

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CONFLICT-OF-INTEREST
WAIVERS GRANTED TO HHS
EMPLOYEES IN 2009**



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OBJECTIVES

1. To assess the extent to which conflict-of-interest waivers granted to Department of Health and Human Services (HHS) employees were documented as recommended in provisions of selected Governmentwide Federal ethics regulations and the instructions of the Secretary of Health and Human Services (Secretary) to describe:
 - the employee’s specific financial interest that poses the conflict of interest;
 - the particular matter(s) in which the employee is permitted to participate; and
 - the particular matter(s), if any, in which the employee is prohibited from participating.
2. To determine whether HHS employees signed and dated their conflict-of-interest waivers.

BACKGROUND

HHS employees, including special Government employees (SGE) serving as subject-matter experts on Federal advisory committees (committees), play an influential role in the Federal Government’s public health policies. HHS employees may have conflicts of interest that prohibit them from participating in certain official Government matters affecting their personal financial interests. These interests may include outside employment, grants, and stock ownership.

The Office of Government Ethics (OGE) promulgates Governmentwide Federal ethics regulations for all Executive Branch employees and oversees all Federal agencies’ ethics programs. With oversight and guidance from the HHS Office of the General Counsel (OGC), an HHS Operating Division (OPDIV) or Staff Division (STAFFDIV) may grant conflict-of-interest waivers to its employees if the OPDIV or STAFFDIV determines that the conflict is not likely to affect the integrity of the employees’ services to the Government. For SGEs on committees, in particular, an OPDIV or STAFFDIV may grant a waiver if the need for an SGE’s services outweighs the potential for a conflict of interest. Waivers permit employees who have conflicts of interest to act in an official Government capacity on matters in which they would otherwise be prohibited from participating. In 2009, HHS granted 342 waivers; 334 waivers were granted to SGEs on committees.

According to Governmentwide Federal ethics regulations and the Secretary's instructions, all waivers should describe, among other things, employees' specific conflicts of interest and the particular matters in which employees are permitted to participate. Further, if the OPDIV or STAFFDIV determines that employees are not permitted to fully participate in particular matters related to their conflicts of interest, the employees' waivers are considered "limited." Limited waivers should describe the particular matters related to the conflicts of interest in which the employees are prohibited from participating, regardless of the other matters being waived. In addition, although it is not a Federal requirement for employees to sign and date their waivers, OGC's sample waivers have a signature line. HHS OPDIVs and STAFFDIVs can document when employees receive and acknowledge waivers by having employees sign and date them. Signatures and dates show that employees received and acknowledged their waivers and may be held accountable for complying with them.

We reviewed a stratified, random sample of 50 conflict-of-interest waivers granted to HHS employees in 2009, including 42 waivers for SGEs on committees. We determined whether the waivers in our sample were documented as recommended in three provisions of selected Governmentwide Federal ethics regulations and the Secretary's instructions. We also determined whether employees signed and dated the waivers in our sample. We do not generalize our findings to all HHS waivers granted in 2009.

FINDINGS

Fifty-six percent of the 50 HHS conflict-of-interest waivers in our review were not documented as recommended in provisions of selected Governmentwide Federal ethics regulations and the Secretary's instructions. Fourteen percent of the sampled waivers did not describe employees' specific interests that posed conflicts. Forty-six percent did not describe the particular matters in which employees were permitted to participate. Twenty-eight percent were limited waivers that did not describe the particular matters in which the employees were prohibited from participating. Twenty-four percent were not documented as recommended in at least two of the three selected provisions and the Secretary's instructions, and 8 percent were not documented as recommended in any of these provisions or instructions. The waivers that were not documented as recommended were granted to employees at five of the nine OPDIVs and STAFFDIVs

in our review. All but one of these waivers were granted to SGEs on committees.

Although not required, 18 percent of the 50 HHS conflict-of-interest waivers in our review included employees' signatures and dates.

While it is not a Federal requirement for waivers to be signed and dated, 18 percent of the 50 waivers in our sample included employees' signatures and dates. These signed and dated waivers had been granted to employees in six of the nine OPDIVs and STAFFDIVs in our review. Most of the waivers in our sample—82 percent—did not include employees' signatures and/or dates. All but two of the waivers that were not signed and/or dated were for SGEs on committees.

Twenty-four of the waivers that were not signed and/or dated were also not documented as recommended in at least 1 of the 3 provisions of selected Governmentwide Federal ethics regulations and the Secretary's instructions, and 14 of these 24 were limited waivers. These 14 limited waivers represent the greatest vulnerability. The employees receiving them may not know they have waivers or understand the limitations imposed on their participation in official duties. If these employees are not aware of their waivers or do not clearly understand them, they may violate the criminal conflict-of-interest statute by participating in prohibited matters.

RECOMMENDATIONS

According to OGE, evaluating whether to grant a waiver is one of the more significant duties that agency ethics officials perform. If conflict-of-interest waivers are not clearly documented to show that employees understand their conflicts of interest and the matters, if any, in which they are prohibited from participating, employees may inadvertently violate the criminal conflict-of-interest statute. In addition, if waivers do not clearly describe the particular matters in which employees are permitted to participate, employees may incorrectly refrain from providing their expertise when it would benefit HHS's programs. Further, if waivers are not documented so that the public understands the employees' conflicts of interest and their effect on the employees' official Government duties, the public may question the integrity of the employees' services to the Government.

Therefore, we recommend that the HHS OGC:

Require OPDIVs and STAFFDIVs to document conflict-of-interest waivers as recommended in Governmentwide Federal ethics regulations and the Secretary's instructions.

Develop additional guidance and training to assist OPDIVs and STAFFDIVs in documenting conflict-of-interest waivers as recommended in Governmentwide Federal ethics regulations and the Secretary's instructions.

Take action to revise the conflict-of-interest waivers in our review that were not documented as recommended in Governmentwide Federal ethics regulations and the Secretary's instructions, if the waivers are still in effect.

Expand the review of conflict-of-interest waivers for SGEs on committees.

Require all employees to sign and date their conflict-of-interest waivers or otherwise document that they received and acknowledged them.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

OGC and OGE provided written comments on a draft of this report. In response to OGC's and OGE's comments, we conducted a second review of many of the waivers in our sample. We continued to find that many waivers were not documented as recommended in the selected regulatory provisions and the Secretary's instructions, and we updated our findings accordingly.

We made other technical and clarifying changes to the report based on OGC's and OGE's comments. For the full text of OGC's and OGE's comments, see Appendix H. Because OGC included OGE's comments as an attachment to its comments, we do not provide OGE's comments separately.

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 - the employee’s specific financial interest that poses the conflict of interest;
 - the particular matter(s) in which the employee is permitted to participate; and
 - the particular matter(s), if any, in which the employee is prohibited from participating.
2. To determine whether HHS employees signed and dated their conflict-of-interest waivers.

BACKGROUND

Federal employees play an influential role in the Federal Government’s public health policies. Federal agencies must ensure that their employees’ conflicts of interest do not compromise the integrity and credibility of Federal programs.¹ The Office of Government Ethics (OGE) promulgates Governmentwide Federal ethics regulations for all Executive Branch employees and oversees all Federal agencies’ ethics programs.² Further, in January 2009, the Secretary issued additional instructions on granting waivers and the contents of waivers.³ The HHS Designated Agency Ethics Official and other staff in the HHS Office of the General Counsel (OGC) Ethics Division provide guidance and oversight of ethics programs in HHS Operating Divisions (OPDIVs) and Staff Divisions (STAFFDIVs).⁴

¹ We use the term “conflict of interest” to refer to financial interests covered by the criminal conflict-of-interest statute (18 U.S.C. § 208). This includes both actual and potential financial conflicts of interest.

² Ethics in Government Act, 5 U.S.C. app. IV §§ 401 and 402, 5 CFR pt. 2600.

³ Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009.

⁴ OGC Ethics Division, *Deputy Ethics Counselor HHS Ethics Program Statement of Functions, Responsibilities, and Authority*, revised August 15, 2007.

HHS employees include special Government employees (SGEs) serving on Federal advisory committees (committees), regular Government employees, SGEs not serving on committees, and political appointees.^{5, 6} Hereinafter, we will refer to HHS regular Government employees, SGEs not serving on committees, and political appointees as “all other HHS employees.”

SGEs serving on committees are subject-matter experts who provide “expert advice, ideas, and diverse opinions” to the Federal Government. SGEs are typically actively involved in work outside the Government in the same areas as their official Government work.⁷ The category of “all other HHS employees” includes agency heads and program directors who typically work on broad policy matters related to their agencies or programs.⁸

Executive Branch employees, including HHS employees, must not participate personally and substantially in an official capacity in any particular matters that would have a direct and predictable effect on

⁵ Federal Advisory Committee Act, 5 U.S.C. app. II §§ 2(a) and 3(2)(c). OGE Memorandum to Designated Agency Ethics Officials, *Federal Advisory Committee Appointments*. DO-05-012, August 18, 2005. Accessed at http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2005/do05012.pdf on July 10, 2009.

⁶ HHS employees are appointed in the civil service, act in an official capacity, or are supervised by a Federal official. The President, the Secretary, and other HHS officials may appoint HHS employees to their positions.

⁷ 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. Accessed at http://www.usoge.gov/laws_regs/other_ethics_guidance/othr_gdnc/og_sge_coi_00.pdf on July 10, 2008.

⁸ Although there are many other types of Federal employees, their official duties are usually narrower in scope than those of agency heads or program directors. Therefore, other employees would not likely receive a waiver for their conflicts of interest and would, instead, be required to withdraw (i.e., recuse themselves) from the matter(s) related to their conflicts. The official duties of agency heads and program directors are usually broader in scope, making recusal more difficult. When determining how to resolve an employee’s conflict of interest, ethics officials should first consider whether recusal would resolve the conflict if an “employee’s duties can easily be adjusted to avoid a waiver.” OGE Memorandum to Designated Agency Ethics Officials, *Waivers Under 18 U.S.C. § 208*. DO-07-006, February 23, 2007, p. 4. Accessed at http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2007/do07006.pdf on September 20, 2010.

their financial interests.^{9, 10} These interests may include outside employment, grants, assets, board membership, or ownership of publicly traded stock in excess of minimal values.^{11, 12} The employee must withdraw (i.e., recuse himself or herself) from matters relating to the interest, unless he or she receives a conflict-of-interest waiver.^{13, 14}

An appropriate OPDIV or STAFFDIV official (i.e., the granting official) responsible for an HHS employee's appointment may grant a waiver to permit the employee to act in an official Government capacity in particular matters in which he or she would otherwise be prohibited from participating. According to OGE, evaluating whether to grant a waiver is:

one of the more significant duties that [OPDIV or STAFFDIV] ethics officials perform to ensure public confidence in the Government's operations and programs. Both the individual employee's interests and those of the

⁹ 18 U.S.C. § 208; 5 CFR § 2635.402. Executive Branch employees' interests refer to both the employees' own interests and those attributed to them on behalf of another person or entity (e.g., spouse, minor child, employer). 5 CFR 2635.402(b)(2).

¹⁰ We use the term "particular matters" to refer to official duties that involve 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).

¹¹ SGEs on committees have a regulatory exemption (i.e., do not need a waiver) to participate in committee work regarding particular matters of general applicability that would affect their employer to the same extent as similarly situated entities (e.g., the employer's competitors). However, SGEs on committees must not participate in committee work that would have a special or distinct effect on the financial interests of their employers. 5 CFR § 2640.203(g).

¹² 5 CFR §§ 2640.202(a) and (c) provide de minimis exemptions for values of publicly traded stock owned by employees who participate in particular matters involving specific parties and particular matters of general applicability, respectively. Specifically, an employee who holds publicly traded stock in excess of \$15,000 in companies affected by a specific party matter is prohibited from officially participating in that matter. Further, if an employee holds stock 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 employee is prohibited from participating in official duties that could affect all companies within that sector.

