Transportation	Problems with the Financial Disclosure System, Federal Aviation Administration, FPCD-76-50, 8/4/76
Department of Commerce	Problems Found In the Financial Disclosure System For Department Of Commerce Employees, FPCD-76-55, 8/10/76.
Small Business Administration	Management Control Functions Of The Small Business Administration--Improvements Are Needed, GGD-76-74, 8/23/76
Export-Import Bank	Export-Import Bank's Finacial Disclosure System For Employees and Its Procurement Practices, ID-76-81, 10/4/76

APPENDIX II

STAFF MANUAL GUIDE
FOOD AND DRUG ADMINISTRATION

GUIDE FDA 3118.2

PERSONNEL - SPECIAL GOVERNMENT EMPLOYEES

PROTECTION AGAINST CONFLICT OF INTEREST

1. Purpose
2. Applicability
3. Employee Responsibilities
4. Federal Conflict of Interest Statutes
5. Interpretation of Certain Statutory Terms
6. Preappointment Screening
7. Investments
8 Employment
9. Grants and Contracts
10. Investigators of Products Subject to Premarket Clearance
11. Post Employment Restrictions
12. Summary of Restrictions

Attachment A - Subpart "L" - Department Standards of Conduct

Attachment B - CSC Regulations - Prohibitions on Conduct

Attachment C - Subpart "G" - Standards of Conduct and Conflict of Interest (FDA FR Notice of May 27, 1976)

1. PURPOSE. The purpose of this guide is to set forth Agency policy and procedures for avoiding conflicts of interest on the part of special Government employees (SGE's), and dealing with the appearance of such conflicts.

2. APPLICABILITY. These regulations apply to all SGE's serving as FDA advisory committee members, panel members, ad hoc consultants and advisors, and expert reviewers. Employees of other Federal agencies (e.g., NIH, VA) who serve FDA in the above-mentioned capacities are also expected to comply with these regulations for purposes of Federal Conflict of Interest Statutes and Department Standards of Conduct Regulations. These regulations do not apply to state or local Food and Drug Officials commissioned under the Food, Drug and Cosmetic Act, or other Acts administered by the Agency.

3. EMPLOYEE RESPONSIBILITIES. An SGE must conduct himself according to ethical behavior of the highest order. He must refrain from any use of his position which is, or even appears to be, motivated by a private gain for himself or other persons. To comply with these requirements, an SGE should familiarize himself with the Federal Conflict of Interest Statutes quoted from the following section; Subpart "L" of the DHEW

APPENDIX II

Standards of Conduct (Attachment A); the CSC Regulations covering Prohibitions on Conduct (Attachment B); and Subpart "G" of the FDA Procedural Regulations (Attachment C). One must also be familiar with the specific FDA guidance provided in this document. In circumstances where this guidance is not specific or clear, it is the employee's responsibility to seek advice on such matters. The Executive Secretary of the Committee or Panel with which he is serving and/or the Committee Management or Administrative staffs of the FDA Bureau, Regional Office or other sub-organization which processed his appointment can refer an SGE to the appropriate FDA officials who will assist in resolving such questions.

4 FEDERAL CONFLICT OF INTEREST STATUTES. The Federal statutes pertaining to Conflict of Interest provide the basis for Civil Service Commission, Departmental, and Agency regulations. All prospective SGE's should familiarize themselves with the relatively brief statutes which are reproduced in full below.

18 U.S.C. § 203, Compensation to Members of Congress, officers, and others in matters affecting the Government.

(a) Whoever, otherwise than as provided by law for the proper discharge of official duties, directly or indirectly receives or agrees to receive, or asks, demands, solicits, or seeks, any compensation for any services rendered or to be rendered either by himself or another–

(1) at a time when he is a Member of Congress, Member of Congress Elect, Resident Commissioner, or Resident Commissioner Elect; or
(2) at a time when he is an officer or employee of the United States in the executive, legislative, or judicial branch of the Government, or in any agency of the United States, including the District of Columbia.

in relation to any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest, before any department, agency, court-martial, officer or any civil, military, or naval commission, or

(b) Whoever, knowingly, otherwise than as provided by law for the proper discharge of official duties, directly or indirectly gives, promises, or offers any compensation for any such services rendered or to be rendered at a time when the person to whom the compensation is given, promised, or offered, is or was such a member, Commissioner, officer, or employee–

Shall be fined not more than $10,000 or imprisoned for not more than two years, or both; and shall be incapable of holding any office of honor, trust, or profit under the United States.

