



DEPARTMENT OF HEALTH AND HUMAN SERVICES

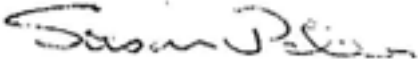
Public Health Service

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: December 17, 2004

TO: Special Government Employees

FROM: Susan Peters 
Lead Public Health Analyst
Advisors and Consultants Staff
Center for Drug Evaluation and Research, FDA

RE: Annual Ethics Training for Special Government
Employees (SGEs)

The Office of the Government Ethics (OGE) requires that all special Government employees (SGEs) who file an annual financial disclosure report (OGE-450) or the optional and more widely used FDA Form-3410, receive annual ethics training. 5 CFR §2638.704(d) (3)(iii). To that end, we are distributing the attached "Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees," and ask that you read the eleven-page document.

If you have questions regarding the material, please call me at (301) 827-6760.

Attachment

ETHICS RULES FOR ADVISORY COMMITTEE MEMBERS AND OTHER INDIVIDUALS APPOINTED AS SPECIAL GOVERNMENT EMPLOYEES (SGEs)

Introduction

This summary has been prepared primarily for individuals appointed to serve as “special Government employees” (SGEs) on Department of Health and Human Services (HHS) advisory committees or Presidential boards, councils, or commissions that are attached to HHS for purposes of administration. The information also will be useful to other SGEs without advisory committee responsibilities, such as “experts or consultants” or “personal services contractors.”

New appointees, especially those that provide temporary, intermittent services only a few days a year, often are surprised by, or even resentful of, the complexity of the rules governing Federal employees. The ethics rules do not appear to many people to be logical, intuitive, or even, fair. Ignoring these rules, however, can result in serious consequences or embarrassment, both personally and for the Department. Criminal conflict of interest violations are “strict liability” offenses, and even an inadvertent, “technical” violation will require the initiation of an Inspector General investigation and possible referral to the Department of Justice. Moreover, the entire matter in which a violator participates may be considered so compromised that the Department may have to nullify, cancel, or retract any agency action that is perceived as tainted by the conflict. Therefore, if you have questions on any of the topics covered in this guidance, you should consult with the Designated Federal Official responsible for your committee or the Deputy Ethics Counselor assigned to your operating or staff division.

Definition of a Special Government Employee (SGE)

A “special Government employee” is an officer or employee in the executive branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. 18 U.S.C. § 202(a). This status is important because the ethics rules for SGEs are somewhat less restrictive than the rules for other Federal employees and officials. Some members of advisory committees are appointed for a multi-year term. During each year of their term of appointment, committee members generally will not be expected to perform work for HHS in excess of 130 days during any period of 365 consecutive days. Thus, most committee members will be considered “SGEs.”

In addition, individuals who provide advice as an “expert or consultant” or render assistance under a “personal services contract” for a period that is not expected to exceed 130 days do so as the functional equivalent of an employee and thus are treated as SGEs for ethics purposes. Only “true” independent contractors are excluded from the definition. Although several factors are evaluated to determine independent contractor status, this category, for the most part, comprises individuals who produce a defined “end product” or “deliverable” without detailed supervision by a Federal employee.



Financial Disclosure Reporting Requirements

HHS advisory committee members appointed as SGEs are required under the Ethics in Government Act, as amended by the Ethics Reform Act of 1989, and 5 C.F.R. Part 2634, to file a financial disclosure report when first appointed and annually thereafter on the anniversary date of their appointment. Committee members also may be required to update the information on the report before each meeting throughout their term of appointment. (Certain committee members are permitted to utilize an alternative reporting system, e.g., FDA Form 3410, that focuses solely on each filer's assets and associational interests that are directly implicated by the subjects on the meeting agenda.) The information reported is used to determine the matters for which a committee member must be disqualified under the criminal financial conflict of interest statute, 18 U.S.C. § 208(a), and the matters for which a committee member may be granted a waiver under 18 U.S.C. § 208(b).

Complete reporting is essential to protect the committee member from inadvertently violating any of the criminal conflict of interest statutes, and to assure the public that the advice provided by an HHS advisory committee is free from any real, or perceived, conflicts of interest. The information reported by committee members is confidential and may not be released except under the limited circumstances described in the Privacy Act notice provided with the report or by order of a Federal court. (SGEs who serve more than 60 days in any period of 365 consecutive days and who are compensated at certain pay levels may be required to file a publicly available financial disclosure report.)