¹³ Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009.

¹⁴ 18 U.S.C. § 208. The term "waiver" refers to waivers issued under 18 U.S.C. §§ 208(b)(1) or (b)(3). Waivers issued under 208 (b)(1) may be granted to any Federal employee of the Executive Branch. 5 CFR § 2640.301. Waivers issued under 208(b)(3) may be granted only to SGEs on committees. 5 CFR § 2640.302.

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

Government are best served when this process is carried out in a careful and consistent manner.¹⁵

OPDIVs and STAFFDIVs should document waivers in a manner that allows all interested parties (e.g., the HHS employees receiving the waivers, their supervisors, the Designated Federal Official assigned to the SGE's committee, the general public) to understand the specific conflicts of interest and their effect on employees' official Government duties.^{16, 17} In addition, while it is not a Federal requirement that waivers be signed and dated by employees, waivers can be documented with the employees' signatures and dates to indicate when the employees received and acknowledged the waivers. If employees do not comply with their waivers, they may be in violation of the criminal conflict-of-interest statute and can be prosecuted by the Federal Government. In HHS, alleged violations of criminal conflict-of-interest statutes must be reported to the Office of Inspector General (OIG).¹⁸

If employees do not sign and date their waivers, the Government may not be able to hold them accountable for complying with their

¹⁵ OGE Memorandum to Designated Agency Ethics Officials, *Guidance on Waivers Under 18 U.S.C. § 208(b), Authorizations Under 5 C.F.R. § 2635.502(d), and Waivers of Requirements Under Agency Supplemental Regulations*. DO-10-005, April 22, 2010, p. 5. Accessed at http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2010/do10005.pdf on September 23, 2010.

¹⁶ Waivers are publicly available upon request. 5 CFR § 2640.304(a). Further, the White House has urged Federal agencies to make all waivers granted to scientific committee members publicly available. Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies, *Scientific Integrity*. December 17, 2010, p. 3. HHS may withhold certain information (e.g., exact number and value of stock, company name) before making a waiver available to the public. 18 U.S.C. § 208(d); 5 CFR § 2640.304(b).

¹⁷ The Designated Federal Official is assigned to each committee to call, attend, and adjourn committee meetings; ensure efficient operations; and maintain publicly available committee records; among other responsibilities. Federal Advisory Committee Act, 5 U.S.C. app. II § 10(e). General Services Administration, *The Federal Advisory Committee Act (FACA) Brochure*. Accessed at <http://www.gsa.gov/portal/content/101010> on November 18, 2010.

¹⁸ HHS, *General Administration Manual*, ch. 5-10, "Responsibility and Procedures for Reporting Misconduct and Criminal Offenses," December 26, 2006.

waivers.¹⁹ For example, as described in a previous report, OIG found that in 2007, seven SGEs on committees at the Centers for Disease Control and Prevention (CDC) participated in particular matters when their waivers prohibited such participation.²⁰ OIG reviewed information regarding these seven SGEs and determined that, largely as a result of CDC's systemic lack of oversight of the ethics program for SGEs identified in the OIG report, the actions of the seven SGEs did not rise to the level of criminal violations of the conflict-of-interest statute.²¹ Among other things, CDC's lack of oversight included failure to obtain SGEs' signatures on some 2007 waivers, in violation of CDC policy.

If OPDIVs and STAFFDIVs do not clearly document waivers to show that employees understand their conflicts of interest and the matters, if any, in which they are prohibited from participating, employees may inadvertently violate the criminal conflict-of-interest statute. In addition, if waivers do not clearly describe the particular matters in which employees are permitted to participate, employees may incorrectly refrain from providing their expertise when it could benefit HHS's programs. Further, if waivers are not documented so that the public understands employees' specific conflicts of interest and their

¹⁹ Some waivers (i.e., limited waivers) contain recusal obligations requiring employees to withdraw from matters related to their conflicts. Although OPDIVs or STAFFDIVs grant waivers to employees, the ultimate responsibility for abiding by the recusal obligations in the waivers rests with the employees. OGE Memorandum to Designated Agency Ethics Officials, *Effective Screening Arrangements for Recusal Obligations*. DO-04-012, June 1, 2004. Accessed at http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2004/do04012.html on September 28, 2010. In cases in which a waiver with a recusal obligation is granted but the employee never signs the waiver, and the employee violates the criminal conflict-of-interest statute by participating in matters requiring recusal, it may be difficult to prove that the employee ever saw the waiver or knew that the waiver contained the recusal obligation. The employee could argue that he or she thought a waiver had been granted but was unaware of the recusal required by the waiver. In such cases, it may be difficult, if not impossible, to hold the employee accountable for the ethics violation.

²⁰ OIG, *CDC's Ethics Program for Special Government Employees on Federal Advisory Committees*, OEI-04-07-00260, December 2009. Accessed at <http://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf> on July 13, 2010.

²¹ After reviewing the matters surrounding these seven SGEs, the OGC Ethics Division, in consultation with OGE, determined that CDC issued the waivers based on an incorrect analysis of 18 U.S.C. § 208. That is, OGC and OGE determined that the conflicts of interest addressed by the waivers were not conflicts under 18 U.S.C. § 208. According to OGC, while the SGEs may have violated the terms of their waivers, they did not violate 18 U.S.C. § 208 because they did not participate in particular matters related to a conflict of interest covered by 18 U.S.C. § 208.

effect on the employees' official Government duties, the public may question the integrity of the employees' services to the Government.

Additionally, waivers that do not contain employees' signatures and dates may raise questions about whether the HHS OPDIVs or STAFFDIVs actually presented the waivers to the employees and whether the employees had a chance to review and understand them.

Thus, if waivers are not clearly documented and/or there is no evidence that employees received and acknowledged their waivers (e.g., via signatures and dates on waivers or other documentation), OIG has difficulty investigating reports of alleged violations and holding employees accountable for complying with the criminal conflict-of-interest statute.

HHS Ethics Programs

With oversight and guidance from the HHS OGC Ethics Division, each HHS OPDIV and STAFFDIV administers an ethics program for its employees. When administering these programs, OPDIV and STAFFDIV ethics officials must take into account the requirements placed on HHS employees pursuant to the criminal conflict-of-interest statute, 18 U.S.C. § 208.²² In addition, ethics programs should be administered in accordance with Governmentwide Federal ethics regulations and the Secretary's January 2009 instructions.²³

HHS OPDIV and STAFFDIV ethics programs rely on HHS employees' disclosing their personal financial interests. HHS employees who serve in certain positions must file financial disclosure reports either publicly or confidentially.²⁴ In addition, OPDIVs and STAFFDIVs may collect

²² 5 CFR § 2638, OGE and Executive Agency Ethics Program Responsibilities.

²³ Ibid. 5 CFR §§ 2640.301 and 302. HHS Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009.

²⁴ Financial disclosure filing requirements are set forth in 5 CFR § 2634 Subpart B (for public filers) and 5 CFR § 2634 Subpart I (for confidential filers). Public filers disclose financial interests on Standard Form 278; confidential filers disclose financial interests on OGE Form 450. Ethics in Government Act, 5 U.S.C. app. §§ 101 and 107. Alternate procedures for filing financial disclosures are allowed under 5 CFR § 2634.905. According to OGC, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) use alternate filing procedures for SGEs. Most committees at FDA use another form instead of OGE Form 450. In addition, SGEs at NIH annually file updates to their OGE Form 450 rather than filing a complete OGE Form 450 each year.

other documents, such as employees' curricula vitae or résumés, to supplement information in the financial disclosure reports.

Once employees disclose their interests, ethics officials can assist them in avoiding conflicts between their official Government duties and their personal financial interests. To do this, ethics officials review an employee's financial disclosure file, which includes financial disclosure forms and other documents (e.g., the employee's curriculum vitae), to determine whether the employee has any conflicts of interest.²⁵ The granting official in the OPDIV or STAFFDIV then determines case by case whether to grant a waiver.²⁶ Unless an employee who has a conflict of interest receives a waiver, he or she is prohibited from participating in certain official matters affecting the interest.

HHS OPDIV and STAFFDIV ethics officials may consult with the HHS OGC Ethics Division and other appropriate parties (e.g., employees, employees' supervisors, and the Designated Federal Official assigned to the SGE's committee) to determine whether waivers may be needed and for assistance documenting them.²⁷ In accordance with the Secretary's instructions, the OGC Ethics Division is required to review SGEs' waivers "where practicable" prior to an OPDIV or STAFFDIV granting the waivers.²⁸ Once an SGE's waiver has been finalized, a copy must be provided to the OGC Ethics Division.²⁹ The OGC Ethics Division is also required to review all waivers for all other HHS employees.³⁰ Periodically, the OGC Ethics Division conducts program reviews, including reviews of waivers, to ensure that selected HHS OPDIVs' and STAFFDIVs' ethics programs are complying with Federal ethics requirements.³¹

²⁵ We use the term "ethics officials" to refer to HHS staff, including the Deputy Ethics Counselor, the Ethics Coordinator, and other staff who provide ethics guidance and support.

²⁶ 5 CFR §§ 2640.302(a) and 2640.301(a).

²⁷ OGC Ethics Division, *Deputy Ethics Counselor HHS Ethics Program Statement of Functions, Responsibilities, and Authority*, revised August 15, 2007.

²⁸ The HHS Designated Agency Ethics Official (or another appropriate ethics official) must review 208(b)(3) waivers "where practicable." Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009, p. 2.

²⁹ *Ibid.*

³⁰ Specifically, the Designated Agency Ethics Official within the Ethics Division must review all waivers for all other HHS employees.

³¹ OGC Ethics Division, Program Review Section, *Guidelines for Conducting Ethics Program Reviews at the Department of Health and Human Services*. February 2010.

HHS ethics officials are also required to consult with OGE “when practicable” prior to granting a waiver.³² An April 2010 OGE memorandum notes that “where practicable” is a “high standard requiring agencies to consult [with OGE] in all but the most exigent circumstances. Waiving a criminal conflict of interest statute is not to be taken lightly.”³³

In 2009, OPDIVs and STAFFDIVs granted 342 waivers to HHS employees, representing a decrease of 24 percent since 2007. Ninety-eight percent (334 of 342) of the waivers HHS granted in 2009 were to SGEs on committees.³⁴ Appendix A provides the number of waivers by OPDIV or STAFFDIV and type of employee (i.e., SGE or other Federal employee) from 2007 to 2009.

Federal Ethics Requirements and Recommendations for HHS Conflict-of-Interest Waivers

There are many Federal ethics regulations that pertain to conflict-of-interest waivers.³⁵ For example, for a waiver to be legally effective, it must be in writing, signed and dated by the appropriate granting official, and granted under the appropriate statutory authority.³⁶ That is, an OPDIV or STAFFDIV may grant a waiver to an SGE on a committee if, after reviewing the SGE’s financial disclosures, the appropriate granting official certifies that the need for the employee’s services outweighs the potential for a conflict of interest created by the financial interest involved, as required by statute and regulation.³⁷ Similarly, an OPDIV or STAFFDIV may grant a waiver that allows a Federal employee (other than an SGE on a committee) to work on a particular matter if the granting official determines that the financial interest is not so substantial as to be deemed likely to affect the integrity of the employee’s services to the Government.³⁸

³² 5 CFR 2640.303.

³³ OGE Memorandum to Designated Agency Ethics Officials, *Guidance on Waivers Under 18 U.S.C. § 208(b), Authorizations Under 5 C.F.R. § 2635.502(d), and Waivers of Requirements Under Agency Supplemental Regulations*. DO-10-005, April 22, 2010, p. 5. Accessed at http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2010/do10005.pdf on September 23, 2010.