(c) A special Government employee shall be subject to subsection (a) only in relation to a particular matter involving a specific party or parties (1) in which he has at any time participated personally and substantially as a Government employee or as a special Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise, or (2) which is pending in the department or agency of the Government in which he is serving: Provided, That clause (2) shall not apply in the case of a special Government employee who has served in such department or agency no more than sixty days during the immediately preceding period of three hundred and sixty-five consecutive days. (Added Pub. L. 87-849, § 1(a), Oct. 23, 1962, 76 Stat. 1121.)

18 U.S.C. § 205. Activities of officers and employees in claims against and other matters affecting the Government.

Whoever, being an officer or employee of the United States in the executive, legislative, or judicial branch of the Government or in any agency of the United States, including the District of Columbia, otherwise than in the proper discharge of his official duties–

(1) acts as agent or attorney for prosecuting any claim against the United States, or receives any gratuity, or any share of or interest in any such claim in consideration of assistance in the prosecution of such claim, or

(2) acts as agent or attorney for anyone before any department, agency, court, court-martial, officer, or any civil, military, or naval commission in connection with any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest--

Shall be fined not more than $10,000 or imprisioned for not more than two years, or both.

A special Government employee shall be subject to the preceding paragraphs only in relation to a particular matter involving a specific party or parties (1) in which he has at any time participated personally and substantially as a Government employee or as a special Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise, or (2) which is pending in the department or agency of the Government in which he is serving: Provided, That clause (2) shall not apply in the case of a special Government employee who has served in such department or agency no more than sixty days during the immediately preceding period of three hundred and sixty-five consecutive days.

Nothing herein prevents an officer or employee, if not inconsistent with the faithful performance of his duties, from acting without compensation as agent or attorney for any person who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings.

Nothing herein or in section 203 prevents an officer or employee, including a special Government employee, from acting, with or without compensation, as agent or attorney for his parents, spouse, child, or any person for whom, or for any estate for which, he is serving as guardian, executor, administrator, trustee, or other personal fiduciary except in those matters in which he has participated personally and substantially as a Government employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, or which are the subject of his official responsibility, provided that the Goverment official responsible for appointment to his position approves.

Nothing herein or in section 203 prevents a special Government employee from acting as agent or attorney for another person in the performance of work under a grant by, or a contract with or for the benefit of, the United States provided that the head of the department or agency concerned with the grant or contract shall certify in writing that the national interest so requires.

Such certification shall be published in the Federal Register.

Nothing herein prevents an officer or employee from giving testimony under oath or from making statements required to be made under penalty for perjury or contempt. (Added Pub. L. 87-849, § 1(a), Oct. 23, 1962, 76 Stat. 1122.)

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18 U.S.C. § 207. Disqualification of former officers and employees in matters connected with former duties or official responsibilities; disqualification of partners.

(a) Whoever, having been an officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia, including a special Government employee, after his employment has ceased, knowingly acts as agent or attorney for anyone other than the United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially as an officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, while so employed, or

(b) Whoever, having been so employed, within one year after his employment has ceased, appears personally before any court or department or agency of the Government as agent, or attorney for, anyone other than the United States in connection with any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter involving a specific party or parties in which the United States is a party or directly and substantially interested, and which was under his official responsibility as an officer or employee of the Government at any time within a period of one year prior to the termination of such responsibility--

Shall be fined not more than $10,000 or imprisoned for not more than two years, or both: Provided, That nothing in subsection (a) or (b) prevents a former officer or employee, including a former special Government employee, with outstanding scientific or technological qualifications from acting as attorney or agent or appearing personally in connection with a particular matter in a scientific or technological field if the head of the department or agency concerned with the matter shall make a certification in writing, published in the Federal Register, that the national interest would be served by such action or appearance by the former officer or employee.

