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**TO:** Thomas R. Frieden, M.D., M.P.H.  
Director  
Centers for Disease Control and Prevention

**FROM:** Daniel R. Levinson *Daniel R. Levinson*  
Inspector General

**SUBJECT:** OIG Final Report: *CDC's Ethics Program for Special Government Employees on Federal Advisory Committees*, OEI-04-07-00260

Attached is our final report entitled *CDC's Ethics Program for Special Government Employees on Federal Advisory Committees*.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions about this report, please do not hesitate to call me or one of your staff may contact Linda Abbott, Deputy Director, Evaluation Planning and Support Division, at (410) 786-4662 or through email [[Linda.Abbott@oig.hhs.gov](mailto:Linda.Abbott@oig.hhs.gov)]. To facilitate identification, please refer to report number OEI-04-07-00260 in all correspondence.

Attachment

cc: Edgar Swindell  
Designated Agency Ethics Official  
Office of the General Counsel

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CDC'S ETHICS PROGRAM FOR  
SPECIAL GOVERNMENT EMPLOYEES  
ON FEDERAL ADVISORY  
COMMITTEES**



Daniel R. Levinson  
Inspector General

December 2009  
OEI-04-07-00260

# *Office of Inspector General*

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## OBJECTIVE

To determine the extent to which the Centers for Disease Control and Prevention (CDC) and its special Government employees (SGE) on Federal advisory committees (committees) complied with ethics requirements.

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## BACKGROUND

Committees play an influential role in decisionmaking for the Federal Government. Committee members (i.e., SGEs) are typically involved in work outside the Federal Government in the same areas as their committees' work. To protect the committees' integrity and credibility, agencies must not permit SGEs with conflicts of interest to inappropriately influence their committees' work.

At CDC, committees address important public health topics. For example, in 2007, one committee recommended the routine vaccination of young females in the United States to prevent cervical cancer. In 2009, this same committee recommended that H1N1 influenza vaccination efforts focus on five target groups in the United States.

CDC must obtain from SGEs Confidential Financial Disclosure Reports, Office of Government Ethics (OGE) Forms 450, containing information such as the SGEs' assets, sources of income, and non-income-earning activities. Before permitting SGEs to participate in committee meetings, CDC must review these forms and certify them to indicate that they are complete and that it has identified and resolved all conflicts of interest. CDC must create ethics agreements (e.g., waivers) to resolve SGEs' conflicts of interest. CDC collaborates with the Department of Health and Human Services' (HHS) Office of the General Counsel to identify and resolve conflicts of interest.

CDC must also provide initial and annual ethics training to SGEs within required timeframes and obtain ethics training certificates from SGEs to document that they received the training. Finally, CDC must monitor SGEs' compliance with ethics requirements during committee meetings. That is, SGEs must not participate in committee work during committee meetings without current, certified OGE Forms 450 or participate in committee work related to particular matters if their waivers prohibit such participation.

We reviewed financial disclosure files (e.g., current, certified OGE Forms 450 and ethics agreements) for 246 SGEs on 17 CDC committees in

2007. We determined whether SGEs' OGE Forms 450 were complete after CDC certified them. Then, we determined whether CDC identified potential conflicts of interest that we identified. We also determined the extent to which CDC created ethics agreements and adequately documented them to resolve potential conflicts of interest. Further, we determined whether CDC ensured that SGEs' financial disclosure files contained ethics training certificates to document that SGEs received ethics training within required timeframes. Finally, we determined whether SGEs complied with ethics requirements during committee meetings.

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## FINDINGS

**For almost all special Government employees, CDC did not ensure that financial disclosure forms were complete in 2007.** CDC certified OGE Forms 450 with at least one omission in 2007 for 97 percent of SGEs. Most of the forms had more than one type of omission.

**CDC did not identify or resolve potential conflicts of interest for 64 percent of special Government employees in 2007.** Sixty-four percent of SGEs had potential conflicts of interest in 2007 that CDC did not identify and/or resolve before it certified their OGE Forms 450. Specifically, 58 percent of SGEs had potential conflicts of interest that CDC did not identify. In addition, 32 percent of SGEs had potential conflicts of interest that CDC identified but did not resolve. Twenty-six percent of SGEs had both CDC-unidentified and unresolved potential conflicts of interest.

**CDC did not ensure that 41 percent of special Government employees received required ethics training in 2007.** CDC did not ensure that 41 percent of SGEs had ethics training certificates on file to document that SGEs received initial or annual ethics training within required timeframes in 2007.

**Fifteen percent of special Government employees did not comply with ethics requirements during committee meetings in 2007.** Fifteen percent of SGEs did not comply with ethics requirements during committee meetings in 2007. Specifically, 13 percent of SGEs participated in committee meetings in 2007 without having current, certified OGE Forms 450 on file. In addition, 3 percent of SGEs voted on particular matters when their waivers prohibited such participation. Four SGEs both participated in committee meetings without current, certified OGE Forms 450 on file and voted on particular matters when their waivers prohibited such participation.

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## RECOMMENDATIONS

We found that CDC had a systemic lack of oversight of the ethics program for SGEs. That is, CDC and its SGEs did not comply with ethics requirements in 2007.

To address our findings, we recommend that CDC:

**Ensure that special Government employees' Confidential Financial Disclosure Reports are complete before certifying them.**

**Require special Government employees to disclose their involvement in grants and other relevant interests that could pose conflicts but that are not disclosed on the Confidential Financial Disclosure Report.**

**Identify and resolve all conflicts of interest for special Government employees before permitting them to participate in committee meetings.**

**Increase collaboration among CDC officials and with the HHS Office of the General Counsel.**

**Ensure that special Government employees and CDC employees receive ethics training.**

**Monitor special Government employee compliance with ethics requirements during committee meetings.**

**Track special Government employee compliance with ethics requirements.**

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC concurred with all seven of our recommendations. Since the time of our review, CDC indicated that it has begun or plans to implement improvements that coincide with our recommendations.

We made technical changes to the report based on CDC's comments.

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## OBJECTIVE

To determine the extent to which the Centers for Disease Control and Prevention (CDC) and its special Government employees (SGE) on Federal advisory committees (committees) complied with ethics requirements.

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## BACKGROUND

Committees provide “expert advice, ideas, and diverse opinions” to the Federal Government and play an influential role in public policy and decisionmaking.<sup>1, 2</sup> To protect the committees’ integrity and credibility, Federal agencies must not permit committee members with conflicts of interest to inappropriately influence their committees’ work.<sup>3, 4</sup> OGE issues regulations regarding conflicts of interest and oversees Federal agencies’ ethics programs.<sup>5</sup>

SGEs are voting committee members who are temporary employees of the Federal Government.<sup>6</sup> SGEs are subject matter experts and typically are actively involved in work outside the Government in the same areas as their committees’ work.<sup>7</sup> Therefore, SGEs may have

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<sup>1</sup> Federal Advisory Committee Act, 5 U.S.C. app. II §§ 2(a) and 3(2)(c)(i).

<sup>2</sup> Office of Government Ethics (OGE) Memorandum to Designated Agency Ethics Officials, “Federal Advisory Committee Appointments.” DO-05-012, August 18, 2005. Available online at [http://www.usoge.gov/ethics\\_guidance/daeograms/dgr\\_files/2005/do05012.pdf](http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2005/do05012.pdf). Accessed on July 10, 2009.

<sup>3</sup> In this report, we will use the term “committee work” to include preliminary discussions, interim evaluations, votes, and final recommendations.

<sup>4</sup> In this report, we will use the term “conflict of interest” to refer to interests covered by the criminal conflict-of-interest statute (18 U.S.C. § 208) and/or the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR § 2635).

<sup>5</sup> Ethics in Government Act, 5 U.S.C. app. IV §§ 401 and 402, 5 CFR pt. 2600.

<sup>6</sup> SGEs may serve in many roles in the Federal Government. 18 U.S.C. § 202(a). In this report, we will use the term “SGE” to refer only to SGEs on committees at CDC. In the Department of Health and Human Services (HHS), most committee members are appointed as SGEs. HHS, Office of the General Counsel Ethics Division. “Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (SGE),” p. 1, October 2004. SGEs may serve multiyear terms on committees but may not serve in excess of 130 days during any 365-day period. 18 U.S.C. § 202(a).

<sup>7</sup> OGE, “Conflict of Interest and the Special Government Employee: A Summary of Ethical Requirements Applicable to SGEs.” Attachment to the OGE Memorandum to Designated Agency Ethics Officials, DO-00-003, February 15, 2000. Available online at [http://www.usoge.gov/laws\\_regs/other\\_ethics\\_guidance/otr\\_gdnc/og\\_sge\\_coi\\_00.pdf](http://www.usoge.gov/laws_regs/other_ethics_guidance/otr_gdnc/og_sge_coi_00.pdf). Accessed on July 10, 2008.



financial interests that conflict with their official duties as committee members.

At CDC, committees address important public health topics, such as breast and cervical cancer, immunization, smoking, tuberculosis, and clinical laboratory improvement. For example, in 2007, one committee recommended the routine vaccination of young females in the United States to prevent cervical cancer.<sup>8</sup> In 2009, this same committee recommended that H1N1 influenza vaccination efforts focus on five target groups in the United States.<sup>9</sup>

On December 31, 2007, 259 SGEs were serving on 17 CDC committees. The President, Congress, or the HHS Secretary may appoint SGEs to these committees. See Appendix A for a list of the 17 committees.

### **CDC's Ethics Program for Special Government Employees**

CDC's Management Analysis and Services Office (MASO) is responsible for managing CDC's ethics program for SGEs.<sup>10</sup> MASO coordinates with each committee's Designated Federal Official to ensure that SGEs comply with Federal ethics statutes and regulations, as well as CDC policy. Hereinafter, we refer to Federal ethics statutes and regulations and CDC policy as "ethics requirements."

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<sup>8</sup> CDC, *Morbidity and Mortality Weekly Report*, "Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices." March 23, 2007. Available online at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s\\_cid=rr5602a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s_cid=rr5602a1_e). Accessed on September 9, 2009.

<sup>9</sup> CDC, *Morbidity and Mortality Weekly Report*. "Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices." August 28, 2009. Available online at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s\\_cid=rr5810a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s_cid=rr5810a1_e). Accessed on September 9, 2009.

<sup>10</sup> OGE requires each Department to assign a Designated Agency Ethics Official to establish, maintain, and carry out the Department's various ethics programs. 5 CFR § 2638.201. The HHS Designated Agency Ethics Official has delegated daily responsibility for administering HHS's ethics programs to Deputy Ethics Counselors in each operating division. HHS Office of the General Counsel Ethics Division, "Deputy Ethics Counselor HHS Ethics Program Statement of Functions, Responsibilities, and Authority," revised August 15, 2007. HHS Office of the General Counsel, Ethics Division, Designated Agency Ethics Official, "DAEO Supplemental Instruction No. 06-2," December 14, 2006. CDC's Deputy Ethics Counselor has further delegated certain aspects of the administration of CDC's SGE ethics program to the Director of MASO. CDC Policy, CDC-GA-2001-05 (formerly CDC-94), "Financial Disclosure for Federal Advisory Committee Members Appointed as Special Government Employees," July 5, 2001. Available online at <http://www.cdc.gov/maso/FACM/pdfs/policy294.pdf>. Accessed on July 10, 2009.