Criminal Conflict of Interest Statutes

The following **criminal** conflict of interest statutes apply to SGEs:

18 U.S.C § 201. Section 201, commonly known as the "bribery and illegal gratuities" statute, prohibits Federal employees, including SGEs, from seeking, accepting, or agreeing to receive anything of value in return for being influenced in the performance of an official act.

18 U.S.C. § 203. Section 203 prohibits an SGE from receiving compensation for representational services rendered by the employee or another person before HHS or another Federal agency or other specified entity (such as a court or commission) in any particular matter involving a specific party (i) in which the SGE has participated personally and substantially as a Government employee, or (ii) which is pending in the Government agency in which the SGE is serving if the SGE has served for more than 60 days during the immediately preceding 365 days.

Exempted from this rule are representations required in the proper discharge of official duties. Also exempted are representations determined by the head of the agency to be required in the performance of work under a grant, contract or other agreement with or for the benefit of the Government.

A particular matter involving specific parties is a matter that is focused upon the interests of identified persons in a specific proceeding or an isolatable transaction or related set of transactions. Examples include, but are not limited to, reviews of grant proposals or contract applications, or similar funding decisions; recommendations or approvals of scientific studies, projects, clinical trials, new drug applications; and other actions that involve deliberation, decision, or action affecting the legal rights of identified parties.

In contrast, a particular matter of general applicability is a matter that is focused on the interests of a discrete and identifiable class of persons or entities, but does not involve specific parties. Examples include recommendations or consideration of legislative proposals, regulatory initiatives, or policy development that affect an industry, group of manufacturers, or health care providers.

Pay close attention to which type of particular matter is involved in your assignment because the ethics rules may differ depending upon whether a “specific party matter” or a “general policy matter” is involved. The terms “matter” or “particular matter,” without more description, are deemed to encompass both types.

Representational services include communications (written or oral) and appearances made on behalf of someone else, generally with the intent to influence or persuade the Government. An inquiry as to the status of a pending matter is not necessarily a representation, although depending upon the context of the inquiry, it could give rise to the appearance of a prohibited representation.

To avoid appearance problems, during the period in which a committee is in session, committee members are advised not to contact Department staff concerning any matters pending before the agency, or as to which the agency has an interest. Such matters would include, for example, applications for Federal funding, progress reports regarding Cooperative Research and Development Agreements (CRADAS) or clinical trials, and pending drug investigations or applications.

18 U.S.C. § 205. Section 205 prohibits an SGE from representing a party, with or without compensation, before HHS or another Federal agency or other specified entity (such as a court or commission) in any particular matter involving a specific party in which the United States is a party or has a direct and substantial interest: (i) that the SGE participated in personally and substantially as a Government employee; or (ii) which is pending in the agency in which the SGE is serving, if the SGE has served for more than 60 days during the immediately preceding 365 days.

18 U.S.C. § 207. Section 207, the "post-employment" statute, imposes a lifetime ban on a former SGE from representing another person or entity to HHS or another Federal agency or other specified entity (such as a court or commission) in any particular matter involving a specific party in which the former SGE participated personally and substantially while serving in the Government. In addition, for two years after terminating Federal employment, an SGE may not make such representational communications to the Government regarding specific party matters that were pending under his or her official responsibility during the last year of Government service. Moreover, "senior employees," those paid at an annual rate equivalent to level ES-5 in the Senior Executive Service, are subject to a one-year "cooling-off" period which precludes any contacts with their former agency on any matter for which official action is sought, even if the former employee had no involvement with the matter while in Government service. For SGEs, this one-year "cooling-off" period does not apply if the SGE served less than 60 days in the one-year period prior to termination of senior employee status.

18 U.S.C. § 208. Section 208(a), the main conflict of interest statute, prohibits an SGE from participating personally and substantially in any particular matter that could affect the financial interests of the SGE, the SGE's spouse, minor child, general partner, an organization in which the SGE serves as an officer, director, trustee, general partner, or employee, or an organization with which the SGE is negotiating or with which the SGE has an arrangement for prospective employment.

Under this statute, for example, an SGE would be prohibited from reviewing a grant application submitted by a researcher from the same university in which the SGE is employed, or a contract proposal from an association for which the SGE serves as a member of the board of directors. In these instances, the SGE would be required to recuse from participation in the reviews.

Section 208 might also prohibit the SGE from participating in setting standards for grantees or contractors in general, to the extent that the SGE's university (or any organization with which the SGE is affiliated as an officer or board member) would be affected by those standards. (Under this scenario, however, a waiver could be issued to permit the SGE to participate in such general policy matters. Also, a regulatory waiver might apply to this situation. See discussion below.)