(c) Whoever, being a partner of an officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia, including a special Government employee, acts as agent or attorney for anyone other than the United States, in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest and in which such officer or employee of the Government or special Government employee participates or has participated personally and substantially as a Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise, or which is the subject of his official responsibility

Shall be fined not more than $5,000, or imprisoned not more than one year, or both.

A partner of a present or former officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia or of a present or former special Government employee shall as such be subject to the provisions of sections 203, 205, and 207 of this title only as expressly provided in subsection (c) of this section. (Added Pub. L. 87-849, § 1(a), Oct. 23, 1962, 76 Stat. 1123.)

18 U.S.C. § 208. Acts affecting a personal financial interest.

(a) Except as permitted by subsection (b) hereof, whoever, being an officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia, including a special Government employee, participates personally and substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest–

Shall be fined not more than $10,000, or imprisoned not more than two years, or both.

(b) Subsection (a) hereof shall not apply (1) if the officer of employee first advises the Government official responsible for appointment to his position of the nature and circumstances of the judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter and makes full disclosure of the financial interest and receives in advance a written determination made by such official that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such officer or employee, or (2) if, by general rule or regulation published in the Federal Register, the financial interest has been exempted from the requirements of clause (1) hereof as being too remote or too inconsequential to affect the integrity of Government officers' or employees' services. (Added Pub. L. 87-849, § 1(a), Oct. 23, 1962, 76 Stat. 1124.)

18 U.S.C. § 209. Salary of Government officials and employees payable only by United States.

(a) Whoever receives any salary, or any contribution to or supplementation of salary, as compensation for his services as an officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia, from any source other than the Government of the United States, except as may be contributed out of the treasury of any State, county, or municipality; or

Whoever, whether an individual, partnership, association, corporation, or other organization pays, or makes any contribution, to, or in any way supplements the salary of, any such officer or employee under circumstances which would make its receipt a violation of this subsection–

Shall be fined not more than $5,000 or imprisoned not more than one year, or both.

(b) Nothing herein prevents an officer or employee of the executive branch of the United States Government, or of any independent agency of the United States, or of the District of Columbia, from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit-sharing, stock bonus, or other employee welfare or benefit plan maintained by a former employer.

(c) This section does not apply to a special Government employee or to an officer or employee of the Government serving without compensation, whether or not he is a special Government employee, or to any person paying contributing to, or supplementing his salary as such.

(d) This section does not prohibit payment of acceptance of contributions, awards, or other expenses under the terms of the Government Employees Training Act (Public Law 85-507, 72 Stat. 327; 5 U.S.C. 2301-2319, July 7, 1958). (Added Pub. L. 87-849, § 1(a), Oct. 23, 1962, 76 Stat. 1125.)

5. INTERPRETATION OF CERTAIN STATUTORY TERMS. The Conflict of Interest Statutes and regulations are designed intentionally to cover a variety of employment situations and relationships with private sector organizations in government agencies with widely differing missions. As a result, the statutes contain several key statements and phrases which need to be given a specific interpretation in the light of FDA's regulatory role and its specific use of SGE's:

a. Personal and Substantial Participation. Each of the aforementioned Federal Conflict of Interest Statutes apply specifically when an SGE participates "personally and substantially" in a particular matter. As a general principle, participation "personally and substantially as an...SGE" shall be deemed to have occurred in a particular matter if the SGE conducted an in-depth review of an application or a special evaluation of data (e.g., expert review of an IND or NDA, food additive petition, product preclearance, or detailed review of data submitted to an OTC panel), or if the SGE has served as chairman of an advisory committee or panel.

There have been a number of questions about the extent to which participation by a member of an advisory committee (as opposed to the chairman or experts) should be considered personal and substantial. The agency has considered this question carefully and although the extent to which a single committee member could influence the outcome of a committee may be somewhat less than the chairman or an expert reviewer, the agency has concluded that participation would probably be considered "substantial" by those most familiar with these statutes and responsible for interpreting them whenever a committee acts through a decision, recommendation, approval, disapproval, the rendering of advice, or other action described in 18 U.S.C. 205 (with or without a formal vote).