³⁴ OIG review of data provided by OGC, 2010.

³⁵ 5 CFR pt. 2640.

³⁶ *Ibid.*

³⁷ 18 U.S.C. § 208(b)(3); 5 CFR § 2640.302(a)(3).

³⁸ 18 U.S.C. § 208(b)(1); 5 CFR § 2640.301(a)(4).

Further, waivers both for SGEs on committees and all other HHS employees should describe:

1. the employee’s specific financial interest that poses the conflict of interest;^{39, 40}
2. the particular matter(s) in which the employee is permitted to participate;^{41, 42} and
3. the particular matter(s), if any, in which the employee is prohibited from participating.^{43, 44}

Appendix B contains the provisions of Governmentwide Federal ethics regulations regarding the issuance of individual waivers for SGEs on committees and all other HHS employees. Hereinafter we will refer to the provisions of selected Governmentwide Federal ethics regulations included in our review as “selected regulatory provisions.”

The OGE-promulgated regulations state that the disqualifying financial interest, the particular matter or matters to which the waiver applies, and the employee’s role in such matters do not need to be described with any particular degree of specificity to be legally sufficient.⁴⁵ As such, the regulations allow agency flexibility to respond to a wide variety of

³⁹ For SGEs, “[w]aivers issued pursuant to 18 U.S.C. 208(b)(3) should comply with the following requirements . . . [t]he facts upon which the certification is based should be fully described in the waiver, including the nature of the financial interest. . .” 5 CFR § 2640.302(a)(4).

⁴⁰ For all other HHS employees, “waivers issued pursuant to 18 U.S.C. 208(b)(1) should comply with the following requirements . . . [t]he waiver should describe the disqualifying financial interest . . .” 5 CFR § 2640.301(a)(3). Further, “the information contained in the waiver . . . should provide a clear understanding of the nature and identity of the disqualifying financial interest, the matters to which the waiver will apply, and the employee’s role in such matters.” 5 CFR § 2640.301(a), Note to paragraph (a).

⁴¹ For SGEs, “[w]aivers issued pursuant to 18 U.S.C. 208(b)(3) should comply with the following requirements . . . [t]he facts upon which the certification is based should be fully described in the waiver, including . . . the particular matter or matters to which the waiver applies. . .” 5 CFR § 2640.302(a)(4).

⁴² For all other HHS employees, “[w]aivers issued pursuant to 18 U.S.C. 208(b)(1) should comply with the following requirements . . . [t]he waiver should describe. . .the particular matter or matters to which it applies.” 5 CFR § 2640.301(a)(3).

⁴³ For SGEs, “[w]aivers issued pursuant to 18 U.S.C. 208(b)(3) should comply with the following requirements . . . [t]he waiver should describe any limitations on the individual’s ability to act in the matter or matters.” 5 CFR § 2640.302(a)(5).

⁴⁴ For all other HHS employees, “[w]aivers issued pursuant to 18 U.S.C. 208(b)(1) should comply with the following requirements . . . [t]he waiver should describe. . .any limitations on the employee’s ability to act in such matters.” 5 CFR §2640.301(a)(3).

⁴⁵ 5 CFR § 2640.301, Note to paragraph (a).

situations. These situations may include cases in which agencies and employees have more or less information available to them concerning the particular matters in which employees might participate, employees' roles in such matters, and the financial impact of such matters. The regulations also state, however, that a waiver should provide a clear understanding of the nature and identity of the employee's financial interest that poses the conflict, the matters to which the waiver applies, and the employee's role in such matters.⁴⁶ Further, in proposing these regulations in 1995, OGE stated that "agencies should endeavor to formulate waivers with enough specificity that a member of the public would have a clear understanding of the circumstances to which the waiver applies."⁴⁷

The Secretary's January 2009 instructions state that, among other things, waivers "must fully describe the potential conflict [and] document the basis for the waiver." These instructions also state that waivers "must . . . reflect an individualized assessment of the [employee's] circumstances."⁴⁸ Appendix C contains the Secretary's January 2009 instructions.

Description of the specific financial interest that poses the conflict of interest. Waivers may apply to present and future interests (e.g., future receipt of grant funds or appointment as a board member), provided the interests are described with sufficient specificity.⁴⁹ For SGEs' waivers, the regulations promulgated by OGE state that "the facts upon which the [waiver] is based should be fully described in the waiver, including the nature of the financial interest."⁵⁰ For all other HHS employees' waivers, the regulations state that "the waiver should describe the disqualifying financial interest" and that "the information contained in the waiver . . . should provide a clear understanding of the nature and identity of the disqualifying financial interest."⁵¹ Furthermore, the

⁴⁶ Ibid.

⁴⁷ OGE. *Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting a Personal Financial Interest)* (proposed rule), 60 Fed. Reg. 47222 (Sept. 11, 1995).

⁴⁸ Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009, p. 2.

⁴⁹ 5 CFR §§ 2640.302(a)(7) and 2640.301(a)(6).

⁵⁰ 5 CFR § 2640.302(a)(4).

⁵¹ 5 CFR § 2640.301(a), Note to paragraph (a).

Secretary’s instructions state that “the waiver must fully describe the potential conflict”⁵²

Description of the particular matter(s) in which the employee is permitted to participate. A waiver should describe the particular matter(s) to which it applies.⁵³ That is, the waiver should describe the particular matter(s) related to the conflict(s) of interest that the employee is permitted to undertake as part of his or her official duties. Employees must not participate in the matter(s) until the waiver is granted.⁵⁴ If a waiver applies to all particular matters under an employee’s responsibility, the waiver should contain a reasonably detailed description of these responsibilities.⁵⁵ The Secretary’s instructions state that “[c]ategories of official actions to which a waiver applies must be narrowly drawn to ensure that permission for the employee to act in an otherwise conflicting situation is appropriately limited.”⁵⁶ Thus, the waiver should specify the particular matter(s) in which the employee is permitted to participate.

Description of the particular matter(s), if any, in which the employee is prohibited from participating. In cases in which the granting official does not permit the employee to fully participate in matters related to the conflict of interest, the official must grant a “limited” waiver. Limited waivers should describe limitations on the employee’s participation in his or her official duties.⁵⁷ For example, a limited waiver may permit the employee to participate in official matters related to an existing contract but prohibit the employee from participating in matters related to any future contract negotiations.

In HHS, the Secretary has emphasized the importance of any limitations described in waivers by pointing out: “Vigilant internal agency practice must provide for effective screening and monitoring

⁵² Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009, p. 2.

⁵³ 5 CFR §§ 2640.302(a)(4) and 2640.301(a)(3).

⁵⁴ 5 CFR §§ 2640.301(a)(5) and 2640.302(a)(6).

⁵⁵ OGE Guidance 07 x 4. *Memorandum dated February 23, 2007, from Robert I. Cusick, Director, to Designated Agency Ethics Officials Regarding Waivers Under 18 U.S.C. 208.*

⁵⁶ Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009, p. 2.

⁵⁷ 5 CFR §§ 2640.301(a)(3) and 2640.302(a)(5).

mechanisms when an employee has received a limited waiver from the conflict of interest statutory requirements.”⁵⁸

Employee Signature and Date on HHS Conflict-of-Interest Waivers

OPDIVs or STAFFDIVs must grant waivers prior to employees’ taking any action in matters for which they have conflicts.⁵⁹ While it is not a Federal ethics requirement for them to do so, HHS OPDIVs and STAFFDIVs can document when employees receive and acknowledge their waivers by having employees sign and date them.⁶⁰ Employees’ signatures and dates also document that they are accountable for complying with the waivers. The OGC Ethics Division makes sample waivers for SGEs and all other HHS employees available to OPDIVS and STAFFDIVs on its Intranet site.⁶¹ The sample waiver for SGEs has a signature line for the SGE and an acknowledgment statement.⁶² The sample waivers for all other HHS employees have signature lines for the employee or the Deputy Ethics Counselor indicating that the

⁵⁸ Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009, p. 3.

⁵⁹ 5 CFR §§ 2640.301(a)(5) and 2640.302(a)(6).

⁶⁰ At least one OPDIV or STAFFDIV has a policy that requires employees to sign waivers. For example, see CDC Policy CDC-GA-2001-05 (formerly CDC-94), *Financial Disclosure for Federal Advisory Committee Members Appointed as Special Government Employees*, July 5, 2001. Accessed at <http://www.cdc.gov/maso/facm/pdfs/policy294.pdf> on July 13, 2010.

⁶¹ OGC, “Sample Waiver of Conflict of Interest for Special Government Employees (SGEs) on Federal Advisory Committees [18 U.S.C. 208(b)(3)],” “Sample Waiver of Actual Conflict for Officers or Directors [18 U.S.C. 208(b)(1)],” and “Sample Waiver of Actual Conflict of Interest for Regular Employees [18 U.S.C. 208(b)(1)].”

⁶² The acknowledgment states that “[t]he undersigned confirms, acknowledges, and agrees to the terms of the waiver and will recuse from official participation in any particular matters involving specific parties that arise before the {Advisory Committee name} that will have a direct and predictable effect on his/her own or imputed financial interests.” OGC, “Sample Waiver of Conflict of Interest for Special Government Employees (SGEs) on Federal Advisory Committees [18 U.S.C. 208(b)(3)].”

individual signing the waiver has “confirmed and acknowledged” the waiver.⁶³

As an alternative to obtaining employees’ signatures and dates, OPDIVs and STAFFDIVs can document other actions to ensure that employees understand their conflicts of interest and any limitations on their participation in official duties. Such other actions could include emailing employees to notify them about their waivers, receiving emails from employees to confirm that they understand their waivers, and/or documenting that the employees received oral counseling about their waivers.

However, regardless of when the employee signs the waiver, it is not considered effective until the OPDIV or STAFFDIV granting official signs and dates it.⁶⁴

Related Office of Inspector General Work

In a 2009 report, OIG cited vulnerabilities in waivers for SGEs on committees at CDC in 2007. Eight percent (18 of 212) of SGEs on CDC’s 17 committees had approved waivers on file in 2007. OIG found that none of these 18 waivers was adequately documented.⁶⁵

METHODOLOGY

Scope

We reviewed a stratified, random sample of 50 conflict-of-interest waivers that OPDIVs and STAFFDIVs granted in 2009 to determine whether they were documented as recommended in 3 selected regulatory provisions and the Secretary’s instructions. We also determined whether HHS employees signed and dated their waivers.

Our review did not include a complete determination of whether the waivers in our sample were legally sufficient or valid, and we do not

⁶³ The sample waiver for “officers or directors” has a signature line for the employee; the sample waiver for “regular employees” has a signature line for the employee or the Deputy Ethics Counselor. The HHS Designated Agency Ethics Official has delegated daily responsibility for administering HHS’s ethics programs to Deputy Ethics Counselors in each OPDIV or STAFFDIV. April 7, 2011. Accessed at <http://www.hhs.gov/ogc/contact/contacts.html> on May 2, 2011.

⁶⁴ 5 CFR 2640.301(a).

⁶⁵ OIG, *CDC’s Ethics Program for Special Government Employees on Federal Advisory Committees*, OEI-04-07-00260, December 2009, p. 20. Accessed at <http://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf> on July 13, 2010.

intend to cast doubt on the legality of any of the waivers we reviewed. Additionally, we did not review whether the waivers in our sample met all Federal ethics requirements or recommendations beyond the three selected regulatory provisions in our review and the Secretary's instructions. For example, we did not assess whether HHS employees who received waivers in 2009 should have been granted the waivers. We also did not assess whether employees had conflicts of interest that were not addressed by their waivers. Further, we did not determine whether the OPDIV or STAFFDIV ethics official who signed each waiver was the appropriate granting official. We also did not determine whether each waiver was granted under the appropriate statutory authority.