A waiver for advisory committee members may be granted under 18 U.S.C. § 208(b)(3). Section 208(b)(3) authorizes issuance of a waiver to an SGE who serves on a committee subject to the Federal Advisory Committee Act if the official responsible for the individual's appointment certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest created by the particular financial interest involved. The waiver granted is considered a "general" waiver, in that it allows participation in matters that affect all institutions, or types of institutions, similarly. Even with a general waiver, however, SGEs must disqualify themselves from participation in all matters that specifically and uniquely affect their financial interests.

The Designated Federal Official responsible for a committee will explain the procedures for disqualification. SGEs who do not serve on advisory committees are subject to more exacting waiver requirements in 18 U.S.C. § 208(b)(1), and a Deputy Ethics Counselor should be consulted.

In addition, under regulations issued by the Office of Government Ethics, a regulatory (i.e., automatic) waiver of the disqualification requirement of 18 U.S.C. § 208 is available under certain circumstances, including instances involving the following classes of financial interests:

- interests held in broadly diversified investment funds;
- publicly traded securities of \$15,000 or less;
- publicly traded securities of \$25,000 or less if the matter is a general policy matter and the total value of all investments in the affected industry sector is no more than \$50,000;
- employment in one campus of a multi-campus state university if the matter affects only another campus and the employee does not have multi-campus responsibilities.

In addition, there is an automatic exemption which allows SGEs serving on Federal advisory committees to participate in particular matters of general applicability where the otherwise disqualifying financial interest arises solely from the committee member's non-Federal employment or prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class. This exemption is unavailable if the employee (or those persons whose interests are imputed to the employee) owns stock, stock options, or has some other financial interest in the employer other than his or her employment interest.

18 U.S.C § 219. Section 219 prohibits an SGE from acting as an "agent of a foreign principal" as defined under the Foreign Agents Registration Act (FARA) or a "lobbyist" on behalf of a foreign entity that is required to register under the Lobbying Disclosure Act of 1995 (LDA).

The ban on participating in foreign agent activities covered by FARA prohibits representation of foreign governments or foreign political parties before the United States Government, as well as a number of other activities conducted within the United States on behalf of such entities: (1) political activities; (2) public relations counseling; (3) publicity agent activities; (4) information services; (5) political consulting; and (6) solicitation or disbursement of contributions, loans, money, or other things of value; where such services are rendered with the intent to influence the American public or the Government, with reference to formulating the domestic or foreign policies of the United States, or with reference to the political or public interests, policies or relations of a government of a foreign country or a foreign political party.

There are certain FARA exceptions related to trade or commerce, legal representation, humanitarian fundraising, and religious, scholastic, or scientific pursuits. The head of an agency may authorize the employment of an agent for a foreign entity as a special Government employee upon a certification that such action is in the national interest. The LDA ban prohibits certain lobbying of covered legislative and executive branch officials on behalf of foreign corporations, associations, or other organizations.

Standards of Ethical Conduct

In addition to criminal statutes, the conduct of SGEs is governed by a series of ethics rules that apply 24 hours per day and even on days during which the SGE provides no Federal services. The following are some of the major Standards of Ethical Conduct regulations (5 C.F.R. Part 2635) that pertain to HHS SGE advisory committee members during the term of their appointment:

I. *Teaching, Speaking and Writing in a Personal Capacity (i.e., Other Than as a Government Employee)*

Generally, during their term of appointment, committee members may continue to receive fees, honoraria, and other compensation for teaching, speaking and writing undertaken in their personal or non-Governmental capacities. However, there are some limitations:

- (A) An SGE is prohibited from receiving compensation for teaching, speaking, and writing that "relates to the employee's official duties." 5 C.F.R. § 2635.807. The "relatedness" test is met for an SGE if:
 - (1) the activity is undertaken as an official Government duty;
 - (2) the circumstances indicate that the invitation to engage in the activity was extended to the SGE primarily because of the employee's position in the Government rather than the employee's expertise in the particular subject matter;
 - (3) the invitation to engage in the activity or the offer of compensation for the activity was extended to the employee, directly or indirectly, by a person who has interests that may be affected substantially by the performance or nonperformance of the employee's official duties; or
 - (4) the information conveyed through the activity draws substantially on ideas or official data that are confidential or not publicly-available.