This is important because 18 U.S.C. 207 places certain restrictions on the post-employment activities of an employee, including an SGE, concerning any particular matter in which the employee has personally and substantially participated. However, FDA

believes most questions which might concern an SGE in this regard will ordinarily be resolved on the basis of whether the participation involved a particular matter, or the same particular matter, rather than whether the participation was personal and substantial. This is discussed in Section 5b below.

It is not the intention of the FDA to preclude SGE's from continuing to work in their field or to place them in danger of violating the law. Therefore, the Agency is prepared to advise present and former SGE's in any situation where an SGE is uncertain whether his current or past participation on behalf of FDA would be considered as "Personal and Substantial." Section 11 of this guide discusses post-employment restrictions in greater detail.

b. Particular Matter Involving a Specific Party. Each of the aforementioned Federal Conflict of Interest Statutes also applies specifically when an SGE is involved with a "particular matter involving a specific party or parties in which the United States is a party." This wording is important, because where a particular matter is considered there is the possibility of post-employment restrictions on current and former employees as defined in 18 U.S.C. 207. In many situations in FDA, this phrase can be understood and applied easily. For example, an individual product manufactured by a single firm which is the subject of a premarket clearance review or other regulatory action is clearly a "particular matter." A particular matter may involve only a specific use of a single product, e.g., an NDA requesting a new indication for an approved drug. In such cases, identification of the particular matter is relatively easy. In some cases, however, participation involves assistance in the formulation of general policy guidelines or procedures. Policy guidelines and procedures affecting a number of products are generally not considered particular matters by FDA.

It is the conclusion of the Agency that products of different firms, even if chemically identical, are different particular matters so long as they are the subject of separate petitions or applications, and receive separate reviews. On the other hand the Agency has concluded that decisions relating to different quantities or dose levels of the same product used for the same indication or purpose are not different particular matters.

Other situations present more difficult judgments. Opinions vary about whether different indications or uses of the same product are to be considered the same particular matter.

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In situations where the indications for use or purposes are closely related, FDA would err on the side of concluding that the decisions respecting them comprise the same particular matter. Where the indications are clearly unrelated, FDA would generally consider decisions respecting them to be different particular matters.

Activities such as the development of monographs concerning Over-the-Counter Drugs and the development of standards for classes of medical devices contemplated in the recent enactment of PL 94-295 deserve separate mention. In one sense these are broad policy documents concerned with ingredients or components that do not ordinarily have any proprietary value and may have been or will be in the future used by many different firms in many different products. A monograph or standard itself is clearly not a particular matter. Representing a product covered by the monograph or standard which includes only ingredients or components common to many products would not ordinarily be viewed as returning to the Agency on the same particular matter. Similarly, representing a product which was developed after the applicable monograph or standard was developed would not be considered returning to the Agency on the same particular matter. However, some products have an ingredient or component that is product specific, i.e., unique to that product. Where a monograph or standard deals with a product specific ingredient, the Agency would consider a decision respecting the ingredient to be a particular matter, and the SGE should not represent the product before the Agency in the future without a specific statutory exemption. There will always be instances in attempting to apply these criteria where judgment will be required. In any instance where an SGE is not certain of his legal exposure, he should seek advice from the Agency as described in Part 3 of this Staff Manual Guide.

Once having established that a particular matter exists, an SGE must determine if he faces any potential conflict of interest because of the firms involved. Normally, he must only be concerned if he or other persons specified in the statutes have an interest in the firms involved. But, there are occasional circumstances when an SGE should avoid participation in particular matters involving firms in which he has no interest.

- An SGE should avoid participation in a particular matter involving a specific firm if there is any genuine likelihood of involvement with that firm on the same matter subsequent to employment with FDA (See Section 11).