## I N T R O D U C T I O N

The Designated Federal Official is not a committee member, but a CDC employee who serves as the committee's Executive Secretary, attends each meeting, and manages the committee's day-to-day operations.<sup>11, 12</sup>

CDC (i.e., MASO and Designated Federal Officials) is responsible for:

1. ensuring that Confidential Financial Disclosure Reports (OGE Forms 450) are complete,
2. identifying and resolving SGEs' conflicts of interest,
3. providing and documenting initial and annual ethics training to SGEs, and
4. monitoring SGEs' compliance with ethics requirements during committee meetings.<sup>13</sup>

The ethics program is based on a confidential financial reporting system. This system enables CDC to identify SGEs' conflicts of interest and assists them in avoiding conflicts between their official duties and financial interests or affiliations.<sup>14</sup> SGEs must submit OGE Forms 450 to CDC, on which they disclose all financial interests and positions held in the previous 12 months.<sup>15, 16</sup>

SGEs must complete four sections of the form:

- Part I - Assets and Income
- Part II - Liabilities

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<sup>11</sup> Federal Advisory Committee Act, 5 U.S.C. app. II § 10(e). CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>12</sup> At CDC, the Designated Federal Official's primary employment responsibilities exist outside the committee. This official is usually employed in a CDC program related to particular matters addressed by the committee.

<sup>13</sup> CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>14</sup> OGE, *OGE Form 450: A Review Guide*, September 1996, pp. 26 and 27. Available online at [http://www.usoge.gov/forms/oge450\\_pdf/rf450guide\\_96.pdf](http://www.usoge.gov/forms/oge450_pdf/rf450guide_96.pdf). Accessed on July 10, 2009.

<sup>15</sup> OGE, Memorandum to Designated Agency Ethics Officials, DO-03-021. *Financial Disclosure Reporting Requirements for Special Government Employees*, October 23, 2003. Available online at [http://www.usoge.gov/ethics\\_guidance/daeograms/dgr\\_files/2003/DO03021.HTML](http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2003/DO03021.HTML). Accessed on September 9, 2009. In January 2007, OGE issued an updated OGE Form 450.

<sup>16</sup> SGEs are required to report interests (e.g., assets, positions) held at any point in the previous 12 months, even if they are not held at the time of the filing. SGEs must also report financial interests attributed to them on behalf of another person or entity (e.g., a spouse or dependent child). For the purposes of this report, SGEs' financial interests refer to both the SGEs' own interests and those attributed to them during the reporting period.

## I N T R O D U C T I O N

- Part III - Outside Positions
- Part IV - Agreements and Arrangements<sup>17</sup>

CDC also requests (but does not require) SGEs to submit an updated curriculum vitae with the OGE Form 450.<sup>18</sup> CDC uses the curriculum vitae to identify grants that pose potential conflicts of interest because this information is not required on the OGE Form 450.<sup>19</sup> CDC also uses the curriculum vitae to identify other interests that could pose conflicts.

CDC must maintain financial disclosure files for SGEs, by committee, including the current and prior OGE Forms 450 and supporting documentation (e.g., curriculum vitae).<sup>20</sup>

### **Ensuring Complete Disclosure of Financial Information**

Once CDC receives an SGE's OGE Form 450, it must ensure that the form is complete before approving (i.e., certifying) it.<sup>21</sup> MASO reviewers take the SGEs' disclosures on OGE Forms 450 at "face value."<sup>22</sup> That is, MASO reviewers assess the extent to which forms are complete based on omissions that they can identify given the interests that are disclosed by the SGEs anywhere in their financial disclosure files (e.g., curricula vitae, 2006 and 2007 OGE Forms 450). MASO reviewers are not required to identify omissions that result from interests that the SGEs consistently fail to disclose anywhere in the file.

If CDC determines that a form is incomplete, it must contact the SGE to obtain additional information.<sup>23</sup> CDC then annotates the form with the additional information.<sup>24</sup>

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<sup>17</sup> SGEs are not required to complete Part V – Gifts and Travel Reimbursement.

<sup>18</sup> A curriculum vitae is similar to a résumé but is a more comprehensive account of an individual's professional history (e.g., education, employment, publications, grants).

<sup>19</sup> Information regarding SGEs' involvement in grants that are awarded to their employers is not required to be disclosed on the OGE Form 450.

<sup>20</sup> CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>21</sup> 5 CFR §§ 2634.605(b)(1)(i) and (b)(2). OGE, "OGE Form 450: A Review Guide," loc. cit.

<sup>22</sup> 5 CFR § 2634.605(b)(2).

<sup>23</sup> CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>24</sup> Ibid.

## I N T R O D U C T I O N

An OGE Form 450 is incomplete if, for example:

- items are not fully described or listed in all appropriate sections of the form, according to OGE guidance and the form’s instructions;<sup>25</sup>
- the form does not contain all items that require disclosure;<sup>26</sup> or
- CDC’s annotations to the form (i.e., amendments) do not indicate that the SGE authorized the changes or include the reviewer’s initials or the date of the changes.<sup>27</sup>

### **Identifying Conflicts of Interest**

CDC reviews committee charters to determine the scope of the matters generally addressed by each committee.<sup>28</sup> Then, CDC examines each SGE’s OGE Form 450 and curriculum vitae in relation to the committee charter to identify potential conflicts of interest.<sup>29, 30</sup>

If CDC identifies a potential conflict of interest, it obtains additional information or legal guidance to determine whether a conflict actually exists. To do so, MASO consults with the SGE, the Designated Federal Official, and/or the HHS Office of the General Counsel.<sup>31</sup>

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<sup>25</sup> For example, compensated non-Federal employment listed in Part II - Outside Positions must also be disclosed as a source of income in Part I - Assets and Income. OGE, *OGE Form 450: Confidential Financial Disclosure Report*, January 2007.

<sup>26</sup> For example, relevant items listed on the SGE’s curriculum vitae or prior OGE Form 450 must also be listed on the current year’s form. CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>27</sup> CDC Policy, CDC-GA-2001-05, loc. cit. OGE, *OGE Form 450: A Review Guide*, loc. cit.

<sup>28</sup> Committee charters outline the authority, purpose, and function of each committee.

<sup>29</sup> We use the term “potential” conflicts of interest to refer to interests that have not yet been deemed conflicts of interest. Additional information is needed to determine whether these interests do, in fact, pose conflicts.

<sup>30</sup> MASO reviewers take the OGE Form 450 at “face value.” 5 CFR § 2634.605(b)(2). Further, CDC (and the HHS Office of the General Counsel) must rely on SGEs’ self-reported interests (e.g., those on the curricula vitae and OGE Forms 450) to identify potential conflicts of interest. Therefore, CDC cannot identify potential conflicts of interest that result from interests SGEs did not disclose on the current OGE Forms 450 if SGEs consistently fail to disclose these interests in other documents (e.g., curricula vitae and prior OGE Forms 450) in the financial disclosure files.

<sup>31</sup> Attorneys within the HHS Office of the General Counsel Ethics Division provide conflict-of-interest and ethics-program expertise. Attorneys within the Public Health Division (i.e., program attorneys) provide expertise on program matters (i.e., knowledge of the committee’s work that is more extensive than the summary found in the charter). HHS Office of the General Counsel Ethics Division, “Deputy Ethics Counselor HHS Ethics Program Statement of Functions, Responsibilities, and Authority,” revised August 15, 2007.

MASO's practice is to maintain in the SGEs' financial disclosure files documentation of email and phone correspondences with the SGEs, Designated Federal Officials, and the HHS Office of the General Counsel pertaining to the identification and resolution of SGEs' conflicts of interest.<sup>32</sup>

There are two main types of conflicts of interest that apply to SGEs on CDC's committees. SGEs may have conflicts of interest covered by the criminal conflict-of-interest statute, 18 U.S.C. § 208, or by the Standards of Ethical Conduct for Employees of the Executive Branch (i.e., the Standards of Ethical Conduct), 5 CFR § 2635.

*Conflicts of interest covered by the criminal conflict-of-interest statute.*

SGEs must not participate in committee work regarding particular matters that could have a direct and predictable effect on their financial interests.<sup>33</sup> A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any anticipated effect of the matter on the financial interest. The effect does not need to be immediate to be direct. A particular matter will have a predictable effect if there is a real, as opposed to a speculative, possibility that the matter will affect the financial interest. The effect does not need to be of a specific magnitude or dollar amount to be direct.

For example, in certain cases, SGEs may not participate in committee work that would affect a company if they hold that company's publicly traded stock in excess of certain minimal (i.e., de minimis) values.<sup>34, 35</sup>

Specifically, an SGE who holds stock in excess of \$15,000 in a company is prohibited from participating in committee work that could affect that

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<sup>32</sup> There is no statutory or regulatory requirement that CDC maintain this documentation. However, CDC policy requires MASO to maintain official files for each committee, which includes OGE Forms 450 and other pertinent information in accordance with the CDC Records Schedule. CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>33</sup> 5 CFR § 2635.402.

<sup>34</sup> We will use the term "particular matter" to refer to committee work that involves the interests of a specific entity (e.g., a company) or a class of entities (e.g., a sector of similar companies). 5 CFR § 2640.103 (a)(1).

<sup>35</sup> 18 U.S.C. § 208. 5 CFR § 2640.202. OGE, Memorandum to Designated Agency Ethics Officials, DO-02-006. *Publication of Final Rule Amending 5 CFR pt. 2640*. March 19, 2002. Available online at [http://www.usoge.gov/ethics\\_guidance/daeograms/dgr\\_files/2002/do02006.html](http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2002/do02006.html). Accessed on July 10, 2009.

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specific company.<sup>36</sup> Further, if an SGE holds stock with a value exceeding \$25,000 in a company or an aggregate of stock exceeding \$50,000 in a sector (i.e., a group of companies in a related industry), the SGE is prohibited from participating in committee work that could affect all companies within that sector.<sup>37</sup>

SGEs are required to list names of certain stock holdings, but not values, on the OGE Form 450. When CDC identifies a stock that poses a potential conflict of interest, it should contact the SGE to determine whether it exceeds de minimis values. Further, CDC should determine whether it must prohibit the SGE from participating in committee work involving individual companies or an entire sector of companies.

In addition, SGEs are prohibited from participating in committee work that would affect their employment, grants, assets, or board membership. For example, an SGE's employment with a vaccine manufacturer may pose a conflict of interest covered by the criminal conflict-of-interest statute if committee work could directly and predictably affect that specific vaccine manufacturer.<sup>38</sup> However, an SGE's grant, for example, would normally not pose a conflict of interest covered by the criminal conflict-of-interest statute if the committee deliberates on a particular grant or contract held by a different vaccine manufacturer.

*Conflicts of interest covered by the Standards of Ethical Conduct.* SGEs must not participate in committee work regarding particular matters if a reasonable person would question their impartiality on these matters. Such impartiality concerns could arise because of SGEs' own interests or those attributed to them on behalf of persons or entities with which SGEs have certain personal or business relationships.<sup>39</sup> For example, SGEs' impartiality may be questioned if they receive

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<sup>36</sup> 5 CFR § 2640.202(a).

<sup>37</sup> 5 CFR § 2640.202 (c) provides de minimis exemptions for values of stock owned by employees who participate in particular matters of general applicability.

<sup>38</sup> SGEs serving on committees have a regulatory exemption to participate in committee work regarding particular matters of general applicability that would affect their employer to the same extent that similarly situated entities would be affected. However, an SGE must not participate in committee work that would affect the financial interests of his or her specific employer but not similarly situated entities. 5 CFR § 2640.203(g).