- (B) Additionally, if a committee member serves for 60 days or less during a one-year period, the SGE may not accept compensation for teaching, speaking, and writing if the subject matter of the teaching, speaking or writing concerns a particular matter involving specific parties in which the SGE participated or is participating personally and substantially as a Government employee.

For example, an AIDS researcher has been appointed to a four-year term as a member of an advisory committee established for the purpose of surveying and recommending modification of procedures that deter the development of treatments for HIV infection and HIV-related diseases. The committee member is not expected to serve more than 60 days each year during her four-year term of appointment.

The committee member may accept compensation for an article or speech about the deterrent effect of certain procedures required for clinical investigations and trial designs even though such issues are being discussed by the advisory committee. Clinical procedures in general are not a particular matter involving specific parties. The committee member could not accept compensation for an article or speech which recounts committee deliberations that took place in a closed meeting, or which relies upon other, non-public information. In addition, the committee member could not accept compensation for an article or speech about specific collaborations in the HIV drug development process which were discussed by the committee, since the collaborations are considered a particular matter involving specific parties.

- (C) If a committee member serves for **more** than 60 days, the SGE is additionally prohibited from receiving compensation for teaching, speaking, and writing if the subject of the activity deals in significant part with any matter to which the SGE is presently assigned or was assigned during the previous one-year period.

EXCEPTIONS:

1. This rule does not preclude a committee member from receiving compensation for teaching, speaking, or writing on a subject within the committee member's discipline or inherent area of expertise based on the SGE's educational background or experience. The outside activity must not be about or distinctly related to the work the SGE is providing to the Government.
2. These restrictions also do not apply to teaching a course requiring multiple presentations that is part of the regularly established curriculum of an institution of higher education, an elementary or secondary school, or a program of education or training sponsored and funded by the Federal, State, or local government.

II. *Gifts*

Any gift given to a committee member because of the member's service on an HHS advisory committee would raise concerns. The Designated Federal Official responsible for the committee should be consulted should this situation arise. Gifts given to an SGE because of the SGE's position or achievements in the private (non-Government) sector generally are not problematic.

III. *Charitable Fundraising*

A committee member may engage in charitable fundraising in a personal capacity as long as the committee member does not personally solicit funds or other support from any person or entity known to the committee member to be a person or entity whose interests may be substantially affected by the performance or nonperformance of the committee member's Federal duties.

5 C.F.R. § 2635.808. If specific questions concerning particular fundraising events or activities should arise, the Designated Federal Official responsible for the committee should be consulted.

IV. *Expert Witness*

A committee member cannot serve as an expert witness, in a proceeding before a United States court or agency in which the United States is a party or has a direct and substantial interest, except on behalf of the United States, if the committee member participated, while a Federal employee, in the particular proceeding, unless authorized by the HHS Designated Agency Ethics Official (DAEO), who can be reached at (202) 690-7258.

In addition, a committee member who was appointed by the President, serves on a commission established by statute, or has served or is expected to serve for more than 60 days in a period of 365 consecutive days, cannot serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a United States court or agency in which the committee members's employing agency is a party or has a direct and substantial interest unless authorized by the DAEO. 5 C.F.R. § 2635.805.

V. *Impartiality*

Although committee members are prohibited under 18 U.S.C. § 208(a) from participating in matters in which they have a financial interest, there may be other circumstances in which a committee member's participation in a particular matter involving specific parties would raise a question regarding the member's impartiality in the matter. For example, a committee member asked to review a grant application submitted

by the SGE's mentor, or someone with whom the SGE has a close personal or professional relationship, would raise a concern about the committee member's impartiality in the review. In such circumstances, the committee member should discuss the relationship with the Designated Federal Official responsible for the committee and a determination will be made as to whether the member should be disqualified from participation in the specific party matter, or should be granted an "authorization" to permit the member to participate in such matter. 5 C.F.R § 2635.502.

VI. *Misuse of Position*

Committee members are subject to a number of prohibitions intended to address the use, or appearance of use, of "public office for private gain." 5 C.F.R. Part 2635, Subpart G. These prohibitions include:

- (A) Using their HHS titles or referring to their Government positions for their own private gain, the private gain of friends, relatives, or anyone with whom they are affiliated in a non-Governmental capacity (including nonprofit organizations which they serve as officers, members, employees, or in any other business relationship), or for the endorsement of any product, service, or enterprise.
- (B) Using their HHS titles or Government positions to coerce or induce another person to provide any benefit to themselves or another person.
- (C) Using non-public Government information in a financial transaction to further their private interests or those of another, or disclosing confidential or non-public information without authorization.
- (D) Using Government property for unauthorized purposes.