- An SGE should avoid participation in a particular matter if his financial interests, although not directly involved in the matter, would be "directly and predictably affected" by the outcome of the matter. The Department's regulations, in explaining 18 U.S.C. 208, instruct that an SGE should not participate in a matter which will have a "direct and predictable effect" on the SGE's financial interests. There are a variety of circumstances under which an SGE's participation might appear to have a direct and predictable effect on an SGE's financial interests even though the specific matter under consideration does not involve a firm in which the SGE has an interest, e.g., an adverse decision on a competitor's product in a market where only two firms compete. The Agency frequently will not be able to foresee all such situations at the time of appointment. Thus, SGE's must exercise judgment in avoiding participation in such situations and should seek Agency advice whenever a question arises.

c. Financial Interest. The phrase "financial interest" contained in 18 U.S.C. 208 shall include interests of an SGE, the spouse, minor child, partner, or organization with which the SGE is employed or negotiating employment. The interests include financial assets, investments, salaries, consultant fees, retainers, or contractural relationships with firms involved with products regulated by the particular FDA bureau/office employing the SGE. The term "firms" is used repeatedly in Sections 7, 8, 9, and 10 of this guide, and in those Sections it shall apply only to firms involved with products regulated by the particular FDA bureau/office employing the SGE.

Interests also include research grants and contracts to the laboratory under an SGE's direction, special support such as an endowed professional chair, the employment of a spouse or minor children, as well as any payments "in kind." "Personal financial interest" shall not ordinarily include grants or contracts to the SGE's university which are controlled by other members of the faculty, or investments in corporations held by the university since these financial interests are generally considered "too remote" as defined in 18 U.S.C. 208 (b)(2). Additional interests that are considered "too remote" or "too inconsequential" are discussed in Sections 7 and 8.

6. PREAPPOINTMENT SCREENING. The statutes do not establish any restriction on the decision to employ individuals who have significant financial interests related to employment activities. Rather, the

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statutes place the responsibility on the individual during and after his employment to avoid any situations involving the appearances of, or real conflict of interest. Therefore, as a strict legal matter, an agency may adopt a policy of appointing any qualified individual as an SGE, regardless of his financial interests, providing the Agency ensures conformance with the statutory requirement (i.e., avoidance of conflict or their appearances) during and after an individual's appointment. FDA has determined however, that a more stringent policy is warranted for several reasons:

- The appointment of many individuals with significant financial interests related to FDA activities would increase the probability that a statutory violation could occur through carelessness or ignorance.

- Public confidence in FDA's decisions could be affected adversely if many SGE's were believed to have significant financial interests related to FDA activities, even though each individual SGE scrupulously complied with the statutory requirement to avoid participation in particular matters involving his financial interests.

- Employment of an SGE with financial interests that would significantly restrict his activities may not be an optimal utilization of Agency funds since he would be excluded from matters in which an individual with fewer or no financial interests could participate.

For the preceding reasons, FDA has established a requirement that potential SGE's be screened thoroughly for possible conflicts of interest prior to their appointment so that any limitations on participation are established before the Agency appoints an individual. These limitations fall into three general categories:

- No restriction on an SGE's participation.

- Disqualification from participation in particular matters (including specific products, etc.) related to specific firms.

- Disqualification from participation in matters related to specific firms plus public disclosure of any substantial interests.

Whenever possible, the Agency prefers to appoint individuals whose financial interests in firms defined in Section 5c of this Guide are not substantial. However, there are situations where available

manpower in a specific scientific discipline is extremely limited in number, and/or only a few individuals have specifically needed qualifications. Moreover, certain individuals, such as industry and consumer representatives to advisory committees and members of the National Food and Drug Advisory Committee, are selected as SGE's precisely because of their specific point of view or interests.

Where an individual has financial interests or other circumstances that might make his objectivity subject to question, FDA may appoint such an individual after careful review but require public disclosure of the interest prior to appointment, which will protect the Agency, the individual, and public confidence in FDA. In these cases the Commissioner or his designee will approve the appointment.

The threshold standards for the three preceding categories, which generally correspond with increasing financial interests or degree of involvement in matters related to FDA activities, are described in the following sections. Notwithstanding these thresholds or the language in section 5c which limits FDA's concern with an SGE's financial interests to only those which are related to products regulated by the appointing bureau, the Agency shall always exercise reasonable judgment in making appointments and/or requiring disclosure. In no instance shall this preclearance process permit an SGE to participate in a particular matter in which he has an interest, unless the conditions and procedures set forth in 18 U.S.C. 208(b) have been met.