Finally, we did not determine whether HHS employees complied with their waivers after the OPDIVs or STAFFDIVs granted them.

Sample Selection

Three hundred forty-two conflict-of-interest waivers were granted to HHS employees at nine OPDIVs and STAFFDIVs in 2009.⁶⁶ We selected a stratified, random sample of waivers from each of these OPDIVs and STAFFDIVs. To select this sample, we initially grouped the waivers into 11 strata (see Table 1).

We developed one stratum for each of the five OPDIVs and STAFFDIVs that granted waivers to SGEs on committees in 2009. From each of these strata, we selected a simple random sample of waivers (ranging from 2 to 30), in general proportion to the number of waivers in the stratum. For example, we selected the most waivers in our sample from the NIH stratum because it granted the largest number of HHS waivers in 2009. We selected the next-highest number of waivers from the Food and Drug Administration stratum because it granted the second-largest number of HHS waivers in 2009. We selected the fewest waivers from the Agency for Healthcare Research and Quality and the Health Resources and Services Administration strata because they granted the fewest HHS waivers in 2009.

⁶⁶ One OPDIV uses the word "addendum" to describe a conflict-of-interest waiver that is an update to a previous waiver. Because the OPDIV indicated that these "addenda" are separate and distinct from the waivers they "amend," we treated them as waivers and included them in the total count of waivers in our analysis.

Table 1: Number of HHS Conflict-of-Interest Waivers Granted in 2009 and Number in the Sample, by OPDIV/STAFFDIV and Type of Employee

| OPDIV/STAFFDIV | Waivers granted in 2009 | Waivers in sample |
|---|-------------------------|-------------------|
| Waivers for SGEs on Federal advisory committees | 334 | 42 |
| National Institutes of Health | 287 | 30 |
| Food and Drug Administration | 23 | 5 |
| Centers for Disease Control and Prevention | 12 | 3 |
| Agency for Healthcare Research and Quality | 6 | 2 |
| Health Resources and Services Administration | 6 | 2 |
| Waivers for all other HHS employees | 8 | 8 |
| National Institutes of Health | 3 | 3 |
| Assistant Secretary for Planning and Evaluation | 1 | 1 |
| Centers for Medicare & Medicaid Services | 1 | 1 |
| Food and Drug Administration | 1 | 1 |
| Indian Health Service | 1 | 1 |
| Office of the General Counsel | 1 | 1 |
| Total | 342 | 50 |

Source: OIG analysis of OGC data, 2009.

In 2009, 84 percent (287 of 342) of HHS’s waivers were for SGEs on committees at NIH in 24 of NIH’s 27 Institutes and Centers.⁶⁷ From each of the 24 Institutes and Centers, we selected a simple random sample of waivers (ranging from 1 to 3) in general proportion to the number of waivers granted to SGEs on committees at each of these 24 Institutes and Centers. Appendix D provides the number of HHS waivers granted in 2009 to SGEs on committees at NIH, by Institute or Center.

We also developed one stratum for each of the six OPDIVs and STAFFDIVs that granted waivers to all other HHS employees in 2009. We included all eight of these waivers in our review.

Data Collection

We reviewed selected regulatory provisions and the Secretary’s instructions regarding HHS’s conflict-of-interest waivers in 2009.

We obtained HHS OGC data pertaining to the 342 conflict-of-interest waivers that HHS OPDIVs and STAFFDIVs granted in 2009. We then

⁶⁷ NIH maintains over 150 chartered committees—the largest number of committees in any Executive Branch agency. NIH, Office of Federal Advisory Committee Policy, *About Us*. Accessed at <http://ofacp.od.nih.gov/about/overview.html> on July 20, 2010. Therefore, NIH has more SGEs on committees than any other HHS OPDIV or STAFFDIV.

obtained from OGC copies of the 50 waivers in our sample. We also contacted OPDIVs and STAFFDIVs directly to request the waivers and any associated documentation.⁶⁸ That is, in addition to the waivers, we reviewed any documentation associated with the employees' interests referenced in the waivers, as well as any other documentation that the OPDIV or STAFFDIV provided. In addition to the waivers, we requested copies of:

1. employees' financial disclosure forms (i.e., OGE Form 450 or Standard Form 278) that correspond to waivers in our sample; and
2. other documents pertaining to the interests reflected in each waiver in our sample (e.g., emails or correspondence, employees' curricula vitae or résumés).

Data Analysis

We reviewed the 50 waivers in our sample and associated documentation to determine whether the waivers were documented as recommended in 3 selected regulatory provisions and the Secretary's instructions and whether they included employees' signatures and dates.

Selected regulatory provisions and the Secretary's instructions. We determined whether the waivers contained an individualized assessment of the employees' circumstances and provided a clear understanding of the circumstances to which the waivers applied. We reviewed waivers to determine:

1. Whether each described employees' specific financial interests that posed the conflict. We classified a description as specific if it provided a clear understanding of the nature and identity of the employee's financial interest that posed the conflict. We classified a description as not specific if it contained broad categories of types of interests. Further, if SGEs' waivers identified specific interests, we determined whether the interests were also reflected in SGEs' financial disclosure files to indicate whether granting officials based the waivers on their reviews of the files.

⁶⁸ To confirm that the supporting documentation we received from OPDIVs and STAFFDIVs corresponded to the waivers in our sample, we compared copies of waivers obtained from OGC to those from the OPDIVs and STAFFDIVs and ensured that the waivers were the same.

2. Whether each described the particular matters in which employees were permitted to participate (i.e., those matters to which the waiver applied). We classified a waiver as containing this description if it set forth the employee’s official duties and the matters being waived. We classified a waiver as not containing this description if:
 - the waiver contained only a broad statement that the employee may participate in general matters related to the conflict of interest and (1) did not state what the conflict was by name somewhere in the waiver and (2) did not state the committee’s duties (for SGEs’ waivers) or the employee’s official duties (for all other HHS employees’ waivers).
 - the waiver contained contradictory information regarding the employee’s official duties and/or the matters being waived, either within the waiver or with other documents we received from the OPDIV or STAFFDIV.
 - the granting official did not document in the waiver the decision to grant or deny the waiver.⁶⁹

3. Whether each was designated as a limited waiver and described the particular matters in which an employee was prohibited from participating. First, we designated a waiver as limited if it was documented as limited (i.e., it contained language such as, “This is a limited waiver ...”) and/or contained any reference to matters in which the employee must not participate. Then, we classified a waiver as describing the limitations on the employee’s participation if it provided any explanation of the types of matters on which the employee must not participate. We classified a waiver as not containing this description if:
 - it contained only a broad statement that the employee must not participate in particular matters related to the conflict of interest and did not provide any detail about the matters in which the employee must not participate.
 - it contained contradictory information regarding the particular matters in which the employee was prohibited from

⁶⁹ HHS waivers contain checkboxes and signature lines for the granting officials to document decisions to grant or deny waivers.

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participating, either within the waiver or with other documents we received from the OPDIV or STAFFDIV.

Employee signature and date. We reviewed the waivers to determine whether they contained employees' signatures and dates. For both signed and unsigned waivers, we also determined whether they had a line for the employees' signatures. If waivers were not signed, we determined whether there was any documentation to demonstrate that the employees received and acknowledged their waivers. That is, we reviewed emails to determine whether the employees had received the final versions of their waivers or had acknowledged that they understood the contents of their waivers. We also reviewed documentation to determine whether OPDIVs or STAFFDIVs had orally counseled the employees about their waivers.

Finally, for waivers that were not signed and/or dated, we determined how many of them were not documented as recommended in at least one of the three selected regulatory provisions and the Secretary's instructions. Employees receiving these waivers may not know they have a waiver or understand the effect on their participation in official duties. Of these waivers, we also determined how many were limited waivers.

Limitations

We reviewed a stratified, random sample of 50 waivers granted in 2009. We do not generalize our findings to all HHS waivers granted in 2009 because of the small sample size in each stratum.

Standards

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

Fifty-six percent of the 50 HHS conflict-of-interest waivers in our review were not documented as recommended in provisions of selected Governmentwide Federal ethics regulations and the Secretary's instructions

Fifty-six percent (28 of 50) of the waivers from 2009 in our review were not documented as recommended in at least 1 of 3 selected regulatory provisions and the Secretary's instructions.⁷⁰

These 28 waivers were granted to employees at 5 of the 9 OPDIVs or STAFFDIVs in our review.

Fourteen percent (7 of 50) of the waivers did not describe employees' specific interests that posed conflicts.⁷¹ In addition, 46 percent (23 of 50) of the waivers did not describe the particular matters in which employees were permitted to participate.⁷² Finally, 28 percent (14 of 50) were limited waivers that did not describe the particular matters in which the employees were prohibited from participating.⁷³ Twenty-four percent (12 of 50) of the waivers were not documented as recommended in at least 2 of the 3 selected regulatory provisions and the Secretary's instructions, and 8 percent (4 of 50) were not documented as recommended in any of these provisions or instructions.⁷⁴

Of the 28 waivers that were not documented as recommended in at least 1 of the 3 selected regulatory provisions and the Secretary's instructions, all but 1 were granted to SGEs on committees. Appendix E provides the number and percentage of waivers from 2009 in our review that were not documented as recommended in each of the three selected regulatory provisions and the Secretary's instructions for SGEs and all other HHS employees.

⁷⁰ Ten of these twenty-eight waivers were addenda to waivers. These addenda are separate and distinct from the waivers they amend.

⁷¹ One of the seven waivers that did not describe employees' specific interests was an addendum.

⁷² Ten of the twenty-two waivers that did not describe the particular matters in which employees were permitted to participate were addenda.

⁷³ None of the fourteen limited waivers that did not describe prohibitions on employees' participation were addenda.

⁷⁴ One of the eight waivers that were not documented as recommended in at least two of the three selected regulatory provisions and the Secretary's instructions was an addendum. None of the four waivers that were not documented as recommended in any of these provisions or instructions were addenda.

Appendix F provides the number and percentage of the waivers from 2009 in our review that were not documented as recommended in one, two, or three of the selected regulatory provisions and the Secretary’s instructions. Appendix F also provides this information for limited waivers (for which all three selected regulatory provisions and the Secretary’s instructions apply) and nonlimited waivers (for which only two selected regulatory provisions and the Secretary’s instructions apply).

Fourteen percent of the 50 waivers in our review did not describe employees’ specific financial interests that posed conflicts

Fourteen percent (7 of 50) of the waivers from 2009 we reviewed did not describe employees’ specific interests that posed conflicts, and/or the interests were not reflected in the employees’ financial disclosure files.⁷⁵ If waivers do not clearly specify the financial interests being waived, the employees receiving the waivers (and/or other interested parties) may have difficulty understanding which interests are waived and which are not. Thus, the employees may inadvertently participate in matters in which they are prohibited from participating and/or may inadvertently not participate on matters in which their expertise may be valuable to HHS’s programs.

All seven of the waivers that did not describe employees’ specific interests were for SGEs on committees, and almost all (six of seven) failed to describe a specific interest that posed a conflict. Instead, these waivers contained general language covering broad categories of interests. For example:

[e]mployment with honoraria or other compensation from the health care industry, research institutions, state and local government, health care product manufacturers, insurance companies, hospitals, medical management delivery organizations, or other organizations ...; and [...] [e]xpert witness, litigation, or advocacy services

⁷⁵ The Centers for Medicare & Medicaid Services (CMS) did not provide documentation pertaining to one employee who was granted a waiver in 2009 because CMS had lost this employee’s financial disclosure file. We obtained the waiver from OGC and determined that it described a specific interest. We could not determine whether the interest was also reflected in the employee’s financial disclosure file. To be conservative, we counted this waiver as being documented as recommended in the selected regulatory provision of describing the employee’s specific conflict of interest.