<sup>39</sup> 5 CFR 2635.501 et seq. sets forth the relevant prohibitions and identifies the five applicable "covered relationships."

consulting fees, honoraria, or speaking fees from companies that could be affected by the committee’s work.

### **Resolving Conflicts of Interest**

CDC may resolve SGEs’ conflicts of interest with ethics agreements, including 18 U.S.C. § 208(b)(3) waivers (i.e., waivers).<sup>40</sup> <sup>41</sup> If CDC does not resolve a conflict of interest with an ethics agreement, it should not certify the SGE’s OGE Form 450 or permit the SGE to participate in committee work.<sup>42</sup>

Waivers acknowledge that a conflict of interest exists but that the need for the SGE’s services outweighs the risk posed by the conflict. CDC collaborates with the HHS Office of the General Counsel to develop waivers.

Adequately documented waivers must, among other requirements, reflect the SGE’s unique conflict(s) of interest.<sup>43</sup> For example, CDC must specify in a waiver:

- the specific interest(s) that pose a conflict(s),
- the general matter(s) in which CDC permits the SGE to participate, and

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<sup>40</sup> In this report, we use the term “ethics agreements” to include waivers, recusal plans, divestitures, and authorizations, which may all be used to resolve SGEs’ conflicts of interest. 5 CFR §§ 2634.802(a) and 2635.502(d). Most ethics agreements that CDC issues are limited waivers, which contain a section that describes the particular matters in which CDC prohibits the SGE from participating (i.e., recusal plans). However, CDC can document these recusal plans for an SGE separately from a waiver in cases where it determines that the SGE should be prohibited from participating in particular matters but should not be granted a waiver to participate in general committee matters. See 5 CFR §§ 2635.402(c) and 2634.804(b)(1). In cases where an SGE owns stock that exceeds established de minimis values, the SGE may be directed to sell (i.e., divest) the portion of the stock that exceeds de minimis values. 5 CFR § 2635.402(e). MASO must document in the SGE’s file that the divestiture occurred. 5 CFR § 2634.804(b)(2). An agency can determine that impartiality concerns pursuant to Subpart E of the Standards of Ethical Conduct require an employee’s recusal from participating in a particular matter. 5 CFR § 2635.502(c)(1). If the agency believes that the SGE should participate in a particular matter despite impartiality concerns, then the agency may grant the SGE an authorization to participate in that particular matter. 5 CFR § 2635.502(d).

<sup>41</sup> 5 CFR part 2634 Subpart H (“Ethics Agreements”) defines these agreements to include “any oral or written promise by a reporting individual to undertake specific actions in order to alleviate an actual or apparent conflict of interest.” Furthermore, “Subpart H of this part applies to both the public and confidential reporting systems.” 5 CFR 2634.909(c).

<sup>42</sup> CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>43</sup> 5 CFR § 2640.302 sets forth requirements for adequately documented waivers.

- any particular matter(s) in which CDC prohibits the SGE from participating.

In addition, CDC must ensure that the SGE signs the waiver to confirm and acknowledge the terms of the waiver.<sup>44</sup>

### **Providing and Documenting Ethics Training**

CDC must provide ethics training to ensure that SGEs are familiar with ethics requirements and their responsibilities not to participate in committee work regarding particular matters related to their conflicts of interest.<sup>45</sup> New SGEs must receive initial ethics training within 90 days of their appointment.<sup>46</sup> Incumbent SGEs must receive annual ethics training anytime in the calendar year.<sup>47</sup> CDC requires SGEs to submit signed and dated training certificates to document that they completed the training and understood their ethics obligations.<sup>48</sup>

### **Monitoring Compliance With Ethics Requirements During Committee Meetings**

CDC must prohibit SGEs from participating in committee meetings if they do not have current, certified OGE Forms 450 on file.<sup>49</sup> That is, new SGEs must file OGE Forms 450 within 30 days of their appointment.<sup>50</sup> Incumbent SGEs must file forms annually within 1 year

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<sup>44</sup> CDC Policy, CDC-GA-2001-05, loc. cit. In addition, pursuant to 5 CFR § 2640.302 (a)(6), SGEs with conflicts of interest may not participate in official duties related to their conflicts of interest until they are granted a waiver.

<sup>45</sup> Ibid.

<sup>46</sup> 5 CFR § 2638.703.

<sup>47</sup> 5 CFR § 2638.705 and CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>48</sup> CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>49</sup> OGE requires the SGE to file “before any advice is rendered by the employee to the agency, or in no event, later than the first committee meeting.” 5 CFR § 2634.903(b)(3). OGE also requires CDC to review and certify the form as complete. 5 CFR § 2634.605(b). Additionally, CDC requires that SGEs file and MASO certify the OGE Form 450 before the SGE participates in committee meetings. CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>50</sup> 5 CFR § 2634.903(b)(1).



of the dates CDC received their prior forms.<sup>51, 52</sup> CDC must certify current forms before SGEs participate in committee meetings.

Additionally, SGEs must not participate in committee work regarding particular matters if their waivers prohibit such participation.<sup>53</sup>

MASO must notify the Designated Federal Official when an SGE is prohibited from participating in committee work.<sup>54</sup> The Designated Federal Official is responsible for actively monitoring committee meetings to ensure that SGEs do not violate ethics requirements.<sup>55</sup>

SGEs who participate in committee meetings without current, certified OGE Forms 450 on file are not in compliance with OGE regulations and/or CDC policy. SGEs who do not comply with the terms of their waivers while participating in committee meetings may violate the criminal conflict-of-interest statute and/or the Standards of Ethical Conduct, depending on the nature of their conflict(s) of interest.

SGEs who do not comply with OGE regulations or CDC policy are subject to agency administrative action.<sup>56</sup> In addition, SGEs who allegedly violate the criminal conflict-of-interest statute are subject to prosecution by the Department of Justice.<sup>57</sup> In HHS, alleged violations

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<sup>51</sup> 5 CFR § 2634.903(b). OGE, Memorandum to Designated Agency Ethics Officials, DO-95-019. *Confidential financial disclosure and special Government employees serving in a position for more than one year*, April 11, 1995. Available online at [http://www.usoge.gov/ethics\\_guidance/daeograms/dgr\\_files/1995/do95019.txt](http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/1995/do95019.txt). Accessed on July 10, 2009. CDC Policy, CDC-GA-2001-05, loc. cit. Therefore, according to CDC policy, each SGE has a unique filing deadline for submitting OGE Forms 450.

<sup>52</sup> Incumbent SGEs submit new forms each year, regardless of whether their financial interests have changed. SGEs are also required to update the forms during the year if their financial interests change. CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>53</sup> OGE, Memorandum to Designated Agency Ethics Officials, DO-04-012. "Effective Screening Arrangements for Recusal Obligations," June 1, 2004. Available online at [http://www.usoge.gov/ethics\\_guidance/daeograms/dgr\\_files/2004/do04012.html](http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2004/do04012.html). Accessed on July 10, 2009.

<sup>54</sup> CDC Policy, CDC-GA-2001-05, loc. cit.

<sup>55</sup> Ibid.

<sup>56</sup> Pursuant to 5 CFR § 2635.106, a violation of OGE regulations justifies appropriate corrective or disciplinary action.

<sup>57</sup> Violations of the criminal conflict-of-interest statute remain allegations until the SGE is prosecuted and the judicial system determines that the SGE has actually violated the statute. 18 U.S.C. § 216 and 18 U.S.C. § 208.

of criminal ethics statutes must be reported to the Office of Inspector General (OIG).<sup>58</sup>

### **Previous Office of Inspector General Work**

In 1994, OIG reported on the National Institutes of Health's (NIH) ethics program for SGEs.<sup>59</sup> OIG found that NIH did not review financial disclosure forms to identify conflicts of interest or have up-to-date guidance on identifying and resolving conflicts of interest.

In response to OIG's recommendations, NIH implemented corrective actions to improve internal controls over conflicts of interest. For example, NIH developed a process to require ongoing updates of financial disclosure information and review of SGEs' financial interests. NIH also developed an alternate financial disclosure form to allow SGEs to disclose non-Federal grants and contracts. Further, NIH developed updated guidance to responsible NIH officials for identifying conflicts of interest and determining when waivers should be issued.

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## **METHODOLOGY**

### **Scope**

We reviewed financial disclosure files for 246 of 259 SGEs on all 17 CDC committees in 2007.<sup>60</sup> See Appendix B for additional details on our methodology, including reasons for excluding 13 SGEs.

### **Data Sources and Collection**

We reviewed ethics requirements and OGE guidance documents.

We collected 2007 data from the following sources:

- SGE financial disclosure files (e.g., OGE Forms 450 and supporting documentation, which include waivers and curricula vitae);
- committee meeting minutes; and
- committee charters.

We reviewed financial disclosure files for SGEs, meeting minutes, and committee charters. Once we reviewed all the documents that

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<sup>58</sup> HHS, *General Administration Manual*, chapter 5-10, "Responsibility and Procedures for Reporting Misconduct and Criminal Offenses," December 26, 2006.

<sup>59</sup> OIG, *Review of the National Institutes of Health's Controls Over Advisory Committees' Potential Conflicts-of-Interest*, A-15-93-00020.

<sup>60</sup> As of December 31, 2007, CDC had assigned SGEs to 17 committees.

pertained to one committee, we met with MASO to request all missing documentation for that committee (e.g., OGE Forms 450, ethics training certificates, and meeting minutes).

### **Data Analysis**

We classified the 246 SGEs as new or incumbent committee members based on their appointment dates.<sup>61</sup> In 2007, 79 percent (195 of 246) of SGEs were incumbents. We accounted for different timeframes for completing ethics requirements (e.g., submitting OGE Forms 450) for new and incumbent SGEs.

We reviewed documents in the financial disclosure files to determine whether SGEs' OGE Forms 450 were complete after CDC certified them.<sup>62</sup> Then, we identified potential conflicts of interest and determined whether CDC identified all those that we identified. We also determined the extent to which CDC created and adequately documented ethics agreements to resolve potential conflicts of interest that it identified. Further, we determined whether SGEs' financial disclosure files contained ethics training certificates. Finally, we determined whether SGEs complied with ethics requirements during committee meetings.

*Complete disclosure of financial information.* We determined whether SGEs' OGE Forms 450 were complete after CDC certified them in 2007. We used OGE review criteria to assess a form's completeness (see Appendix C). That is, we determined the extent to which reportable items were fully described and listed in appropriate sections of the certified forms. We also determined whether relevant items on SGEs' curricula vitae or the prior OGE Forms 450 were disclosed on the certified 2007 forms. In addition, we determined whether reviewers adequately documented their amendments to the forms.

We then counted the number of SGEs with incomplete OGE Forms 450 and determined how many of these SGEs were new and incumbents. Finally, we determined the number of meetings that SGEs with certified, incomplete OGE Forms 450 attended in 2007.

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<sup>61</sup> OIG analysis of CDC's 2007 SGE financial disclosure files, 2008.

<sup>62</sup> CDC certified OGE Forms 450 for 86 percent (212 of 246) of SGEs in 2007. Seventy-six percent (161 of 212) of the SGEs with certified forms were incumbents. (OIG analysis of CDC's 2007 SGE financial disclosure files, 2008.)

*Identification of potential conflicts of interest.* We reviewed committee meeting minutes, charters, and financial disclosure files to identify potential conflicts of interest for SGEs with OGE Forms 450 certified by CDC in 2007. We compared these potential conflicts of interest to those CDC identified. If CDC did not document any contact with the SGE, Designated Federal Official, or HHS Office of the General Counsel regarding those interests, we classified them as potential conflicts of interest not identified by CDC.