7. INVESTMENTS. Investments are a category of financial interests which are defined for purposes of this guide to include any type of financial asset such as stocks, bonds, options, notes or partnership shares which an individual SGE, his (or her) spouse, minor child, partner, employer, or prospective employer owns in firms involved with products regulated by the particular FDA bureau/office with which the prospective SGE will serve.

   a. Very modest investments do not warrant any restrictions on an SGE's participation as advisory committee member. Generally, investments in a single firm of less than $1,000 current market value will be considered "too inconsequential to affect the integrity of Government officers or employees' service" as defined in 18 U.S.C. 208 (b)(2). Also, investments in a corporate pension fund, or a university endowment that are not known or readily determinable by an individual are considered "too remote" as defined in 18 U.S.C 208(b)(2). Similarly, corporate pension funds and university endowments composed of diversified investments are generally considered "too remote."

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However, in cases where the source of funds is principally from a firm defined in Section 5c, a restriction on SGE participation may be necessary and will be included.

b. Certain levels of investments will require an individual to be disqualified from participating in matters involving the firm in which he has investments. Generally, any investments by a consultant or expert reviewer, and investments of more than $1,000 by advisory committee members will require disqualification. An SGE will be informed of these exclusions in writing at the time of appointment.

c. Investments of substantial amount or unusual nature will require an individual not only to be disqualified from matters involving the firm in which he has investments, but also to make public disclosure of such holdings when appointed. Investment in a single firm which exceeds $5,000 current market value is considered to be an amount requiring public disclosure. In addition to the dollar threshold, other circumstances may also warrant public disclosure, e.g., a combination of investments, a retainer and contracts involving a single firm, or some other exceptional situation which might be viewed as potentially embarrassing to the Agency, or misleading to the public. All public disclosure situations will require the approval of the Commissioner or his designee.

d. The Agency would prefer that SGE's not alter investments in firms defined in Section 5c during their period of service. However, in the event that investments in such firms do change, the SGE should notify the Agency immediately so that any restrictions on his participation can be modified accordingly. Individuals should not make substantial investments that might require termination of their service or public disclosure of the interest without prior consultation with the Agency.

8. EMPLOYMENT. Restrictions on SGE participation are appropriate in certain employment situations. When a prospective SGE is employed by a firm or serves as a consultant to a firm involved with products regulated by the particular FDA bureau/office with which he will serve, varying degrees of restrictions apply.

a. Certain employment situations do not warrant any restrictions on SGE participation as advisory committee members. Generally, there will be no restriction if an SGE's total remuneration from a single firm in the past 12 months was less than $1,000 and if his employment was not related to a specific matter before FDA. There are

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some exceptions to this rule noted in paragraph (b) below. Remuneration of less than $1,000 is considered "too inconsequential to affect the integrity of Government officers' or employees' service" as defined in 18 U.S.C. 208 (b)(2). Reimbursement for expenses and/or standard honoraria for presenting a scientific paper to, or participation in a scientific seminar with, the staff of a firm shall not preclude an SGE's participation or be included in the $1,000 limit described above.

b. Certain employment situations will require the individual to be disqualified from matters involving the firm in which he is/was employed. Generally, any remuneration from a firm to a consultant or expert reviewer, and total remuneration from a firm to an advisory committee member that exceeds $1,000 in the past 12 months will require the individual to be disqualified from matters involving that firm. The same restriction shall apply if the SGE receives a retainer from a firm, or serves as a member of its board of directors, regardless of the amount of remuneration received during the past 12 months. Additionally, if an individual has advised a firm at any time in the past on a matter that is now the subject of a proceeding before the Agency, the SGE is disqualified from participating in any decision related to that matter.

c. Certain levels of remuneration will require the individual not only to be disqualified from matters involving the firm with which he has been connected, but also to make public disclosure of such remuneration when the remuneration is of substantial amount or unusual nature. Remuneration from a single firm that exceeds $5,000 in the past 12 months is considered to be an amount that requires public disclosure. In addition to the dollar threshold, other circumstances may also warrant public disclosure, e.g., a substantial royalty from a firm defined in Section 5c. All public disclosure situations will require the approval of the Commissioner or his designee.

d. In some instances, individuals may receive remuneration for publication or editing activities that may be sponsored or supported by firms defined in Section 5c. Since the circumstances surrounding such activities can vary widely in terms of their potential for conflict of interest, such situations will be examined on a case-by-case basis.

e. The Agency would prefer that SGE's not enter into new employment situations with firms defined in Section 5c during their period of service. However, in the event that an SGE makes a new

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employment commitment with such firms, or negotiates with respect to one, he should notify the Agency immediately, so that any restrictions on his participation can be modified or extended accordingly.