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The remaining waiver described a specific interest, but the description contradicted information in the SGE's financial disclosure file. Specifically, the waiver indicated that the spouse's employment posed a conflict with the SGE's official duties. However, the financial disclosure file indicated that the SGE's spouse was unemployed. Because this was a limited waiver, this discrepancy may have prevented the SGE from participating in official duties prohibited by the waiver when, in fact, the interest may not have been held by or attributed to the SGE.

In contrast, most waivers clearly described the employee's specific interests that posed conflicts. For example:

Dr. [A] ... holds stock in [Pharmaceutical Company B]. [Pharmaceutical Company B] is the parent company of [Company C]. [Company C] is a competing firm. [Company C] markets dermal fillers for facial wrinkles. Dr. [A] owns X,XXX shares of [Pharmaceutical Company B] valued at \$XX,XXX. This amount exceeds the exemption of \$15,000 for stock holdings laid out in the regulations issued by the Office of Government Ethics (5 CFR 2640.202(a)). (The meeting is determined to be a particular matter involving specific parties.)

Forty-six percent of the 50 waivers in our review did not describe the particular matters in which employees were permitted to participate

For example, one waiver allows the employee to "participate in matters of general applicability affecting [his] current financial interests and any future interests of the types described above." The financial interests "described above" in the waiver contained general language and covered broad categories of interests.

Another waiver mentioned the employee's specific interests, among other broad categories of interests, but the waiver did not describe the employee's committee or the employee's official duties. Regarding the particular matters on which the employee was permitted to participate, the waiver stated that the employee is "granted a waiver for general matters only" and did not refer to the specific or broad interests contained in the waiver.

Of the 22 waivers that did not describe the particular matters in which employees were permitted to participate, all but 1 were for SGEs on committees.

In contrast, 54 percent (27 of 50) of the waivers from 2009 we reviewed clearly described the matters in which employees were permitted to participate. For example, one employee was permitted to participate in “[d]iscussion and recommendations on the safety and efficacy of [X] THERAPY, sponsored by [Y] Technologies, Inc. (formerly [Z] Technologies, Inc.) for moderate to severe nasolabial fold wrinkles. This is determined to be a particular matter involving specific parties.”

Twenty-eight percent of the 50 waivers in our review were limited waivers that did not describe the particular matters in which employees were prohibited from participating

However, only 31 of the 50 waivers in our sample were limited waivers that should have contained this description; the remaining 19 permitted employees to fully participate in official duties with no limitations. Thus, 45 percent (14 of 31) of the limited waivers in our review did not describe the particular matters in which HHS prohibited employees from participating. All 14 of these waivers were for SGEs on committees.

All of the limited waivers in our review contained broad statements that the employees must not participate in specific matters related to their conflicts of interest. However, 14 limited waivers did not provide any detail about these matters for the employee receiving the waiver or other stakeholders (e.g., the employee’s supervisor, the Designated Federal Official assigned to the SGE’s committee, the public, OIG). Thus, these waivers did not have enough specificity to provide a clear understanding of the circumstances to which the waiver applied.

For example, one employee was granted a waiver “that would allow this individual to participate in general matters that may directly affect [the HHS employee’s] financial interests, but not uniquely affecting the employee’s financial interest.”

In contrast, 55 percent (17 of 31) of limited waivers clearly described the prohibitions on the employee’s participation. For example:

[T]his waiver is intended to be limited in scope in that it does not apply to certain actions. You must have no involvement in any HHS grants, contracts, or other official actions that generate financial support to the [X], such as the procurement of [X] publications or approving expenditures for [X]-sponsored training for [HHS] staff. Likewise, you will have no involvement in HHS decisions

to provide speakers or other support to [X] events. You also will recuse yourself from all charitable solicitation activities by [X] ...

Although not required, 18 percent of the 50 HHS conflict-of-interest waivers in our review included employees' signatures and dates

While it is not a Federal requirement for them to do so, HHS OPDIVs and STAFFDIVs can document when employees receive

and acknowledge their waivers by having employees sign and date them. Employees' signatures and dates also document that they may be held accountable for complying with the terms of their waivers.⁷⁶ On its Intranet site, the OGC Ethics Division makes sample waivers available to OPDIVs and STAFFDIVs. These samples have a signature line for employees to confirm and acknowledge their waivers.

Eighteen percent (9 of 50) of the waivers from 2009 we reviewed included HHS employees' signatures and dates. These waivers were granted to employees in six of the nine OPDIVs and STAFFDIVs in our review.

In contrast, 82 percent (41 of 50) of the waivers we reviewed did not include HHS employees' signatures and/or dates. Seventy-six percent (38 of 50) of the waivers had been neither signed nor dated by the HHS employees receiving them. Thus, these 38 waivers are not documented to indicate that the employees received them or were aware that the waivers existed. Three waivers were signed but were not dated by the HHS employees receiving them. The 41 waivers that were not signed and/or dated were granted to employees at 5 of the 9 OPDIVs and STAFFDIVs in our review.

For the 38 waivers that were not signed or dated, no other documentation was submitted by the OPDIV or STAFFDIV to document that these employees received and/or acknowledged their waivers. For example, there were no documented emails to the 38 employees notifying them that they had waivers, sending them the final versions of their waivers, or asking them to confirm that they understood their waivers.⁷⁷ There was also no documentation that the OPDIV or

⁷⁶ Waivers are not considered to be in effect, however, until they are signed and dated by the OPDIV or STAFFDIV granting official.

⁷⁷ One email documented that an employee received a draft version of the waiver.

STAFFDIV orally counseled the 38 employees to ensure that they understood their conflicts of interest or the limitations on their participation in official duties, as described in their waivers.

Of the unsigned waivers, most (36 of 38) did not have a line for the employee's signature, as included in the OGC sample waivers. In contrast, all 12 of the signed waivers had a line for the employee's signature. These 12 waivers were granted to employees at 8 of the 9 OPDIVs or STAFFDIVs in our review.

Of the 41 waivers that were not signed and/or dated, all but 2 were for SGEs on committees. Appendix G provides the number and percentage of waivers from 2009 in our review that did not include the employees' signatures and/or dates, for SGEs and all other HHS employees.

Twenty-four of the forty-one waivers that were not signed and/or dated were not documented as recommended in at least one of the three selected regulatory provisions and the Secretary's instructions. Thus, the employees receiving these 24 waivers may not be aware of them. Even if they are aware the waivers exist, the employees may not understand their contents or their effect on the employees' official duties.

Twenty-four of the waivers that were not signed and/or dated were limited waivers. These waivers were not documented to indicate that the employees knew of the waivers or the limitations that the waivers imposed on their official duties. Of these 24 unsigned limited waivers, 14 were not documented as recommended in at least 1 of the 3 selected regulatory provisions and the Secretary's instructions. These 14 waivers represent the greatest vulnerability. The employees receiving these waivers may not be aware of them. If they are aware of the waivers, the employees may not understand the limitations imposed on their participation in official duties. If these employees are not aware of their limited waivers or do not clearly understand them, the employees may violate the criminal conflict-of-interest statute by participating in prohibited matters.



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

HHS employees, including SGEs serving as subject-matter experts on committees, play an influential role in the Federal Government’s public health policies. With the HHS OGC Ethics Division’s oversight and guidance, an HHS OPDIV and STAFFDIV may grant conflict-of-interest waivers to its employees. These waivers permit the employees to act in an official Government capacity in which they would otherwise be prohibited. OPDIVs and STAFFDIVs should document waivers as recommended in selected regulatory provisions and the Secretary’s instructions. In addition, HHS OPDIVs and STAFFDIVs can document when employees receive and acknowledge the waivers by having employees sign and date them or by otherwise documenting (e.g., via emails, documentation of oral counseling) that the employees received and acknowledged their waivers. Employees’ signatures and dates (or other documentation) also document that they are accountable for complying with their waivers.

According to OGE, evaluating whether to grant a waiver is “one of the more significant duties that ethics officials perform.”⁷⁸ If conflict-of-interest waivers are not clearly documented to show that employees understand their conflicts of interest and the matters, if any, in which they are prohibited from participating, employees may inadvertently violate the criminal conflict-of-interest statute. In addition, if waivers do not clearly describe the particular matters in which employees are permitted to participate, employees may incorrectly refrain from providing their expertise when it would benefit HHS’s programs. Further, if waivers are not documented so that the public understands the employees’ conflicts of interest and their effect on the employees’ official Government duties, the public may question the integrity of the employees’ services to the Government. Additionally, waivers that do not contain employees’ signatures and dates may raise questions about whether the HHS OPDIVs or STAFFDIVs presented the waivers to the employees and whether the employees had an opportunity to review and understand them.

⁷⁸ OGE Memorandum to Designated Agency Ethics Officials, *Guidance on Waivers Under 18 U.S.C. § 208(b), Authorizations Under 5 C.F.R. § 2635.502(d), and Waivers of Requirements Under Agency Supplemental Regulations*. DO-10-005, April 22, 2010, p. 5. Accessed at http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2010/do10005.pdf on September 23, 2010.

In HHS, reports of alleged violations of the criminal conflict-of-interest statute must be reported to OIG. However, if waivers are not clearly documented and there is no evidence that employees received and acknowledged their waivers (e.g., via signatures and dates on waivers or other documentation), OIG has difficulty investigating, and the Federal Government would have difficulty holding employees accountable for complying with the criminal conflict-of-interest statute when alleged violations occur.

We found that 56 percent of HHS employee conflict-of-interest waivers in our review were not documented as recommended in at least one of three selected regulatory provisions and the Secretary's instructions, and 8 percent were not documented with any of these provisions or instructions. In addition, although not required, 18 percent of waivers we reviewed were signed and dated by HHS employees.

Therefore, we recommend that HHS OGC:

Require OPDIVs and STAFFDIVs to document conflict-of-interest waivers as recommended in Governmentwide Federal ethics regulations and the Secretary's instructions

OGC should work with the Office of the Secretary to reaffirm the Secretary's January 2009 instructions and/or issue a new HHS policy requiring that all waivers be clearly documented to describe:

- the employee's specific financial interest that poses the conflict of interest;
- the particular matter(s) in which the employee is permitted to participate; and
- the particular matter(s), if any, in which the employee is prohibited from participating.

As an alternative to documenting the waivers as recommended in the selected regulatory provisions and the Secretary's instructions, other documents could be attached to or associated with the waivers to assist employees and other stakeholders in understanding them.

Develop additional guidance and training to assist OPDIVs and STAFFDIVs in documenting conflict-of-interest waivers as recommended in Governmentwide Federal ethics regulations and the Secretary's instructions

OGC should revise existing or create new guidance and training for OPDIV and STAFFDIV ethics officials to ensure that waivers meet the requirements and recommendations set forth in the criminal conflict-of-interest statute, Governmentwide Federal ethics regulations, and the Secretary's instructions. This guidance and training should educate ethics officials on how to draft waivers that are individualized for each employee. In addition to including the required legal language, some section of waivers should contain clear, plain (i.e., nonlegal) language that employees and other stakeholders, including employees' supervisors, can easily understand and apply to the employees' work circumstances. Each waiver should also include an individualized interpretation of how it applies to the employees' unique work circumstances and should provide a clear understanding of the circumstances to which the waiver applies or does not apply. Providing clear and understandable guidance would also serve to prevent inadvertent violations of the criminal conflict-of-interest statute.