We then counted the number of SGEs with at least one potential conflict of interest that we identified but CDC did not. We also determined how many of those SGEs were new and incumbents. We consulted with the HHS Office of Counsel to the Inspector General to confirm CDC-identified potential conflicts of interest.

Finally, we determined the number of meetings attended by SGEs in 2007 whose OGE Forms 450 had been certified by CDC even though it had not identified potential conflicts of interest.

*Resolution of potential conflicts of interest.* We determined the extent to which CDC created ethics agreements to resolve the potential conflicts of interest that it identified in 2007. If CDC did not create an ethics agreement for a potential conflict of interest that it identified, we determined whether the documentation in the SGE's file supported CDC's conclusion that an ethics agreement was unnecessary. If CDC did create an ethics agreement (i.e., waiver), we determined whether it was adequately documented. If the documentation in an SGE's file did not support CDC's conclusion regarding a conflict of interest or if the SGE's waiver was inadequately documented, we classified the SGE as having an unresolved potential conflict of interest.

We then counted the number of SGEs with at least one unresolved potential conflict of interest. We also determined how many of those SGEs were new and incumbents. We consulted with the HHS Office of Counsel to the Inspector General to confirm unresolved potential conflicts of interest.

Finally, we determined the number of meetings attended by SGEs in 2007 whose OGE Forms 450 had been certified by CDC even though it had not resolved the potential conflicts of interest that it had identified.

*Documentation of ethics training.* We determined whether CDC ensured that SGEs' financial disclosure files contained ethics training certificates to document that SGEs received ethics training within

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required timeframes. For SGEs with training certificates in their files, we determined whether they were signed by new SGEs within 90 days of their appointment and by incumbents at any time within the 2007 calendar year.

We then counted the number of SGEs who did not have signed certificates on file within the required timeframes. For new SGEs, we also calculated the average and range in the number of days late they signed their ethics training certificates.

Finally, we determined the number of meetings that new SGEs without training certificates on file attended in 2007. We then calculated the average and range of meetings that these SGEs attended in 2007.

*Compliance with ethics requirements during committee meetings.* We reviewed meeting minutes to identify SGEs who attended the meetings, the dates of the meetings, and the particular matters in which SGEs voted.

First, we determined whether SGEs participated in committee meetings without current OGE Forms 450 on file. To do so, we determined whether SGEs submitted their forms within required timeframes in 2007. For new SGEs, we determined whether they participated in committee meetings after their appointment dates and before submitting their OGE Forms 450. For incumbents, we determined whether they participated in committee meetings after the forms were due and before they submitted the forms. Second, we determined whether SGEs participated in committee meetings while having current OGE Forms 450 on file, but before CDC certified the forms.

Then, we determined the number of meetings that SGEs without current, certified forms on file attended in 2007. We also calculated the average and range of meetings that these SGEs attended in 2007.

Finally, we determined whether SGEs complied with the terms of their waivers. To do so, we compared the subjects of SGEs' votes with the particular matters in which they were prohibited from participating, according to the terms of their waivers. We then counted the number of SGEs who voted on particular matters even though the terms of their waivers prohibited such participation.

**Limitations**

We did not attempt to identify all potential conflicts of interest that CDC did not identify or resolve for each SGE. We reported one unidentified and one unresolved potential conflict per SGE, even if we found that the SGE had additional potential conflicts of interest.

We classified CDC-identified potential conflicts of interest based on documented correspondence between CDC and the SGE, the Designated Federal Official, or the HHS Office of the General Counsel. MASO reviewers may have identified, without documenting, potential conflicts of interest that we classified as unidentified. While there is no statutory or regulatory requirement that CDC maintain this documentation, without it, CDC cannot demonstrate that MASO identified an SGE's conflict of interest.

We determined whether CDC ensured that SGEs received ethics training within required timeframes based on the existence of ethics training certificates. MASO is required to collect these certificates from SGEs. We did not search for other indicators that SGEs received required training.

Further, we based our assessment of SGEs' compliance with ethics requirements on a review of meeting minutes. However, CDC was unable to provide minutes for two committee meetings.

We reported when SGEs did not comply with the terms of their waivers only if they voted on particular matters in which they were prohibited from participating, according to the terms of their waivers. However, SGEs may have participated in prohibited committee work in ways other than voting (e.g., preliminary discussions, interim evaluations, final recommendations).

**Standards**

This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

**For almost all special Government employees, CDC did not ensure that financial disclosure forms were complete in 2007**

CDC certified OGE Forms 450 with at least one omission in 2007 for 97 percent (205 of 212) of SGEs with certified forms on file.<sup>63</sup>

Most (186 of 212) of the OGE Forms 450 had more than one type of omission. Seventy-seven percent (157 of 205) of the incomplete, certified 2007 OGE Forms 450 were submitted by incumbent SGEs.

Table 1 lists the number and percentage of certified 2007 OGE Forms 450 that were incomplete, by type of omission. Appendix D contains additional details about the types of omissions on the forms.

<b>Table 1: Of 212 Certified 2007 Confidential Financial Disclosure Reports, Number and Percentage That Were Incomplete, by Type of Omission</b>		
<b>Type of Omission</b>	<b>Number of Certified Forms</b>	<b>Percentage of Certified Forms</b>
Disclosure not made according to the form's instructions	190	90%
Relevant items on other documents not on form	167	79%
Improper amendments to form	34	16%
<b>Total*</b>	<b>205</b>	<b>97%</b>

Source: OIG review of CDC's 2007 SGE financial disclosure files, 2008.

\* Numbers in columns do not sum to total because some forms contained multiple types of omissions.

Seventy-two percent (147 of 205) of SGEs with incomplete, certified forms participated in committee meetings in 2007 after CDC certified their forms. These SGEs participated in an average of 2 committee meetings after CDC certified the forms, ranging from 1 to 16 meetings.

If CDC does not ensure that SGEs submit complete financial disclosure information prior to certifying the OGE Forms 450, it cannot ensure that it has identified and resolved all of the SGEs' potential conflicts of interest before permitting them to participate in committee meetings.

**CDC did not identify or resolve potential conflicts of interest for 64 percent of special Government employees in 2007**

In 2007, 64 percent (136 of 212) of SGEs had potential conflicts of interest that CDC did not identify and/or resolve before it certified

<sup>63</sup> We analyzed 212 forms because 212 of 246 SGEs had certified forms on file in 2007.

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their OGE Forms 450. Specifically, 58 percent (124 of 212) of SGEs had potential conflicts of interest that CDC did not identify. In addition, 32 percent (67 of 212) of SGEs had potential conflicts of interest that CDC identified but did not resolve. Twenty-six percent (55 of 212) of SGEs had both CDC-unidentified and unresolved potential conflicts of interest. Seventy percent (95 of 136) of the SGEs with CDC-unidentified and/or unresolved potential conflicts of interest were incumbents.

Nearly three-fourths (97 of 136) of SGEs with CDC-unidentified and/or unresolved potential conflicts of interest participated in at least one committee meeting in 2007 after their OGE Forms 450 were certified. These SGEs participated in an average of 3 meetings, ranging from 1 to 16 meetings. Appendix E shows the average and range in number of meetings in which these SGEs participated, by type of vulnerability.

Permitting SGEs with unidentified or unresolved conflicts of interest to participate in committee work creates vulnerabilities. That is, the SGEs may inadvertently violate ethics requirements during committee meetings because they are not aware that the conflicts of interest exist. Further, permitting such participation could compromise the integrity of the committees' work if committees make recommendations to the Government that do not best serve the public's interest.

### **Fifty-eight percent of special Government employees with certified Confidential Financial Disclosure Reports had potential conflicts of interest that CDC did not identify**

Fifty-eight percent (124 of 212) of SGEs with certified forms had at least one potential conflict of interest that CDC did not identify in 2007. For these SGEs, CDC did not document any contact with the SGE, the Designated Federal Official, or the HHS Office of the General Counsel to discuss at least one interest that we identified as a potential conflict and determine whether it did pose a conflict. Seventy-one percent (88 of 124) of these SGEs were incumbents.

Potential conflicts of interest that we identified but CDC did not fall into three general categories: employment and grants, equity ownership, and consulting. Table 2 provides the number and percentage of SGEs with CDC-unidentified potential conflicts of interest, by category.



**Table 2: Of 212 Special Government Employees With Certified Confidential Financial Disclosure Reports, Number and Percentage With CDC-Unidentified Potential Conflicts of Interest, by Category**

Category	Number of SGEs	Percentage of SGEs
Employment and grants	85	40%
Equity ownership	28	13%
Consulting	11	5%
<b>Total</b>	<b>124</b>	<b>58%</b>

Source: OIG review of CDC's 2007 SGE financial disclosure files, 2008.

The most common category was employment and grants (e.g., employment with a potential CDC or HHS grantee or contractor, recipient of CDC-funded grant). In 2007, 40 percent (85 of 212) of SGEs had potential conflicts of interest in this category that CDC did not identify. For example, over half (7 of 11) of SGEs on one committee were employed by research institutions that conducted grant-funded studies related to committee work. These research institutions were potential CDC grant recipients. However, CDC did not identify the SGEs' employment as an interest that could conflict with committee work for any of these seven SGEs. As a result, CDC did not inform the SGEs that they would violate the criminal conflict-of-interest statute if they participated in committee work regarding particular matters affecting their specific employers' financial interests.

Equity ownership (e.g., stocks, patents, business partnership) was the second most common category. In 2007, 13 percent (28 of 212) of SGEs had potential conflicts of interest in this category that CDC did not identify. For example, most (26 of 28) of these SGEs held stock in companies related to committee work, and CDC did not identify ownership of the stock as potential conflicts of interest. As a result, CDC did not contact these SGEs regarding the stocks to determine whether they exceeded de minimis values. Further, CDC did not determine, based on the value of the stock, whether it must prohibit the SGE from participating in committee work involving individual companies or an entire sector.

Finally, consulting (e.g., advisory board memberships, honoraria, speaking engagements, and expert witness activities) was the least common category. In 2007, 5 percent (11 of 212) of SGEs had potential conflicts of interest in this category that CDC did not identify.

**Nearly one-third of special Government employees with certified Confidential Financial Disclosure Reports had potential conflicts of interest that CDC identified but did not resolve**

In 2007, 32 percent (67 of 212) of SGEs with certified forms had at least one potential conflict of interest that CDC identified but did not resolve. Sixty-seven percent (45 of 67) of the SGEs were incumbents. For these 67 SGEs, CDC contacted the SGE, the Designated Federal Official, and/or the HHS Office of the General Counsel about the interests. However, CDC did not sufficiently resolve these potential conflicts of interest.

*CDC did not create ethics agreements to resolve potential conflicts of interest for 23 percent (49 of 212) of SGEs.* In 2007, CDC identified potential conflicts of interest for 49 SGEs but did not create ethics agreements to resolve them.