9. GRANTS AND CONTRACTS. Restrictions on SGE participation are appropriate when the SGE is involved in, or the recipient of, certain grants and contracts. Most of the restrictions apply when the grant or contract involves a firm defined in Section 5c. Paragraph (d) of this Section also outlines precautions that must be taken with respect to grants or contracts with the Federal Government.

   a. Certain grant or contract situations will require the individual to be disqualified from matters involving the funding firm. Generally, an SGE will be excluded from matters involving a firm providing any grant or contract support in the past 12 months if the SGE is the principal investigator or is otherwise directly involved, or if he receives financial support for his laboratory, or salary support for himself or member of his research group. Otherwise, the contract or grant is likely to be "too remote" as discussed in Section 7a.

   b. An SGE who has received more than $5,000 in grant or contract support from a single firm in the past 12 months will not only be disqualified from matters involving the firm but shall also be required to make public disclosure of such interests. In addition to the dollar threshold, other circumstances may also warrant public disclosure, e.g., a long history of contracts with a single firm even if none has existed in the past 12 months. All public disclosure situations will require the approval of the Commissioner or his designee.

   c. If, during his service with FDA, an SGE receives new or increased grant or contract support from a firm or begins negotiations with a firm in expectation of such support, he should inform the Agency immediately so that restrictions on his participation can be modified or extended accordingly.

   d. FDA recognizes that SGE's may participate in grant or contract related activities that are not funded by firms defined in Section 5c. An SGE must exercise caution that any Federal grant and contract activities do not violate the provisions of 18 U.S.C. 203 and 205. These statutes prohibit a special Government employee from acting as an agent for anyone in relation to a particular matter (any proceeding, application,

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contract or other matter) which is pending in the department or agency of the Government in which he is serving as an SGE. Thus representation to the same Government department on behalf of an institution with respect to a grant or contract could inadvertently produce a violation. However, the statutes provide an exception to these restrictions when the department concerned utilizes the SGE's services for no more than 60 days during the immediately preceding 365 consecutive days. Individuals involved in such situations should be aware of the 60 day limitation, and carefully review any personal involvement in negotiation of a new Federal grant or contract for themselves or their employer or an institution with which they are affiliated. Time applied to work on a contract or grant does not count toward the 60 day limit; only time as an SGE applies.

10. INVESTIGATORS OF PRODUCTS SUBJECT TO PREMARKET CLEARANCE. Restrictions on participation are appropriate in certain situations where an SGE serves as an investigator of products subject to FDA premarket clearance.

a. Normally, there will be no restriction on an SGE who has been involved as an investigator with applications that are no longer pending before the Agency, even if he may be involved with related applications in his SGE duties.

b. An SGE ordinarily will be disqualified from participation in matters for which he has been a past or current investigator on a premarket clearance application pending before FDA, unless the Agency requires advice that cannot be obtained elsewhere. In such case the situation will be publicly disclosed. Disclosure may also be required if an SGE's past investigations or other activities have prominently identified him with a particular point of view in regard to a product or issue.

c. Investigators shall be subject to the restrictions in Section 8 if they receive any remuneration for their services, or the restrictions in Section 9 if they are funded by a grant or contract mechanism. In instances where the firm simply supplies the product under test without charge to an SGE investigator and reimburses no other costs, such restrictions shall not apply.

d. If, during his service with FDA, an SGE initiates new investigator activities, he should inform the Agency immediately so that any restrictions on his participation can be modified or extended accordingly.

11. RESTRICTION ON POST-EMPLOYMENT ACTIVITIES. 18 U.S.C. 207 prevents individuals who have left Government service, including former SGE's, from representing another person in connection with certain matters in which they participated personally and substantially on behalf of the Government. The matters are those involving a specific party or parties in which the United States is also a party or has a direct and substantial interest.