Guidance should also include a detailed description of the applicable Federal ethics regulations and should provide examples and sample language to illustrate how waivers should be documented. For example, the guidance could explain in more detail that a waiver should clearly describe the following:

- *The employee's specific interest and the potential for conflict.* The waiver's description should contain sufficient detail for the employee and the public to understand the nature and identity of the specific interest and how the interest may conflict with the employee's official duties.
- *The particular matters in which the employee is permitted to participate.* The waiver's description should contain sufficient detail for the employee and the public to understand the scope of the employee's permission to act in official duties related to the specified interest and the particular matters to which the waiver applies.
- *The particular matters in which the employee is prohibited from participating.* When a limited waiver is required, its description should contain sufficient detail for the employee and the public to understand the particular matters that are not being waived and in which the employee is prohibited from participating. Further, the waiver should instruct the employee what to do if a matter related to the interest arises and the employee is unsure whether he or she can participate.

OGC should also revise existing training or provide additional training to ethics officials in OPDIVs and STAFFDIVs. The training should include an overview of the process for developing and granting waivers to comply with Governmentwide Federal ethics regulations and the Secretary's instructions. The training should also provide hypothetical examples of HHS employees who have conflicts of interest and should educate ethics officials on whether a waiver should be granted and, if so, how to clearly document it.

Take action to revise the conflict-of-interest waivers in our review that were not documented as recommended in Governmentwide Federal ethics regulations and the Secretary's instructions, if the waivers are still in effect

OGC should work with OPDIVs and STAFFDIVs to determine if any waivers in our review are still in effect (i.e., if the employee is still working for HHS, if the employee still has the same conflict of interest and is working on the same official duties). If any of the waivers are still in effect, OGC should assist OPDIVs and STAFFDIVs in their revision of these waivers to document them according to the three selected regulatory provisions and the Secretary's instructions. OGC should ensure that the OPDIVs and STAFFDIVs clarify waiver terms to help employees understand and comply with the waivers.

OGC should focus first on the 14 limited waivers that were not documented as recommended in at least 1 of the 3 selected regulatory provisions and the Secretary's instructions and were also not signed and/or dated by the employee receiving the waiver. These limited waivers represent the greatest vulnerability. If these employees are not aware of their limited waivers or do not understand them, and if the waivers are still in effect, the employees may inadvertently violate the criminal conflict-of-interest statute by taking part in matters in which they are prohibited from participating.

Expand the review of conflict-of-interest waivers for SGEs on committees

Consistent with the Secretary's January 2009 memorandum, the OGC Ethics Division must review waivers for SGEs on committees "where practicable."⁷⁹ Most HHS waivers granted in 2009 were for SGEs on committees, and these SGEs' waivers constitute most of the problems we found.

⁷⁹ Secretary, Memorandum to Deputy Secretary and Chiefs of Staff, Heads of Operating and Staff Divisions, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)*. January 16, 2009, p. 2.

Therefore, when OGC receives copies of HHS waivers that were granted by OPDIVs and STAFFDIVs, it should thoroughly check a sample—if not all—of the waivers from each OPDIV or STAFFDIV, particularly focusing on waivers for SGEs, to ensure that the waivers are documented as recommended in Federal ethics regulations and the Secretary’s instructions. As part of this review, OGC should obtain the employee’s financial disclosure file from the OPDIV or STAFFDIV to fully understand the nature of the employee’s conflicts of interest. If OGC identifies problems with waivers within an OPDIV or STAFFDIV, it should ensure that the OPDIV or STAFFDIV clarifies with the employees the matters in which they are permitted to participate and any matters in which they are prohibited from taking part. OGC should also work with OPDIV or STAFFDIV ethics officials to revise these waivers and require that the ethics officials work more closely with OGC before granting future waivers.

Require all employees to sign and date their conflict-of-interest waivers or otherwise document that they received and acknowledged them

OGC should work with the Office of the Secretary to issue official HHS policy that requires all employees to sign and date their waivers. OGC should also require that waivers have a line for the employee’s signature and date so that it is clear that the document must be signed and dated, as demonstrated in the OGC Ethics Division’s sample waivers.⁸⁰

As an alternative to signing and dating waivers, the policy could permit other methods for documenting that employees received and acknowledged their waivers, such as by retaining emails from employees confirming that they understand their waivers and/or documenting oral counseling provided to employees about their waivers.

While waivers are considered legally in effect once they are signed and dated by the appropriate granting official, employees should sign and date their waivers to (1) acknowledge the waivers, (2) document when they understood any limitations on their participation in official Government duties, and (3) confirm that the waivers accurately describe their specific circumstances and conflicts of interest. Employees’

⁸⁰ OGC, “Sample Waiver of Conflict of Interest for Special Government Employees (SGEs) on Federal Advisory Committees [18 U.S.C. 208(b)(3)],” “Sample Waiver of Actual Conflict for Officers or Directors [18 U.S.C. 208(b)(1)],” and “Sample Waiver of Actual Conflict of Interest for Regular Employees [18 U.S.C. 208(b)(1)].”

signatures and dates on waivers also demonstrate that OPDIVs or STAFFDIVs presented the waivers to the employees and that the employees had a chance to review and understand them. Requiring employees to sign and date their waivers, or otherwise documenting that they received and understood the waivers, may also assist in ensuring that they are held accountable for complying with the waivers.

Waivers are not considered to be in effect until OPDIV or STAFFDIV granting officials sign and date them. Therefore, employees' signatures and dates should be obtained on waivers as soon as possible after the granting official signs and dates them.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

OGC and OGE provided written comments on a draft of this report. We provide, below, a summary of these comments and our responses to each. In addition, in response to OGC's and OGE's comments, we conducted a second review of many of the waivers in our sample. OIG continued to find that many waivers were not documented as recommended in the selected regulatory provisions and the Secretary's instructions, and we updated our findings accordingly.

Comments from the HHS Office of the General Counsel. OGC stated that the OIG report is incorrect and ignores the wide latitude that OGE contemplated when making recommendations for waiver content. OGC also disagreed with the finding that the waivers in our sample were not documented as recommended in OGE regulations and stated that our contrary conclusion was based on several fundamental errors. Further, OGC stated that it reviewed each of the 50 waivers in our sample and determined that none of the waivers failed to meet legal requirements and that the waivers contained descriptions satisfying the OGE recommendations and were consistent with the conditions stated in the Secretary's instructions.

OGC concurred with two of the five recommendations in the draft report. Specifically, OGC concurred with the recommendation that it should develop additional guidance and training to assist OPDIVs and STAFFDIVs in documenting waivers as recommended in Governmentwide Federal ethics regulations. OGC reiterated that it disagreed with the draft report's interpretation of waiver documentation recommendations in Federal ethics regulations, but OGC stated that guidance and training based on the correct interpretation will benefit

the HHS waiver process. OGC also concurred that it should expand the review of waivers for SGEs on committees, while noting that it has already revised its review and oversight process for waivers in a manner that is more expansive than the actions we recommend.

OGC did not concur with three recommendations: that it require OPDIVs and STAFFDIVs to document waivers as recommended in Governmentwide regulations; that it take action to revise the conflict-of-interest waivers in our review that were not documented as recommended in these regulations; and that it require all employees to sign and date, or similarly document, their waivers. However, OGC acknowledged that additional detail may be helpful for some of the waivers in our sample and stated that it has been working with one of the OPDIVs to revise the model waivers that it provides to ethics officials within the OPDIV.

OIG disagrees with OGC's statements that our report contains fundamental errors and that we ignored the wide latitude in OGE's recommendations for waiver content. OGE affords agencies wide latitude to craft waivers that are both legally sufficient and meet agencies' policy objectives, such as the Secretary's instructions.

We believe that documenting waivers in a manner that reflects OGE's recommendations and the Secretary's instructions is important to preserve the integrity of HHS's programs and policies by ensuring that employees and other stakeholders are aware of employees' conflicts of interest and act accordingly when those interests arise in the course of the employees' official Government duties.

Given the importance of accountability, OIG continues to emphasize its recommendation that OGC require employees to sign and date, or similarly document, their waivers. OGC's concern about a "one size fits all" approach is accommodated by our recognition that this can be accomplished by other means (i.e., similarly documenting waivers) to ensure employee accountability. Further, OIG maintains that unsigned limited waivers that are not documented as recommended in the selected regulatory provisions and the Secretary's instructions represent the greatest vulnerability. The employees receiving these waivers may not be aware of them or the limitations on the employees' participation. If these employees are not aware of their limited waivers or do not clearly understand them, the employees may violate the criminal conflict-of-interest statute by participating in prohibited matters.

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

Comments from the Office of Government Ethics. OGE also provided comments on a draft of this report but was not asked to indicate whether it concurred with the report's recommendations. However, OGE did state that, as a general matter, the recommendations in the report support good documentation practices that it strongly recommends. OGE also expressed concern that the draft report did not adequately recognize that, by regulation and policy, OGE has afforded agencies certain latitude to create waivers that are both legally sufficient and meet agencies' policy objectives. OGE emphasized that waivers do not need to be described with any particular degree of specificity to be legally sufficient and that the agency issuing the waiver can describe the employee's duties in a general way or describe a class of matters. Further, OGE indicated that the draft report did not account for the location or availability of information in places other than the actual waiver.

OGE also expressed concern regarding our finding of insufficient detail in limited waivers and indicated that similar language describing limitations has been used in waivers for decades, including in OGE's own waivers. OGE expressed concern that our report casts doubt on the clarity and enforceability of similar limiting language that has long been used in the Executive Branch.

Finally, OGE acknowledged that neither OGE regulations nor guidance require employees to sign and acknowledge their waivers. OGE indicated that agencies have various means, apart from the actual waiver, to apprise employees of the scope of their permitted duties and any recusal obligations.

We made revisions to the report to clearly underscore that neither OGE regulations nor OGE guidance provides a clear definition of the degree of specificity required in waivers and that waivers may be legally sufficient without this information. However, we note that the Secretary's 2009 instructions provide additional clarity regarding the contents of HHS's waivers, including limited waivers, and we have revised the report accordingly. We maintain that—regardless of the language used in HHS waivers prior to January 2009—for waivers to be documented consistently with the Secretary's January 2009 instructions, some section of the waivers should contain clear language so that employees and other stakeholders (e.g., employees' supervisors, the public, OIG) can understand the waivers and so that employees may be held accountable for complying with them.

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

We made other technical and clarifying changes to the report based on OGC's and OGE's comments. For example, we clarified that (1) we did not determine the legal sufficiency of the waivers, (2) we used the Secretary's instructions when reviewing the waivers, and (3) we considered other documents provided by OPDIVs and STAFFDIVs when determining whether employees received and acknowledged their waivers. For the full text of OGC's and OGE's comments, see Appendix H. Because OGC included OGE's comments as an attachment to its comments, we do not provide OGE's comments separately.