Employment by, or Gifts from, Foreign Governments

The Constitution prohibits a committee member's employment by a foreign government, including political subdivisions of a foreign government. For SGEs, this provision has particular relevance to positions with foreign universities that are government-operated, as opposed to private institutions. United States Constitution, art. I § 9, cl. 8. There are also statutory provisions restricting acceptance of gifts from foreign governments. 5 U.S.C. § 7342. Committee members should consult with the Designated Federal Official responsible for their committee for details about these restrictions. Employment or consultation with a foreign entity for the purpose of providing foreign agent representation or lobbying is barred by a criminal statute; see the discussion above concerning 18 U.S.C. § 219. All SGEs are required to complete HHS Form 697, Foreign Activities Questionnaire, for the purpose of determining whether a committee member's foreign connections are incompatible with Federal service.

Lobbying Activities

In their official capacities or as a group, committee members are prohibited from engaging in any activity which directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. 18 U.S.C. § 1913. When authorized, committee members may appear before any individual or group for the purpose of informing or educating the public about a particular policy or legislative proposal. Committee members also may communicate to Members of Congress at the request of any Representative or Senator. Communications to Members of Congress initiated by committee members, in their official capacity as members of the committee, should be coordinated through the Office of the Assistant Secretary for Legislation.

As private citizens, committee members may express their personal views (but not the views of the committee as a whole or the opinions of HHS) to anyone. In doing so, committee members may state their affiliation with the committee, may factually state the committee's official position on the matter (to the extent that non-public information is not used), but may not take new positions and represent those views as the committee's position on the matter. Moreover, in expressing their private views, as with all other personal (non-Governmental) activities, committee members are not permitted to use Government computers, copiers, telephones, letterhead, staff resources, or other appropriated funds. All personal activities must occur "off duty time."

Committee members are prohibited in their personal capacities from making representations on behalf of others, to the Government, on particular matters involving specific parties in which they were involved as Federal employees. (See discussion above under 18 U.S.C. §§ 203 and 205.)

Political Activities

The Hatch Act (5 U.S.C. §§ 7321-7328) prescribes the restrictions on certain political activities of Federal employees (see the explanatory chart on the following page). Unlike the criminal conflict of interest statutes and the ethics rules which are fully applicable to an SGE throughout the SGE's entire term of appointment, the Hatch Act restrictions apply only during the period of any day in which the SGE actually is performing government business. For example, if an SGE attends an advisory committee meeting from 8:00 a.m. - 1:00 p.m., the SGE could attend a political fund raiser at 3:00 p.m. and even solicit political contributions from the attendees.

A series of criminal political statutes (18 U.S.C. §§ 595, 600-603, 606-607, 610) applies to SGEs even on non-duty hours. These sections, which focus on patronage crimes and election offenses, prohibit coercive "political shakedowns," intimidation regarding political activities, campaign fundraising on Federal property, and the use of public office or authority for the purpose of affecting the outcome of an election.

HATCH ACT POLITICAL ACTIVITY RESTRICTIONS

Permissible Activities	Prohibited Activities (while on duty)
<ul style="list-style-type: none"> * <i>May be candidates for public office in nonpartisan elections</i> * <i>May register and vote as they choose.</i> * <i>May assist in voter registration drives.</i> * <i>May express opinions about candidates and issues.</i> * <i>May contribute money to political organizations.</i> * <i>May attend political fund raising functions.</i> * <i>May attend and be active at political rallies and meetings.</i> * <i>May join and be an active member of a political party or club.</i> * <i>May sign nominating petitions.</i> * <i>May campaign for or against referendum questions, constitutional amendments, municipal ordinances.</i> * <i>May campaign for or against candidates in partisan elections.</i> * <i>May distribute campaign literature in partisan elections.</i> * <i>May hold office in political clubs or parties (except Treasurer).</i> 	<ul style="list-style-type: none"> * <i>May not use their official authority to interfere with an election.</i> * <i>May not collect political contributions, unless both individuals are members of the same Federal labor organization and the one solicited is not a subordinate employee.</i> * <i>May not knowingly solicit or discourage the political activity of any person who has business before the agency.</i> * <i>May not engage in political activity while on duty.</i> * <i>May not engage in political activity in any Government office.</i> * <i>May not engage in political activity while wearing an official uniform.</i> * <i>May not engage in political activity while using a Government vehicle.</i> * <i>May not solicit political contributions from the general public.</i> * <i>May not actively participate as a candidate for public office in a partisan election.</i>