For 25 of the 49 SGEs, our review of the SGEs' files indicated that conflicts of interest clearly existed and ethics agreements were necessary, but CDC had not developed ethics agreements to resolve the conflicts. For example, one SGE was a member of a committee that reviewed CDC grant applications. This SGE listed a CDC-funded grant, which was active in 2007, related to committee work on his curriculum vitae. CDC contacted the SGE regarding this grant, but it did not create an ethics agreement to resolve this conflict of interest. Further, CDC did not notify this SGE that he was prohibited from participating in particular matters regarding his specific employer and/or grant.<sup>64</sup>

For the remaining 24 of the 49 SGEs, our review of the SGEs' files indicated that conflicts of interest may have existed, but CDC did not gather the necessary information to support its conclusion that conflicts did not exist. For example, one SGE emailed CDC indicating that she likely owned stock in a company related to committee work in excess of \$25,000. The Designated Federal Official and a program attorney within the HHS Office of the General Counsel advised MASO that ownership of stock in that company did not pose a conflict because the SGE's committee would not likely discuss that specific company. However, CDC should prohibit an SGE with stock in excess of \$25,000 from participating in committee work that could affect the entire sector of companies. CDC documented its determination that there was no conflict of interest without first confirming whether the stock was above \$25,000.

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<sup>64</sup> CDC subsequently issued an ethics agreement for this SGE, citing this grant, in March 2008.

*CDC created waivers but did not adequately document them for 8 percent (18 of 212) of SGEs.* Eight percent (18 of 212) of SGEs had waivers on file in 2007. However, CDC certified these SGEs' OGE Forms 450 in 2007 without adequately documenting their waivers. Specifically, all (18 of 18) of these SGEs had waivers that did not specify the SGEs' conflicts of interest, the general matters in which they were permitted to participate, or the particular matters in which they were prohibited from participating.

That is, CDC used general language in these waivers covering broad categories of interests to describe the SGEs' conflicts that it identified during its review of the OGE Forms 450 and curricula vitae. Identical language was often repeated in different SGEs' waivers. For example:

- “[e]mployment or consulting with, and honoraria or other compensation from, research institutions, state and local government, pharmaceutical companies, health care industries, or other organizations . . . ;”
- “[g]rants, contracts, or other funding for research or other services that he may receive from the Federal government and from non-Federal sources;” and
- “[e]xpert witness, litigation or advocacy services.”

CDC did not specify each SGE's unique conflicts of interest by stating, for example, that an SGE's employment with university X, a current CDC grantee, creates a conflict of interest.

Additionally, CDC stated, for example, that the SGE would be granted “a waiver under 18 U.S.C. § 208(b)(3), permitting him to participate in the deliberations and recommendations of [the committee].” However, CDC did not specify the general matters related to the conflicts of interest in which the SGE was permitted to participate.

Further, CDC did not specify the particular matters in which the SGE was prohibited from participating. For example, CDC did not state that the SGE is prohibited from participating in committee work addressing radiation exposure at facility X.

Finally, CDC certified 2007 OGE Forms 450 for 7 of these 18 SGEs with waivers without ensuring that the SGEs signed their waivers to indicate that they were informed of the terms of the waiver and any limitations on

their participation in committee work because of their conflicts of interest.<sup>65</sup>

**CDC did not ensure that 41 percent of special Government employees received required ethics training in 2007**

CDC did not ensure that 41 percent (101 of 246) of SGEs had ethics training certificates on file to document that SGEs received ethics training within required timeframes in 2007.<sup>66</sup>

Thirteen percent (13 of 101) of these SGEs were new committee members who did not have ethics training certificates on file to demonstrate that they received initial ethics training within 90 days of their appointment. On average, these SGEs completed the training 183 days late, ranging from 21 to 288 days late.

Nine of the thirteen new SGEs participated in committee meetings prior to completing initial ethics training in 2007. These SGEs participated in an average of 4 committee meetings before the dates of their training certificates, ranging from 1 to 14 meetings. These SGEs' participation poses a vulnerability because they had not received initial ethics training prior to participating in committee meetings and were not informed about their ethics obligations as an SGE.

The remaining 87 percent (88 of 101) of the SGEs without training certificates were incumbents. These SGEs did not have ethics training certificates on file to demonstrate that they received annual ethics training at any point in 2007.

If CDC does not document SGEs' receipt of ethics training, it cannot demonstrate that SGEs were aware of their ethics requirements when participating in committee work.

**Fifteen percent of special Government employees did not comply with ethics requirements during committee meetings in 2007**

In 2007, 15 percent (36 of 246) of SGEs did not comply with ethics requirements during committee meetings. Specifically, 13 percent

<sup>65</sup> In addition, one SGE signed, but did not date, the waiver. We did not count this SGE among the seven who did not sign their waivers before CDC certified their OGE Forms 450.

<sup>66</sup> We analyzed the entire sample of 246 SGEs rather than only 212 SGEs with certified OGE Forms 450 on file because the existence of a training certificate in an SGE's file is independent of a certified OGE Form 450.

(33 of 246) of SGEs participated in committee meetings in 2007 without having current, certified OGE Forms 450 on file. In addition, 3 percent (7 of 246) of SGEs voted on particular matters when the terms of their waivers prohibited such participation. Four SGEs both participated in committee meetings without current, certified OGE Forms 450 on file and voted on particular matters when their waivers prohibited such participation.

**Thirteen percent of special Government employees participated in committee meetings without having current, certified Confidential Financial Disclosure Reports on file**

Thirteen percent (33 of 246) of SGEs participated in at least one meeting without having current, certified OGE Forms 450 on file in 2007.<sup>67</sup> Almost all (31 of 33) of these SGEs were incumbents.

Specifically, 7 percent (17 of 246) of SGEs participated in at least one committee meeting before submitting 2007 OGE Forms 450. Almost all (16 of 17) of these SGEs were incumbents and, at the time of their participation, had not submitted OGE Forms 450 within 12 months of their prior submissions. One SGE was new and did not submit an OGE Form 450 within 30 days of appointment. These 17 SGEs participated in an average of one meeting without having current forms on file, ranging from one to two meetings.

In addition, 7 percent (18 of 246) of SGEs participated in at least one committee meeting before CDC certified their 2007 OGE Forms 450.<sup>68</sup> Almost all (17 of 18) of the SGEs were incumbents. The 18 SGEs participated in an average of two meetings without having certified forms on file, ranging from one to eight meetings.

To prevent SGEs from participating in committee meetings without current, certified OGE Forms 450, we shared detailed information regarding these 33 SGEs with CDC and the HHS Office of the General Counsel in April 2009.

**Three percent of special Government employees voted on particular matters in which they were prohibited from participating**

Three percent (7 of 246) of SGEs voted on particular matters when the terms of their waivers prohibited such participation. All seven of these SGEs were on one committee, and five were incumbents.

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<sup>67</sup> In 2007, 42 percent (103 of 246) of SGEs did not submit their OGE Forms 450 by the filing deadline. These SGEs submitted their forms an average of 75 days late, ranging from 1 to 361 days late.

<sup>68</sup> Two of these eighteen SGEs also participated in at least one meeting before submitting their 2007 OGE Forms 450.

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To prevent continued noncompliance at subsequent committee meetings, we shared detailed information regarding these seven SGEs with CDC upon discovery and with the HHS Office of the General Counsel in April 2009. These cases were also forwarded to OIG's Office of Investigations for review and evaluation to determine the appropriate course of action.<sup>69</sup>

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<sup>69</sup> The cases were forwarded to the OIG Office of Investigations because the waivers were created pursuant to the criminal conflict-of-interest statute. The OIG Office of Investigations reviewed information regarding these seven SGEs and determined, largely as a result of CDC's systemic lack of oversight of the ethics program for SGEs identified in this report, that the actions of the seven SGEs did not rise to the level of criminal violations of the conflict-of-interest statute.



## R E C O M M E N D A T I O N S

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SGEs on CDC Federal advisory committees are voting members who may have conflicts of interest with their committee work. To protect the committees' integrity and credibility, SGEs with conflicts of interest must not inappropriately influence their committees' work. However, we found that CDC had a systemic lack of oversight of the ethics program for SGEs. That is, for almost all SGEs, CDC did not ensure that they submitted complete financial information in 2007. Additionally, CDC did not identify or resolve potential conflicts of interest for 64 percent of SGEs. CDC also did not ensure that 41 percent of SGEs had ethics training certificates on file to indicate that they received initial or annual ethics training and were informed about their ethics obligations. Finally, 15 percent of SGEs did not comply with ethics requirements during committee meetings.

Therefore, we recommend that CDC:

**Ensure that special Government employees' Confidential Financial Disclosure Reports are complete before certifying them**

During its review of the OGE Forms 450, CDC should ensure that all items are complete and listed in all relevant sections of the form, according to the form's instructions and OGE guidance. In addition, CDC should compare the OGE Form 450 with the SGE's curriculum vitae and the prior OGE Form 450 to ensure that all relevant items disclosed on these documents are contained on the current OGE Form 450. For all items requiring amendments, CDC should ensure that MASO reviewers document the SGE's authorization of the changes. Further, CDC should ensure that MASO reviewers initial and date their amendments. CDC could also implement an automated system for SGEs to submit their OGE Forms 450.

**Require special Government employees to disclose their involvement in grants and other relevant interests that could pose conflicts but that are not disclosed on the Confidential Financial Disclosure Report**

The OGE Forms 450 do not require SGEs to disclose all interests that could pose conflicts. For example, information about SGEs' grant activities and patents are not required to be disclosed on the OGE Forms 450. However, CDC should obtain information regarding SGEs' interests that could pose conflicts, such as their involvement in grants, to identify conflicts of interest posed by these interests. To accomplish this, CDC could require, rather

than request, SGEs to submit updated curricula vitae. However, SGEs do not disclose all necessary information consistently, or at all, on the curricula vitae. Therefore, CDC could also request OGE to approve an alternate OGE Form 450 that requires SGEs to disclose their involvement in grants and other relevant interests that are not disclosed on the OGE Form 450.

**Identify and resolve all conflicts of interest for special Government employees before permitting them to participate in committee meetings**

CDC should thoroughly review each SGE's financial disclosure file to identify conflicts of interest covered by the criminal conflict-of-interest statute or the Standards of Ethical Conduct. CDC should thoroughly review the OGE Forms 450, curricula vitae, committee charters, and meeting minutes to become more familiar with topics covered by the committees and identify interests that could pose a conflict of interest with committee work.

Additionally, CDC could seek SGEs' input on what interests could pose conflicts. That is, for each committee, CDC could develop targeted questionnaires to elicit information from the SGEs to help CDC identify potential conflicts of interest. By virtue of their expertise in the field related to committee work, SGEs may be better positioned to identify potential conflicts of interest with committee work than MASO reviewers. For example, to determine if an SGE who holds stock in a pharmaceutical company has a potential conflict of interest, MASO reviewers would need to be familiar with the drugs currently marketed and under development by the company and all uses for these drugs. While MASO reviewers are typically not as knowledgeable in these areas, SGEs are considered experts.

Alternatively, CDC could implement a system whereby, before each meeting, CDC program staff would generate and share with MASO a list of potential conflicts of interest that pertain to matter(s) that will be discussed during that meeting. Additionally, SGEs would disclose their interests before each meeting so that MASO could identify potential conflicts of interest based on the most up-to-date disclosures. At the meeting, MASO would provide each SGE with a list of his or her own potential conflicts of interest as well as the more general list of potential conflicts of interest developed by CDC program staff prior to the meeting.

Once CDC determines that a conflict of interest does exist, it should resolve it with a properly documented ethics agreement. CDC should ensure that SGEs sign their ethics agreements, especially when the documents describe particular matters in which SGEs are prohibited from participating. CDC should ensure that SGEs sign these ethics agreements before it certifies the OGE Forms 450 and before the SGEs participate in committee meetings.



When CDC develops a waiver for an SGE, it should ensure that the document describes the specific conflict of interest, general matters in which that SGE is permitted to participate, and particular matters in which the SGE is prohibited from participating.