▶ A P P E N D I X ~ A

| Table A-1: Number of Waivers by Department of Health and Human Services Operating Division or Staff Division and Type of Employee, From 2007 to 2009 | | | |
|---|-------------|-------------|-------------|
| Operating Division or Staff Division | 2007 | 2008 | 2009 |
| Agency for Healthcare Research and Quality | 8 | 6 | 6 |
| Waivers for special Government employees (SGEs) on Federal advisory committees (committees) | 8 | 6 | 6 |
| Waivers for all other Department of Health and Human Services (HHS) employees | 0 | 0 | 0 |
| Assistant Secretary for Preparedness and Response | 3 | 3 | 0 |
| Waivers for SGEs on committees | 3 | 3 | 0 |
| Waivers for all other HHS employees | 0 | 0 | 0 |
| Assistant Secretary for Planning and Evaluation | 0 | 0 | 1 |
| Waivers for SGEs on committees | 0 | 0 | 0 |
| Waivers for all other HHS employees | 0 | 0 | 1 |
| Centers for Disease Control and Prevention | 15 | 29 | 12 |
| Waivers for SGEs on committees | 13 | 28 | 12 |
| Waivers for all other HHS employees | 2 | 1 | 0 |
| Centers for Medicare & Medicaid Services | 1 | 4 | 1 |
| Waivers for SGEs on committees | 1 | 4 | 0 |
| Waivers for all other HHS employees | 0 | 0 | 1 |
| Food and Drug Administration | 95 | 37 | 24 |
| Waivers for SGEs on committees | 89 | 33 | 23 |
| Waivers for all other HHS employees | 6 | 4 | 1 |
| Health Resources and Services Administration | 10 | 47 | 6 |
| Waivers for SGEs on committees | 10 | 47 | 6 |
| Waivers for all other HHS employees | 0 | 0 | 0 |
| Indian Health Service | 0 | 0 | 1 |
| Waivers for SGEs on committees | 0 | 0 | 0 |
| Waivers for all other HHS employees | 0 | 0 | 1 |
| National Institutes of Health | 301 | 255 | 290 |
| Waivers for SGEs on committees | 287 | 237 | 287 |
| Waivers for all other HHS employees | 14 | 18 | 3 |
| Office of the General Counsel | 0 | 0 | 1 |
| Waivers for SGEs on committees | 0 | 0 | 0 |
| Waivers for all other HHS employees | 0 | 0 | 1 |
| Office of Public Health Services | 13 | 3 | 0 |
| Waivers for SGEs on committees | 13 | 3 | 0 |
| Waivers for all other HHS employees | 0 | 0 | 0 |
| President's Council on Bioethics | 4 | 3 | 0 |
| Waivers for SGEs on committees | 4 | 0 | 0 |
| Waivers for all other HHS employees | 0 | 3 | 0 |
| Total | 450 | 387 | 342 |
| Waivers for SGEs on Committees | 428 | 361 | 334 |
| Waivers for All Other HHS Employees | 22 | 26 | 8 |

Source: Office of Inspector General analysis of Office of the General Counsel data, 2009.

**5 CFR Pt. 2640 – Interpretation, Exemptions, and Waiver Guidance
Concerning 18 U.S.C. 208 (Acts Affecting a Personal Financial Interest)**

Subpart C—Individual Waivers

5 CFR § 2640.301 – Waivers issued pursuant to 18 U.S.C. 208(b)(1)

(NOTE: Provisions relevant to the analysis in this report are shown in bold.)

(a) *Requirements for issuing an individual waiver under 18 U.S.C. 208(b)(1).* Pursuant to 18 U.S.C. 208(b)(1), an agency may determine in an individual case that a disqualifying financial interest in a particular matter or matters is not so substantial as to be deemed likely to affect the integrity of the employee's services to the Government. Upon making that determination, the agency may then waive the employee's disqualification notwithstanding the financial interest, and permit the employee to participate in the particular matter. **Waivers issued pursuant to section 208(b)(1) should comply with the following requirements:**

(1) The disqualifying financial interest, and the nature and circumstances of the particular matter or matters, must be fully disclosed to the Government official responsible for appointing the employee to his position (or other Government official to whom authority to issue such a waiver for the employee has been delegated);

(2) The waiver must be issued in writing by the Government official responsible for appointing the employee to his position (or other Government official to whom the authority to issue such a waiver for the employee has been delegated);

(3) The waiver should describe the disqualifying financial interest, the particular matter or matters to which it applies, the employee's role in the matter or matters, and any limitations on the employee's ability to act in such matters;

(4) The waiver shall be based on a determination that the disqualifying financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services to the Government. Statements concerning the employee's good character are not material to, nor the basis for making, such decision;

(5) The waiver must be issued prior to the employee taking any action in the matter or matters; and

(6) The waiver must apply to both present and future financial interests, provided the interests are described with sufficient specificity.

Note to paragraph (a): The disqualifying financial interest, the particular matter or matters to which the waiver applies, and the employee’s role in such matters do not need to be described with any particular degree of specificity. For example, if a waiver were to apply to all matters which an employee would undertake as part of his official duties, the waiver document would not have to enumerate those duties. The information contained in the waiver, however, should provide a clear understanding of the nature and identity of the disqualifying financial interest, the matters to which the waiver will apply, and the employee’s role in such matters.

5 CFR § 2640.302 – Waivers issued pursuant to 18 U.S.C. 208(b)(3)

(NOTE: Provisions relevant to the analysis in this report are shown in bold.)

(a) *Requirements for issuing an individual waiver under 18 U.S.C. 208(b)(3).* Pursuant to 18 U.S.C. 208(b)(3), an agency may determine in an individual case that the prohibition of 18 U.S.C. 208(a) should not apply to a special Government employee serving on, or an individual being considered for, appointment to an advisory committee established under the Federal Advisory Committee Act, notwithstanding the fact that the individual has one or more financial interests that would be affected by the activities of the advisory committee. The agency’s determination must be based on a certification that the need for the employee’s services outweighs the potential for a conflict of interest created by the financial interest involved. **Waivers issued pursuant to 18 U.S.C. 208(b)(3) should comply with the following requirements:**

(1) The advisory committee upon which the individual is serving, or will serve, is an advisory committee within the meaning of the Federal Advisory Committee Act, 5 U.S.C. app.;

(2) The waiver must be issued in writing by the Government official responsible for the individual’s appointment (or the Government official to which authority to issue such waivers has been delegated) after the official reviews the financial disclosure report filed by the individual pursuant to the Ethics in Government Act in 1978;

(3) The waiver must include a certification that the need for the individual’s services on the advisory committee outweighs the potential for a conflict of interest;

(4) The facts upon which the certification is based should be fully described in the waiver, including the nature of the financial interest, and the particular matter or matters to which the waiver applies;

(5) The waiver should describe any limitations on the individual’s ability to act in the matter or matters;

(6) The waiver must be issued prior to the individual taking any action in the matter or matters; and

(7) The waiver may apply to both present and future financial interests of the individual, provided the interests are described with sufficient specificity.

5 CFR § 2640.303 – Consultation and notification regarding waivers

When practicable, an official is required to consult formally or informally with the Office of Government Ethics prior to granting a waiver referred to in §§ 2640.301 and 2640.302. A copy of each such waiver is to be forwarded to the Director of the Office of Government Ethics.

5 CFR § 2640.304 – Public availability of agency waivers

(a) *Availability.* A copy of an agency waiver issued pursuant to 18 U.S.C. 208 (b)(1) or (b)(3) shall be made available upon request to the public by the issuing agency. Public release of waivers shall be in accordance with the procedures set forth in section 105 of the Ethics in Government Act of 1978, as amended. Those procedures are described in 5 CFR 2634.603.

(b) *Limitations on availability.* In making a waiver issued pursuant to 18 U.S.C. 208 (b)(1) or (b)(3) publicly available, an agency:

(1) May withhold from public disclosure any information contained in the waiver that would be exempt from disclosure pursuant to 5 U.S.C. 552; and

(2) Shall withhold from public disclosure information in a waiver issued pursuant to 18 U.S.C. 208(b)(3) concerning an individual’s financial interest which is more extensive than that required to be disclosed by the individual in his financial disclosure report under

A P P E N D I X ~ B

the Ethics in Government Act of 1978, as amended, or which is otherwise subject to a prohibition on public disclosure under law.



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN 16 2009

MEMORANDUM

TO: Deputy Secretary
Chief of Staff
Heads of Operating and Staff Divisions

SUBJECT: Delegation of Authority to Grant Conflict of Interest Waivers
Under 18 U.S.C. §§ 203(d), 205(e), and 208(b)

Authority to Delegate:

Pursuant to the authority delegated to me by Executive Order 12674 (April 12, 1989), as amended by Executive Order 12731 (October 17, 1990), I hereby delegate the authority under Title 18, United States Code, §§ 203(d), 205(e), and 208(b), to grant exemptions, certifications, waivers, and/or approvals concerning conflicts of interest to the Deputy Secretary and the Chief of Staff or your successors, for any individual appointed or otherwise serving within the Department, and to the Heads of Operating and Staff Divisions or your successors, for individuals appointed or otherwise serving within your respective operating and staff divisions.

Authorities Delegated:

18 U.S.C. §§ 203 and 205 – Sections 203 and 205 prohibit federal employees from representing others with or without compensation or from accepting compensation for those services rendered by another, in certain matters in which the United States is a party or has a direct and substantial interest.

Sections §§ 203(d) and 205(e) authorize exceptions to these prohibitions for employees who wish to represent their parents, spouse, child, or any person for whom, or for any estate for which, they serve as guardian, executor, administrator, trustee, or other personal fiduciary, provided that the matter is not one in which the employee has participated personally and substantially or which is the subject of his or her official responsibility. Exceptions must be approved by the Government official responsible for the employee's appointment to his or her position. These approval authorities are delegated to you or your successor.

18 U.S.C. § 208 – This section prohibits a federal employee from personally and substantially participating in a particular matter in which he or certain other persons or entities whose interests are attributable to him has a financial interest.

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Under 18 U.S.C. § 208(b)(1), the official responsible for the employee’s appointment may make a written determination that the employee’s interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee, thus permitting the employee to work on the matter in which he has a conflict. The authority to issue such a determination is hereby delegated to you or your successor.

Under 18 U.S.C. § 208(b)(3), concerning special Government employees serving on, or being considered for appointment to, Federal Advisory Committee Act (FACA) committees, the official responsible for the employee’s appointment may waive a potential conflict of interest by certifying in writing that the need for the individual’s services outweighs the potential for a conflict of interest created by the financial interest involved. This authority to make such a certification under 18 U.S.C. § 208(b)(3) is hereby delegated to you or your successor.

Limitations:

The delegated authority under 18 U.S.C. § 208(b)(1) may not be redelegated.

The delegated authorities under 18 U.S.C. §§ 203(d), 205(e), and 208(b)(3) may be redelegated only at a high enough level to be consistent with good management of this authority.

Exercise of these authorities shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary, the Director of the Office of Government Ethics, and the Designated Agency Ethics Official.

Instructions:

Any waivers, exemptions, certifications, and/or approvals granted under this delegation shall be subject to the following conditions:

1. Prior to issuance, each potential waiver under 18 U.S.C. § 208(b)(1) must be reviewed by the Designated Agency Ethics Official (DAEO). Waivers under 18 U.S.C. § 208(b)(3) and approvals under §§ 203(d) and 205(e) must be reviewed, where practicable, by the DAEO, the Alternate DAEO, or a Deputy Ethics Official within the Office of the General Counsel, Ethics Division. Once finalized, a copy of each waiver or approval document must be provided to the DAEO.
2. Categories of official actions to which a waiver applies must be narrowly drawn to ensure that permission to act in an otherwise conflicting situation is appropriately limited. The waiver must fully describe the potential conflict, document the basis for the waiver, and reflect an individualized assessment of the requestor’s circumstances. A description of the precise nature of the individual’s search for employment, when the requestor has sought a waiver for that purpose, must be included.