The questions created by the application of this statutory provision to specific situations are difficult. For example, FDA may appoint advisory committee members to review an entire class of products used by a particular group of scientific or medical specialists. In such situations, the prospective SGE cannot always foresee the particular matters with which he may become involved to a personal and substantial degree.

Because the Conflict of Interest Statutes were not intended to deny the Federal Government access to the highest quality scientific and medical advice, the Agency will utilize the exemption provided in the statutes when necessary. Section 207(b) of 18 U.S.C. permits the government to grant an exemption from post-employment restrictions when it is in the national interest. FDA anticipates that there will be circumstances where it will be in the national interest to consider granting such an exemption to advisory committee members and other consultants and experts.

In addition to the previous restriction, 18 U.S.C. 207 also prevents a former employee for a period of one year after his employment has ceased, from appearing personally for another person before a court, department or agency in any matter that was within the area of his official responsibility at any time during the last year of his Government service. FDA believes that this one year limitation on all particular matters would not ordinarily apply to advisory committee members because they do not have "official responsibility" in the sense intended by the statute. SGE's employed by FDA are usually involved in either broad policy and procedures covering a number of products (which are not considered a particular matter), or particular matters that are not likely to recur.

Whenever an SGE believes his service may result in a post-employment restriction, he should seek advice from FDA by contacting the particular FDA employee who has the administrative responsibility for his employment. This same official should also be contacted whenever a situation arises that pertains to an SGE's involvement with another agency or court on behalf of a party other than the Government over a matter regulated by FDA.

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12. SUMMARY OF RESTRICTIONS. Sections 7 through 10 discuss situations involving various categories of financial interests which could limit an SGE's participation. As an aid to prospective SGE's, the following table summarizes the general restrictions. For specific details and special circumstances, readers should refer to the sections of the guide noted in parentheses in the right hand column of the table.

SUMMARY OF RESTRICTIONS

TYPE OF INTEREST 1/	SIZE OR NATURE OF INTEREST	RESTRICTIONS
INVESTMENTS (Section 7)	Less than $1,000 in single firm.	No restriction in participation involving the firm. 2/ (7a)
	More than $1,000 in single firm.	Disqualified from participation involving the firm. (7b)
	More than $5,000 in single firm.	Disqualified from participation involving the firm and required to make public disclosure.
EMPLOYMENT (Section 8)	Less than $1,000 from single firm in past 12 months.	No restriction in participation involving the firm. 2/ (8a)
	More than $1,000 from single firm in past 12 months; any retainers or membership on Board of Directors.	Disqualified from participation involving the firm. (8b)
	More than $5,000 from single firm in past 12 months.	Disqualified from participation involving the firm and required to make public disclosure. (8c)
GRANT OR CONTRACT (Section 9)	Any support from single firm in past 12 months.	Disqualified from participation involving the firm. (9a)
	More than $5,000 from single firm in past 12 months.	Disqualified from participation involving the firm and required to make public disclosure. (9b)
	Any Federal grant or contract.	Possible post-employment restriction. (9c & 11)
INVESTIGATORS OF PRODUCTS SUBJECT TO PRE-MARKET CLEARANCE 2/ (Section 10)	Past involvement with application no longer pending pending before Agency.	No restriction in participation involving the firm. (10a)
	Past or current involvement with application pending before Agency.	Disqualified from participation involving the firm. (10b)
	Involvement with pending application and individual's advice essential, individual prominently identified with particular point of view.	Public Disclosure. (10b)

1/ *Applies to interests in firms involved with products regulated by the particular FDA bureau/office employing the Special Government Employee.*

2/ *Applies to advisory committee members only. Consultants and expert reviewers will be excluded from participation in matters involving firms in which they have any interest.*

3/ *If remunerated for services, criteria set forth in Section 8 will apply.*

PRINCIPAL OFFICIALS RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
David Mathews	Aug. 1975	Present
Caspar W. Weinberger	Feb. 1973	Aug. 1975
ASSISTANT SECRETARY FOR HEALTH:		
Theodore Cooper	May 1975	Present
Theodore Cooper (acting)	Jan. 1975	May 1975
Charles C. Edwards	Mar. 1973	Jan. 1975
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Alexander M. Schmidt	July 1973	Present