If CDC determines that an interest does not pose a conflict, it should ensure that the documentation in the SGE's file supports this conclusion.

**Increase collaboration among CDC officials and with the HHS Office of the General Counsel**

To improve CDC's ability to identify and resolve conflicts of interest, MASO should increase its collaboration with the Designated Federal Officials and the HHS Office of the General Counsel. For example, when CDC requests additional information from the Designated Federal Official or the HHS Office of the General Counsel, it could request a written explanation to support their conclusion regarding the conflict.

Additionally, CDC should coordinate with both ethics attorneys and program attorneys from the Office of the General Counsel to ensure ethics agreements include language to comply with ethics statutes and regulations, as well as specific language to address particular matters in which SGEs are prohibited from participating.

**Ensure that special Government employees and CDC employees receive ethics training**

CDC should ensure that all SGEs receive required initial and annual ethics training and that receipt of the training is documented in the SGEs' files. To ensure that SGEs receive ethics training as required, CDC should prohibit new SGEs from participating in committee meetings until they submit the training certificates. To facilitate its ability to identify SGEs who have received ethics training, CDC could implement a computer-based training system to automatically generate ethics training certificates and track whether SGEs completed their ethics training.

Further, CDC should develop additional training for SGEs on how to submit complete OGE Forms 450. For example, CDC could identify common technical and substantive errors on the OGE Forms 450 and provide training to SGEs in these areas.

Finally, CDC should also provide training for MASO reviewers and Designated Federal Officials in reviewing forms for completeness, identifying conflicts of interest, and determining when ethics agreements should be developed.

**Monitor special Government employee compliance with ethics requirements during committee meetings**

CDC should prohibit SGEs from participating in any committee meetings if they do not have current, certified OGE Forms 450 on file. MASO should notify the Designated Federal Official when an SGE has not submitted an OGE Form 450 by the filing deadline and advise that the SGE is prohibited from participating in committee meetings. When the SGE subsequently submits the form and CDC certifies it, MASO should notify the Designated Federal Official that the SGE is permitted to participate in committee meetings.

In addition, CDC should ensure that SGEs comply with the terms of their ethics agreements during committee meetings. To do this, CDC could review ethics agreements and remind each SGE about the matters in which they are prohibited from participating before each meeting. Further, CDC should ensure that the Designated Federal Officials prohibit SGEs from participating in particular matters when their ethics agreements prohibit their participation on such matters. To facilitate their ability to monitor the SGEs' compliance with ethics agreements, CDC should ensure that, during committee meetings, the Designated Federal Officials have a list of SGEs and the particular matters in which they are prohibited from participating.

CDC could also have MASO reviewers attend committee meetings to ensure SGEs' compliance with ethics requirements during the meetings.

**Track special Government employee compliance with ethics requirements**

CDC officials, independent of those who attend the committee meetings, should regularly review meeting minutes to determine whether SGEs complied with ethics requirements. Specifically, CDC officials should track whether SGEs participate in committee meetings without certified OGE Forms 450 on file. Additionally, qualified CDC officials should track whether SGEs with ethics agreements participate in particular matters when their ethics agreements prohibit such participation.

Finally, if an SGE does not comply with the criminal conflict-of-interest statute, CDC should notify the SGE and the Designated Federal Official and report the case to the HHS OIG. If an SGE does not comply with the Standards of Ethical Conduct or CDC policy during committee meetings, CDC should notify the SGE and the Designated Federal Official and take appropriate administrative action.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC concurred with all seven of our recommendations. Since the time of our review, CDC indicated that it has begun or plans to implement improvements that coincide with our recommendations. Specifically, CDC noted that (1) CDC has strengthened its controls to ensure that there are no omissions related to reportable information required by the OGE Form 450; (2) CDC will work with HHS and OGE to develop a means of collecting information on interests (e.g., grants) that are not currently required on the OGE Form 450; (3) CDC has implemented a “Record of Analysis” to document that MASO has performed an analysis of potential conflicts of interest; (4) MASO has established a workgroup, which includes the Designated Federal Officials and the HHS Office of the General Counsel Ethics Division, to raise and/or resolve matters relating to the management of CDC’s committees including issues related to financial disclosure and conflicts of interest; (5) CDC is revising its process to allow SGEs to electronically report their receipt and review of ethics training; (6) CDC will consult with other HHS agencies to determine best practices that could be implemented to enhance its program and improve its process for monitoring SGE compliance with ethics requirements during committee meetings; and (7) MASO will have a greater presence at committee meetings and audit minutes to track SGE compliance with ethics requirements.

However, CDC expressed concerns with fully implementing our recommendation to ensure that OGE Forms 450 are complete. That is, CDC indicated that it is impractical to follow up with SGEs to verify interests not found on the OGE Forms 450 if these interests can be found through a comprehensive review of supplementary documents, such as the curricula vitae. CDC indicated that, through this review, it is able to accomplish the primary purpose of financial disclosure, which is to identify and resolve potential conflicts of interest. However, pursuant to Federal regulation, all required information must be documented on the OGE Form 450. Therefore, we recommend that CDC ensure that each required item is disclosed on the OGE Form 450. Accordingly, in assessing OGE Form 450 completeness, CDC should not consider supplemental documents (e.g., the curriculum vitae) to be part of the OGE Form 450. Further, we determined that CDC did not identify and resolve all potential conflicts of interest that we identified based on our review of all the information in the financial disclosure files, including the SGEs’ curricula vitae.

R E C O M M E N D A T I O N S

We made technical changes to the report based on CDC's comments. For the full text of CDC's comments, see Appendix F.

► A P P E N D I X ~ A

**Federal Advisory Committees at the Centers for Disease Control and Prevention, as of December 31, 2007**

Office of the Director

Advisory Committee on Immunization Practices

Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC)

Coordinating Center for Environmental Health and Injury Prevention

Advisory Committee on Childhood Lead Poisoning Prevention

Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry

Board of Scientific Counselors, National Center for Injury Prevention and Control<sup>70</sup>

Coordinating Center for Health Information and Service

Board of Scientific Counselors, National Center for Health Statistics

National Committee on Vital and Health Statistics

Coordinating Center for Health Promotion

Breast and Cervical Cancer Early Detection and Control Advisory Committee

Interagency Committee on Smoking and Health

Coordinating Center for Infectious Diseases

Advisory Council for the Elimination of Tuberculosis

Board of Scientific Counselors, Coordinating Center for Infectious Diseases

CDC/Health Resources and Services Administration Advisory Committee on Human Immunodeficiency Virus and Sexually Transmitted Disease Prevention and Treatment

Clinical Laboratory Improvement Advisory Committee

Healthcare Infection Control Practices Advisory Committee

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<sup>70</sup> This committee was previously chartered as the Advisory Committee for Injury Prevention and Control. 73 Fed. Reg. 80412 (Dec. 31, 2008). Available online at <http://edocket.access.gpo.gov/2008/E8-31111.htm>. Accessed on July 10, 2009.

A P P E N D I X ~ A

*National Institute for Occupational Safety and Health*

Advisory Board on Radiation and Worker Health

Board of Scientific Counselors, National Institute for Occupational  
Safety and Health

Mine Safety and Health Research Advisory Committee

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## DETAILED METHODOLOGY

### Scope

We reviewed financial disclosure files for 246 of 259 special Government employees (SGE) on all 17 Federal advisory committees (committees) to which the Centers for Disease Control and Prevention (CDC) had assigned SGEs. The 246 SGEs were active as of December 31, 2007, (i.e., they were listed on a January 22, 2008, printout from CDC's committee database and were appointed prior to January 1, 2008).

We did not review files for 9 of the 259 SGEs because they were assigned to a committee sponsored jointly by CDC and the Health Resources and Services Administration. These SGEs were technically employed by the Health Resources and Services Administration.

We also excluded an additional four SGEs who were appointed in late 2007 and had not submitted Confidential Financial Disclosure Reports (Office of Government Ethics (OGE) Forms 450) in 2007. These forms were not due until 2008.

### Data Sources and Collection

We reviewed conflict-of-interest statutes, OGE regulations and guidance documents, and CDC policy regarding SGE ethics requirements. Hereinafter, we refer to conflict-of-interest statutes, OGE regulations, and CDC policy as "ethics requirements."

We collected 2007 data from the following sources:

- SGE financial disclosure files (i.e., SGEs' current and prior OGE Forms 450; curricula vitae; official correspondence between CDC and SGEs, Designated Federal Officials, and/or the Department of Health and Human Services (HHS) Office of the General Counsel; ethics agreements; and ethics training certificates);
- committee meeting minutes; and
- committee charters.

We reviewed financial disclosure files for SGEs, meeting minutes, and committee charters. Once we reviewed all the documents that pertained to one committee, we met with the Management Analysis and Services Office to request all missing documentation for that committee (e.g., OGE Forms 450, ethics training certificates, and meeting minutes).

### Data Analysis

We classified the 246 SGEs as new or incumbent committee members based on their appointment dates. We defined new SGEs as those appointed in 2007 or appointed within the last 30 days of 2006. All other SGEs were incumbents. In 2007, 21 percent (51 of 246) of CDC's SGEs were new; 79 percent (195 of 246) were incumbents.<sup>71</sup> We accounted for different timeframes for completion of ethics requirements imposed on new and incumbent SGEs.

CDC certified OGE Forms 450 for 86 percent (212 of 246) of SGEs in 2007. Twenty-four percent (51 of 212) of the SGEs with certified forms were new; 76 percent (161 of 212) were incumbents.<sup>72</sup>

We reviewed financial disclosure files for 212 SGEs with certified 2007 OGE Forms 450 to determine whether their forms were complete after CDC certified them. Then, we identified potential conflicts of interest and determined whether CDC identified all those that we identified.

We reviewed financial disclosure files for all 212 SGEs to determine the extent to which CDC created ethics agreements and adequately documented them to resolve potential conflicts of interest that it identified. Further, we determined whether SGEs' financial disclosure files contained ethics training certificates. Finally, we determined whether SGEs complied with ethics requirements during committee meetings.

*Complete disclosure of financial information.* We determined whether SGEs' OGE Forms 450 were complete after CDC certified them in 2007. Upon receipt, CDC has 60 days to review OGE Forms 450, and it should certify them shortly thereafter.<sup>73</sup> By December 31, 2007, CDC had received 224 OGE Forms 450 from its 246 SGEs. The 12 forms that CDC did not certify by the end of 2007 were received between June 14 and December 31, 2007. Nine of the twelve forms were submitted within the last 60 days of 2007.

To determine whether a certified form was complete, we used relevant criteria from OGE's guide for reviewing OGE Forms 450 (see Appendix C). That is, we determined the extent to which reportable

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<sup>71</sup> OIG analysis of CDC's 2007 SGE financial disclosure files, 2008.

<sup>72</sup> Ibid.

<sup>73</sup> HHS Office of the General Counsel, Ethics Division, Designated Agency Ethics Official (DAEO). "DAEO Supplemental Instruction No. 06-2," loc. cit.



items were fully described and listed in appropriate sections of the form, according to the OGE Form 450 instructions. We also determined whether relevant items on curricula vitae or the prior OGE Form 450 were disclosed on the 2007 certified form. Finally, we reviewed OGE Forms 450 for reviewers' annotations and determined whether the amendments indicated that the SGEs authorized the changes and contained the reviewers' initials and the dates of the changes. That is, we determined whether there was evidence that SGEs approved changes made by MASO to the forms (e.g., email correspondence between MASO and the SGE or MASO documentation indicating that a phone conversation had taken place with the SGE regarding the change). We also determined whether the amendment contained the reviewer's initials and the date of the change.

We then counted the number of SGEs with incomplete forms. We also determined how many of those SGEs were new and incumbents. Finally, we determined the number of meetings that SGEs with certified, incomplete OGE Forms 450 attended in 2007. We counted the number of meetings these SGEs attended between the dates CDC certified their 2007 OGE Forms 450 and December 31, 2007.

*Identification of potential conflicts of interest.* To assess CDC's identification and resolution of conflicts of interest, we reviewed meeting minutes and committee charters to ascertain the scope of the matters generally discussed by each committee. We then reviewed financial disclosure files for SGEs with OGE Forms 450 certified by CDC in 2007 to identify potential conflicts of interest.

We reviewed the certified OGE Forms 450 and determined whether CDC identified all potential conflicts of interest that we identified before it certified them. If CDC did not document any contact with the SGE, Designated Federal Official, or HHS Office of the General Counsel regarding interests we identified as potential conflicts, we classified the interests as not identified by CDC.

We then counted the number of SGEs with at least one interest that we identified but CDC did not. We also determined how many of those SGEs were new and incumbents. We consulted with the HHS Office of Counsel to the Inspector General to confirm the CDC-unidentified potential conflicts of interest.

Finally, we determined the number of meetings attended by SGEs in 2007 whose OGE Forms 450 had been certified by CDC even though it

had not identified the potential conflicts of interest. We counted the number of meetings these SGEs attended between the dates CDC certified their 2007 OGE Forms 450 and December 31, 2007.

*Resolution of potential conflicts of interest.* We determined the extent to which CDC resolved potential conflicts of interest that it identified before certifying OGE Forms 450. If the documentation in an SGE's file did not support CDC's conclusion regarding a conflict of interest or if the SGE's waiver was inadequately documented, we classified the SGE as having an unresolved potential conflict of interest.

If CDC did not create an ethics agreement for an interest that it identified, we determined whether the documentation in the SGE's file supported CDC's conclusion that an ethics agreement was unnecessary. For example, CDC documented advice from Designated Federal Officials to support its determination that a conflict of interest did not exist. In some cases, the documented advice contained only a statement by the Designated Federal Official indicating that he or she did not see a conflict of interest, but the Designated Federal Official did not provide any facts or analysis to support this conclusion. In these cases, we determined that the conclusory statement alone was not sufficient to outweigh other facts in the file suggesting that a potential conflict of interest existed. Additionally, if documented advice was based on an inaccurate interpretation of ethics requirements, we determined that the potential conflict of interest was not resolved.

If CDC did create an ethics agreement to resolve an SGE's conflict of interest, we determined whether it was adequately documented. We classified 18 U.S.C. 208 § (b)(3) waivers (i.e., waivers) as adequately documented if they specified (1) the item(s) that posed the conflict(s) of interest, (2) any general matters in which the SGE was permitted to participate in committee meetings, and (3) particular matters in which the SGE was prohibited from participating. In addition, we determined whether SGEs signed and dated their waivers.

We then counted the number of SGEs with at least one unresolved conflict of interest. We did not consider potential conflicts of interest that CDC did not identify in our count of unresolved potential conflicts of interest. We also determined how many of those SGEs were new and incumbents. We consulted with the HHS Office of Counsel to the Inspector General to confirm that the SGEs had at least one unresolved potential conflict of interest.

Finally, we determined the number of meetings attended by SGEs in 2007 whose OGE Forms 450 had been certified by CDC even though it had not resolved the potential conflicts of interest that it had identified. We counted the number of meetings these SGEs attended between the dates CDC certified their 2007 OGE Forms 450 and December 31, 2007.

*Documentation of ethics training.* We determined whether CDC ensured that SGEs' financial disclosure files contained ethics training certificates to document that SGEs received ethics training within required timeframes. For SGEs with training certificates in their files, we determined whether they were signed by new SGEs within 90 days of their appointment and by incumbents at any time within the 2007 calendar year.

We then counted the number of SGEs who did not have signed certificates on file within the required timeframes. For new SGEs, we also calculated the average and range in the number of days late they signed their ethics training certificates.

One new SGE was appointed less than 90 days prior to the end of 2007 and did not have a training certificate on file. We did not include this SGE in our count of SGEs without training certificates on file because the training certificate was not yet due.

Finally, we determined the number of meetings that new SGEs without training certificates on file attended in 2007. We counted the number of meetings these SGEs attended between the dates their training certificates were due and the dates they signed their training certificates or December 31, 2007. We then calculated the average and range of meetings that these SGEs attended in 2007.

*Compliance with ethics requirements during committee meetings.* We reviewed meeting minutes to identify SGEs who attended the meetings, the dates of the meetings, and the particular matters in which SGEs voted.

First, we determined whether SGEs participated in committee meetings without current OGE Forms 450 on file. To do so, we determined whether SGEs submitted their forms within required timeframes in 2007. That is, we determined the extent to which new SGEs submitted their forms within 30 days of their appointment and incumbent SGEs submitted their forms within 1 year of their prior filing.

For new SGEs, we determined each SGE's appointment date based on the SGEs' official appointment records. We then compared this date to the SGE's 2007 OGE Form 450 submission date to determine whether the SGE submitted the form within the required 30 days. For incumbent SGEs, we determined whether SGEs submitted the 2007 OGE Forms 450 within 1 year of the dates CDC received their prior OGE Forms 450. Eight SGEs each submitted two OGE Forms 450 in 2007. In these cases, we reviewed the most recently submitted OGE Forms 450 in 2007 that CDC had certified by the time of our review (i.e., spring 2008). For these SGEs, we used the prior 2007 OGE Forms 450 to serve as the prior forms.

One SGE submitted an illegible OGE Form 450 in 2007. CDC did not accept this form as a valid submission, so we classified this SGE as not submitting a form in 2007.

We then determined whether SGEs participated in committee meetings before submitting their current OGE Forms 450. For new SGEs, we determined whether they participated in committee meetings after their appointment dates and before submitting their OGE Forms 450. For incumbents, we determined whether they participated in committee meetings after the forms were due and before they submitted the forms.

Second, we determined whether SGEs participated in committee meetings before CDC certified their current OGE Forms 450. That is, we determined whether SGEs participated in committee meetings after submitting their current forms and before CDC certified them.

Then, we determined the number of meetings that SGEs without current, certified forms on file attended in 2007. We also calculated the average and range of meetings that these SGEs attended in 2007.

Finally, we determined whether SGEs complied with the terms of their waivers. To do so, we compared the subjects of SGEs' votes with the particular matters in which they were prohibited from participating, according to their waivers. We reviewed meeting minutes to identify particular matters in which SGEs voted. We compared the subjects of these votes with the particular matters in which the SGEs were prohibited from participating, as outlined in the SGEs' waivers. We counted the number of SGEs who voted on particular matters even though the terms of their waivers prohibited such participation.

## ► A P P E N D I X ~ C

### **Office of Government Ethics Guidance for Determining Whether 2007 Confidential Financial Disclosure Reports Are Complete<sup>74</sup>**

To determine whether Confidential Financial Disclosure Reports (OGE Forms 450) were complete, we used the following criteria from the Office of Government Ethics (OGE) guidance and instructions on the OGE Form 450.<sup>75</sup>

#### *For Part I – Assets and Income*

- Was specific employer listed?
- Were specific names of sector-specific mutual funds listed?
- Were specific names of publicly traded stock disclosed?
- Was type of income indicated (i.e., stock)?
- For honoraria, were dates shown (month and year that services were provided)?
- If sources of income are from outside employment, have they been described in Part III - Outside Positions?

#### *For Part II - Liabilities*

- Is the name and location (city and State) for all reportable creditors indicated?
- Is the type of liability (debt) shown, such as promissory note, mortgage, or loan?
- For mortgages, are there corresponding rental properties reported in Part I?

#### *For Part III - Outside Positions*

- Are name and location (city and State) for the organization indicated?
- Is the organization's purpose or function stated?
- Has the filer indicated the specific position held or nature of activity with the organization?

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<sup>74</sup> OGE, "OGE Form 450: A Review Guide," op. cit., beginning on p. 30.

<sup>75</sup> The OGE guidance was issued in 1996. Because of changes to the OGE Form 450 in January 2007, we excluded some of OGE's original criteria, which no longer apply. An attorney from the Office of Counsel to the Inspector General confirmed that the criteria listed in this Appendix reflect the current review requirements for the January 2007 OGE Form 450.

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- ❑ For positions that would ordinarily produce reportable earned income, such as an employee, consultant, or director, check to see that an entry is shown in Part I - Assets and Income.

*For Part IV - Agreements and Arrangements*

- ❑ Are the basic elements of the agreement or arrangement stated, such as employment terms, effective dates, etc.?
- ❑ Are the parties identified, with location (city and State)?
- ❑ Is a date (month and year) for the agreement or arrangement shown?
- ❑ If the agreement or arrangement is for a pension or for other payments due from a former or current employer, is that asset or source of income reported in Part I - Assets and Income?

➤ A P P E N D I X ~ D

<b>Details Regarding Number and Percentage of Certified 2007 Confidential Financial Disclosure Reports That Were Incomplete, by Type of Omission</b>		
<b>Type of Omission</b>	<b>Number of Certified Forms</b>	<b>Percentage of Certified Forms</b>
Disclosure not made according to form's instructions	190	90%
Items were not fully described (e.g., full name, location, or type of position was not listed in Part III - Outside Positions)	120	57%
Items were not listed in all appropriate sections (e.g., income-earning positions in Part III – Outside Positions were not listed as sources of income in Part I – Income)	170	80%
Relevant items on other documents not on form	167	79%
Relevant item was on curriculum vitae	123	58%
Relevant item was on prior form	103	49%
Improper amendments to form	34	16%
Special Government employee's (SGE) authorization of change was not documented	34	16%
Reviewer did not initial the change	11	5%
Reviewer did not date the change	11	5%
<b>Total*</b>	<b>205</b>	<b>97%</b>

Source: Office of Inspector General review of the Centers for Disease Control and Prevention's 2007 SGE financial disclosure files, 2008.

\* Numbers in columns do not sum to total because some forms contained multiple types of omissions.

➤ A P P E N D I X ~ E

This table provides the number and percentage of special Government employees (SGE) who had vulnerabilities in their files and who participated in committee meetings in 2007, by type of vulnerability and average and range in meeting participation.

<b>Average and Range in Committee Meetings in Which Special Government Employees Participated in 2007 After Their Forms Were Certified, by Type of Vulnerability in Their Files</b>				
<b>Type of Vulnerability</b>	<b>Number of SGEs</b>	<b>Percentage of SGEs</b>	<b>Average Meeting Participation</b>	<b>Range in Meeting Participation</b>
File contained potential conflicts of interest that the Centers for Disease Control and Prevention (CDC) did not identify	124	58%	2	1-16
File contained potential conflicts of interest that CDC did not resolve	67	32%	2	1-14
<b>Total*</b>	<b>136</b>	<b>64 %</b>	<b>2</b>	<b>1-16</b>

Source: Office of Inspector General review of CDC's 2007 SGE financial disclosure files and committee meeting minutes, 2008.

\* Numbers in columns do not sum to total because some forms contained multiple types of omissions.



## AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

NOV 13 2009

TO: Daniel R. Levinson  
Inspector General  
Department of Health and Human Services (HHS)

FROM: Director  
Centers for Disease Control and Prevention

SUBJECT: Draft Report: "The Centers for Disease Control and Prevention's Ethics Program for Special Government Employees on Federal Advisory Committees," (OEI-04-07-00260)

The Centers for Disease Control and Prevention (CDC) Management Analysis and Services Office (MASO) appreciates the opportunity to review and comment on the Office of Inspector General's draft report entitled, "The Centers for Disease Control and Prevention's Ethics Program for Special Government Employees on Federal Advisory Committees." Thank you for your review of this important issue.

As stated in the draft, the objective of this report was to determine the extent to which the CDC and its Special Government Employees (SGEs) on Federal advisory committees complied with ethics requirements. The draft identified four findings related to the administration of the SGEs confidential financial disclosure process and also provided seven recommendations to address the findings.

It is important to recognize that the timing of the OIG report was such that the data that OIG used to reach its findings was based upon processes that had already been determined by CDC to be in need of review and revision. As a result, some findings of the audit are reflective of technical and administrative areas where CDC has already identified opportunities for improvement, has implemented process improvements, or is planning to implement improvements. This response will address OIG findings and recommendations, noting areas where changes in line with those findings and recommendations are planned or already in place.

**CDC Introductory Comments:**

The U.S. Office of Government Ethics (OGE) has regulatory and oversight responsibility for ethics programs across the Executive Branch. OGE regulations pertaining to the confidential financial disclosure reporting requirements for SGEs can be found at Subpart I of Part 2634 in Title 5 of the Code of Federal Regulations.

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The primary purpose for collection of Confidential Financial Disclosure Reports from SGEs is to enable CDC to analyze financial and other interests to determine whether conflicts of interest exist, and thus determine appropriate means of resolving real and apparent conflicts of interest. In April 2009, OIG issued a letter to CDC, including a list of affected SGEs. CDC and HHS/OGC reviewed the preliminary findings, responded to inaccuracies and took immediate action to clarify and improve the 18 U.S.C. § 208(b)(3) waivers in question. CDC recognizes and concurs with the necessity for accurate and appropriate disclosure by SGE filers to ensure and protect the integrity and effectiveness of CDC's Federal advisory committees.

Since the period covered in this review, CDC has strengthened the financial disclosure and conflict of interest process by instituting improved business processes and realigning responsibilities and oversight. Additionally, I am pleased to report that CDC has entered into an interagency agreement with the Department of the Army (DOA) to utilize DOA's Financial Disclosure Management (FDM) system to electronically process CDC's SGEs OGE Form 450. MASO projects implementation of the FDM system to be fully operational by December 31, 2009. OGE indicates that DOA's FDM system "may increase timeliness, consistency, and accuracy of the financial disclosure program."

**CDC Responses to OIG Recommendations:**

**Office of Inspector General (OIG) Recommendation:** Ensure that special Government employees' Confidential Financial Disclosure Reports are complete before certifying them.

**CDC Response:** CDC concurs with this recommendation. MASO has strengthened its documentation, review and approval controls to ensure that there are no omissions related to reportable information per requirements of the Confidential Financial Disclosure Report OGE Form 450 (the specific improvement efforts are noted below). It is noteworthy that OGE implemented its revised Confidential Financial Disclosure Report form in January 2007. It is equally important to note that the OGE Form 450 incomplete filings rate has continued despite the fact that over 75% of the filers have graduate level degrees.

While CDC will continue to strive for complete technical accuracy in the completed OGE Form 450 submitted by SGEs, CDC has found that it is impractical to follow up with SGEs for verification of items that are made obvious because they are verifiable through the comprehensive review of supplementary documents such as the Curriculum Vitae (CV). This accomplishes the primary purpose of financial disclosure, the identification and resolution of actual or apparent conflicts of interest.

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The OIG report failed to address the severity of the individual findings; and OIG did not provide supporting documents (i.e. lists of SGEs for each finding) to enable CDC to validate the findings. The 97% rate of at least one omission on the OGE Form 450, while important, does not impede CDC's ability to analyze and manage conflicts of interest.

**Office of Inspector General (OIG) Recommendation:** Require special Government employees to disclose their involvement in grants and other relevant interests that could pose conflicts, which are not disclosed on the OGE Form 450.

**CDC Response:** CDC concurs in principle with this recommendation. MASO has a longstanding practice of requesting CV from SGEs to identify interests (such as grants) that are not subject to disclosure on the OGE Form 450. In order to implement a reporting requirement related to interests not disclosed on the OGE Form 450, MASO will work with the Department and OGE to develop a means of collecting information related to interests, such as grants, not currently required on the form.

It must be noted that grants to an SGE's employer, rather than to the individual member, are not a personal financial interest of the SGE except to the extent that there is a direct and predictable effect upon the SGE's employment. While the financial interests of the employer are attributed to the SGEs, OGE has promulgated a regulatory exemption permitting SGEs serving on FACA committees to participate in a particular matter of general applicability where the disqualifying financial interest arises from the SGE's non-Federal employment so long as the matter would not have a special or distinct effect on the employee or employer other than as part of an identifiable class, 5 C.F.R. § 2640.203(g). While the OIG report notes this exemption in a footnote, the ramifications of this exemption are not incorporated in the body of the report's findings. Because most CDC advisory committees do not consider matters that would have a special or distinct effect on a specific individual or entity, this exemption significantly diminishes the utility of a heightened disclosure requirement.

**Office of Inspector General (OIG) Recommendation:** Identify and resolve all conflicts of interest for special Government employees before permitting them to participate in committee meetings.

**CDC Response:** CDC concurs with this recommendation. In January 2009, MASO instituted a realignment of functions and responsibilities within the Federal Advisory Committee Management Team. The overall intention of the realignment resulted in improvement of the Confidential Financial Disclosure and Ethics Training processes for SGEs. MASO analyzed workflow and processes, developed corrective actions and standard operating procedures, and ensured that analytical responsibilities associated with conflicts of interest are assigned to sufficiently qualified staff (GS-13 through GS-15) to effectively perform the duties. Specifically, regarding the review and analysis of OGE Form 450 to identify conflicts of interest,

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MASO has implemented the following improvements:

- Evidence of Review/Analysis: an analytical reporting document, the “Record of Analysis” accompanies the OGE Form 450, and serves as evidence and assurance that analysis of potential conflicts of interest was performed by MASO staff in accordance with OGE guidance.
- Standard operating procedure includes interaction among MASO analysts, the designated Federal officer (DFO), and the SGE to ensure that the OGE Form 450 is completed correctly with proper categorization of information per the form instructions.

The OIG findings related to unidentified and/or resolved potential conflict of interests are reflective of the fact that OIG could not find adequate supporting documentation in the appropriate files. While absence of documentation in some files impacted the auditors’ ability to verify whether analysis occurred, it does not equate to MASO not having completed the analysis. Qualifying these findings is important, particularly since some documentation (e.g., CV) is not required by statute, as noted in the limitations section of the OIG report

**Office of Inspector General (OIG) Recommendation:** Increase collaboration among CDC officials and with the HHS Office of General Counsel.

**CDC Response:** CDC concurs with this recommendation. MASO collaborates with committee DFOs, and the HHS Office of General Counsel Ethics Division to ensure that conflicts of interest are identified and appropriately managed (whether by issuing cautionary guidance, conflicts of interest waivers, or authorizations). For instance, in May 2008, MASO established a chartered CDC Federal Advisory Committee Workgroup consisting of all DFOs and representatives from HHS OGC Ethics Division and the Office of the Chief Science Officer. The intent of this collaboration was to raise and/or resolve matters relating to the management of CDC Federal advisory committees including issues related to financial disclosure and conflicts of interest. We will also continue to work with the Ethics Division concerning the review of waivers issued pursuant to 18 U.S.C. § 208(b), as indicated in Secretary Leavitt’s delegation of authority of January 16, 2009.

**Office of Inspector General (OIG) Recommendation:** Ensure that special Government employees and CDC employees receive ethics training.

**CDC Response:** CDC concurs with this recommendation. SGEs serving on CDC’s Federal advisory committees are located throughout the country and world. MASO fulfills its responsibility to ensure all SGEs receive Ethics Training by sending the required training material via email. At the time of the audit, CDC had not established an automated mechanism to ensure that SGEs completed the training. CDC was dependent on SGEs returning training certificates via U.S. mail or facsimile. MASO is currently revising our process to allow SGEs to electronically report their receipt and review of Ethics Training. Beginning in 2010, Ethics Training will be disseminated and tracked through the FDM system.

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It is critical to note that MASO ensures that all new SGEs receive initial Ethics Training upon appointment, and distributes Annual Ethics Training to all SGEs as required. In addition, MASO attends certain advisory committee meetings to provide ethics training. Additionally, MASO employees who work with advisory committees are provided ongoing instruction and coaching on ethics requirements; DFOs are provided the same materials that are sent to SGEs for Annual Ethics training.

**Office of Inspector General (OIG) Recommendation:** Monitor special Government employee compliance with ethics requirements during committee meetings.

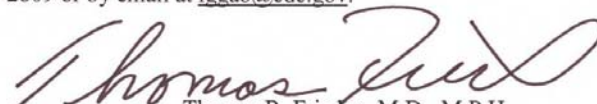
**CDC Response:** CDC concurs with this recommendation. MASO collaborates with DFOs and HHS Ethics advisors to determine when SGEs should not participate in certain matters. As subject matter experts for their respective advisory committees, the DFOs are actively engaged from the onset in helping to identify real and apparent conflicts of interest and to recommend ways to resolve the conflict (disqualification, recusal, divestiture, 18 U.S.C. § 208(b)(3) waiver, authorization under 5 C.F.R. § 2635.502(a)). CDC will continue to seek methods for improvement, by consulting with other HHS agencies to determine best practices that could be implemented to enhance our program.

**Office of Inspector General (OIG) Recommendation:** Track special Government employee compliance with ethics requirements.

**CDC Response:** CDC concurs with this recommendation. Recognizing the role that DFOs hold in this process, MASO also acknowledges its oversight responsibility for SGEs compliance with financial disclosure and ethics requirements. MASO continues to collaborate with internal partners (DFOs, OGC Ethics) involved in the confidential financial disclosure process to track and document SGEs compliance with ethics requirements. MASO will have a greater presence at advisory committee meetings, audit meeting minutes, and continually seek methods to improve and enforce of CDC's Financial Disclosure policy for SGEs.

**CDC Summary Comments to OIG Findings:**

In summary, CDC concurs with the recommendations of the OIG report. Over the past two years, CDC has implemented measures that coincide with these recommendations. Regarding OIG findings, CDC's technical comments on the draft report, previously submitted, are also attached. We appreciate your consideration of the comments contained in this memo and the technical comments as you develop the final report. We are happy to discuss any of these comments with you. Please direct any questions regarding these comments to Mr. Shaun Ratliff by telephone at (404) 639-2809 or by email at [jggao@cdc.gov](mailto:jggao@cdc.gov).



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## A C K N O W L E D G M E N T S

This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office.

Jaime Durley served as the team leader for this study, and Leila Samy served as lead analyst. Other principal Office of Evaluation and Inspections staff who contributed to this report include Starr Daniell, Al Olson, Shaun Owens, Gerius Patterson, and Mina Zadeh from the Atlanta regional office and Robert A. Vito from the Philadelphia regional office; central office staff who contributed include Talisha Searcy. We would also like to acknowledge the contributions of Melinda Golub and Pamela Langer from the Office of Inspector General's Office of Counsel to the Inspector General.