Page 3 – Deputy Secretary

3. In keeping with applicable law and regulations pertaining to conflicts of interest and waivers, and to best ensure that all relevant information is taken into account in issuing a waiver, the Office of Government Ethics (OGE) regulations advise that the responsible official may consider factors such as: (a) the type of interest that is creating the disqualification; (b) the identity of the person whose financial interest is involved, and if the interest is not the employee's, the relationship of that person to the employee; (c) the dollar value of the disqualifying financial interest, if it is known or can be estimated; (d) the value of the financial instrument or holding from which the disqualifying financial interest arises; (e) the nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter; (f) the sensitivity of the matter; (g) the need for the employee's services in the particular matter; and (h) adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that the integrity of the employee's services would be questioned by a reasonable person.
4. Conflict of interest waivers issued in an employment negotiation context must be limited in duration, with each individualized determination regarding the time limit to be based on the requestor's particular circumstances, and its duration clearly stated in the text of the document. One year is the absolute maximum waiver time limit to be permitted in such circumstances.
5. Vigilant internal agency practice must provide for effective screening and monitoring mechanisms when an employee has received a limited waiver from the conflict of interest statutory requirements. Each individual granted a § 208(b)(1) waiver in an employment negotiation context under this delegation must initially report to the DAEO after the waiver is finalized. The DAEO will then communicate with the waiver recipient's Deputy Ethics Counselor (DEC) within the agency. The employee must report periodically to the DEC from that point forward, following a schedule set according to the employee's individualized circumstances, for example, on the status of his employment negotiations. The DAEO will remain available to the DEC for consultation as necessary. This will permit the agency to screen particular matters that might affect prospective employers and their clients, recuse the waiver recipient from those matters, and avoid the potential for conflict of interest, for the ultimate benefit of both employee and agency.

Effective Date:

This delegation is effective immediately.

Effect on Existing Delegations:

This delegation supersedes any prior delegations.

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I hereby affirm and ratify and actions taken by you or your subordinates that involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

A handwritten signature in black ink, appearing to read 'M. O. Leavitt', with a long horizontal flourish extending to the right.

Michael O. Leavitt

cc: Designated Agency Ethics Officials

➤ A P P E N D I X - D

Table D-1: Number of Waivers Granted by the Department of Health and Human Services in 2009 to Special Government Employees on Federal Advisory Committees at the National Institutes of Health, by Institute or Center

| National Institutes of Health Institute or Center | Waivers Granted in 2009 | Waivers in Sample |
|---|--------------------------------|--------------------------|
| Office of the Director | 56 | 3 |
| National Cancer Institute | 42 | 2 |
| National Heart, Lung, and Blood Institute | 21 | 2 |
| National Institute of Environmental Health Sciences | 19 | 2 |
| National Institute of Child Health and Human Development | 16 | 1 |
| National Institute of Allergy and Infectious Diseases | 15 | 2 |
| National Institute of Mental Health | 14 | 1 |
| National Center for Research Resources | 11 | 1 |
| National Human Genome Research Institute | 10 | 1 |
| National Institute of Arthritis and Musculoskeletal and Skin Diseases | 10 | 1 |
| Clinical Center | 9 | 1 |
| National Institute on Drug Abuse | 9 | 1 |
| National Library of Medicine | 9 | 1 |
| National Institute of General Medical Sciences | 7 | 1 |
| National Institute of Neurological Disorders and Stroke | 7 | 1 |
| National Institute of Deafness and Other Communication Disorders | 6 | 1 |
| National Institute of Diabetes and Digestive and Kidney Diseases | 6 | 1 |
| National Institute on Aging | 5 | 1 |
| National Center for Complementary and Alternative Medicine | 5 | 1 |
| National Center on Minority Health & Health Disparities | 3 | 1 |
| National Institute of Nursing Research | 3 | 1 |
| Center for Scientific Review | 2 | 1 |
| Fogarty International Center | 1 | 1 |
| National Eye Institute | 1 | 1 |
| National Institute on Alcohol Abuse and Alcoholism | 0 | 0 |
| National Institute of Biomedical Imaging and Bioengineering | 0 | 0 |
| National Institute of Dental and Craniofacial Research | 0 | 0 |
| Total | 287 | 30 |

Source: Office of Inspector General review of Department of Health and Human Services data, 2010.

Table E-1: Number and Percentage of Waivers From 2009 in Our Review Not Documented as Recommended in Provisions of Selected Governmentwide Federal Ethics Regulations and the Instructions of the Secretary of Health and Human Services, for Special Government Employees and All Other Department of Health and Human Services Employees

| Recommended Provisions and Instructions Not Documented in Waiver | Special Government Employees on Committees (n=42)* | | All Other Department of Health and Human Services Employees (n=8)* | | All Employees (n=50)* | |
|---|--|--------------|--|--------------|-----------------------|--------------|
| | Number | Percentage** | Number | Percentage** | Number | Percentage** |
| Description of employees' specific conflicts of interest | 7 | 17% | 0 | 0% | 7 | 14% |
| Description of particular matters in which employees were permitted to participate | 22 | 52% | 1 | 13% | 23 | 46% |
| Description of particular matters in which employees were prohibited from participating | 14 | 33% | 0 | 0% | 14 | 28% |
| Total | 27 | 64% | 1 | 13% | 28 | 56% |

* Column sums exceed totals because some waivers were not documented as recommended in more than one selected regulatory provision and the instructions of the Secretary of Health and Human Services.

** Percentages are calculated using the total number of waivers for each type of employee. However, only limited waivers must describe particular matters in which employees were prohibited from participating. There were 31 limited waivers in our sample: 26 limited waivers for special Government employees and 5 limited waivers for all other HHS employees.

Source: Office of Inspector General review of Department of Health and Human Services data, 2010.

Table F-1: Number and Percentage of Waivers From 2009 in Our Review Not Documented as Recommended in One, Two, or Three Provisions of Selected Governmentwide Federal Ethics Regulations and the Instructions of the Secretary of Health and Human Services, for Limited and Nonlimited Waivers

| Number of Recommended Provisions and Instructions Not Documented in Waiver | Limited Waivers | | Nonlimited Waivers | | All Waivers | |
|--|-----------------|------------|--------------------|------------|-------------|-------------|
| | Number | Percentage | Number | Percentage | Number | Percentage |
| One | 7 | 14% | 9 | 18% | 16 | 32% |
| Two | 7 | 14% | 1 | 2% | 8 | 16% |
| Three | 4 | 8% | N/A* | N/A* | 4 | 8% |
| None | 13 | 26% | 9 | 18% | 22 | 44% |
| Total | 31 | 62% | 19 | 38% | 50 | 100% |

* Nonlimited waivers do not describe the particular matters in which employees are prohibited from participating.

Source: Office of Inspector General review of Department of Health and Human Services data, 2010.

➤ A P P E N D I X ~ G

Table G-1: Number and Percentage of Waivers From 2009 in Our Review That Did Not Include Employees' Signature and/or Date, for Special Government Employees and All Other Department of Health and Human Services Employees

| Information Not Documented in Waiver | Special Government Employees on Committees (n=42) | | All Other Department of Health and Human Services Employees (n=8) | | All Employees (n=50) | |
|--------------------------------------|---|------------|---|-------------|----------------------|------------|
| | Number | Percentage | Number | Percentage* | Number | Percentage |
| Signature and date | 37 | 88% | 1 | 13% | 38 | 76% |
| Date only | 2 | 5% | 1 | 13% | 3 | 6% |
| Total | 39 | 93% | 2 | 25% | 41 | 82% |

* Column sum exceeds total because of rounding.

Source: Office of Inspector General review of Department of Health and Human Services data, 2010.

▶ A P P E N D I X ~ H

AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

MAY 10 2011

MEMORANDUM

TO: Stuart Wright
Deputy Inspector General for Evaluation and Inspections

FROM: David S. Cade *ISI*
Deputy General Counsel

SUBJECT: OIG Draft Report: *Conflict-of-Interest Waivers Granted to HHS Employees in 2009*, OEI-04-10-00010 (March 2011)

The Office of the General Counsel (OGC) appreciates the opportunity to review and comment on the Office of the Inspector General (OIG) draft report prepared by the Office of Evaluation and Inspections (OEI): *Conflict-of-Interest Waivers Granted to HHS Employees in 2009*, OEI-04-10-00010 (March 2011) (Draft Report). Evaluating possible waivers under the conflict of interest statute, 18 U.S.C. § 208, is one of the more significant duties that ethics officials perform to ensure public confidence in the Government's programs and operations. Both the individual employee's interests and those of the Government are best served when this process is carried out in a careful and consistent manner. OGC shares OEI's goal of ensuring that conflict of interest waivers issued by Departmental components are both legally effective and appropriately documented in order to support the mission of the Department of Health and Human Services (HHS).

OEI review of administrative processes often provides useful insights and recommendations. OEI, in this instance, has undertaken to evaluate legal instruments to ascertain whether the documents contain descriptive elements which OEI characterizes as "recommended in provisions of selected Governmentwide Federal ethics regulations." Draft Report at 1. As OEI crosses into an area of OGC's particular expertise, we do find its legal evaluation wanting. Although we appreciate the time and effort that went into preparing the Draft Report and acknowledge the corrections OEI has already made in response to our informal comments, the report continues to be incorrect.

The Draft Report claims that all conflict of interest waivers should contain very detailed descriptions of: (1) the employee's specific financial interest; (2) the particular matter(s) in which the employee is permitted to participate; and (3) any limitations regarding the particular matter(s) in which the employee remains prohibited from participating. *Id.* The Draft Report then rejects, as insufficient documentation, textual references to broad categories of interests, generalized descriptions of an employee's duties that may affect those interests, and utilization of legal terms of art that delineate classes of matters to which the waiver would apply. Draft Report at 16-19.

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The Office of Government Ethics (OGE), the superintending ethics office for the Executive Branch, reviewed an earlier version of the Draft Report and stressed that the documentation elements against which OEI measured the waivers are not mandatory for legal sufficiency, but merely desirable. Letter from Don W. Fox, General Counsel and Principal Deputy Director, Office of Government Ethics, to Edgar M. Swindell, Associate General Counsel for Ethics and Designated Agency Ethics Official (DAEO), Department of Health and Human Services (March 9, 2011) (OGE GC Letter) (copy attached at Tab 1 and incorporated as part of this response).¹ Although OEI corrected its Draft Report to reflect that OGE regulations state only *recommendations* for waiver content, the Draft Report ignores the wide drafting latitude that OGE contemplated when making those recommendations.

OGE included within the regulations a textual note stating that “[t]he disqualifying financial interest, the particular matter or matters to which the waiver applies, and the employee’s role in such matters do not need to be described with any particular degree of specificity.” 5 C.F.R. § 2640.301(a) (Note). When proposing the regulation, OGE stated in the preamble that “[t]his would, for example, permit the agency issuing the waiver to describe the employee’s duties in a general way or to describe a class of matters to which the waiver would apply.” 60 Fed. Reg. 47207, 47222 (September 11, 1995).

To reiterate that OGE meant precisely what was said on this point, OGE recently took the unprecedented step of writing the HHS DAEO to express concern about OEI’s evaluation of the waivers at issue. Attentive to the Draft Report’s implications for similarly drafted waivers issued by other agencies, OGE questioned OEI’s inclusion of “certain statements in the Draft Report indicating that it is insufficient detail for a waiver to permit participation in ‘general matters’ while requiring recusal from more ‘specific’ matters that ‘uniquely’ affect the employee’s financial interests.” OGE GC Letter at 3. OGE rejected this assertion and instead validated that drafting waivers in this manner is a common, accepted, longstanding, sufficiently detailed, and legally permissible practice. *Id.* at 3-4. OGE further recognized that “agencies have other means, besides the waiver documents themselves, of informing employees about the scope and any limits of their waivers” including, for example, “ancillary memoranda, ethics agreements, training, and individual counseling.” *Id.* at 3.

In response to OEI’s request for formal OGE comments, OGE again expressed serious concerns about the Draft Report. Letter from Robert I. Cusick, Director, Office of Government Ethics, to Daniel Levinson, Inspector General, Department of Health and Human Services (April 20, 2011) (OGE Director Letter) (copy attached at Tab 2 and incorporated herein by reference). OGE acknowledged OEI’s efforts to encourage the inclusion within waiver documents of those

¹ “Section 208 does not impose the three documentation elements identified in the Draft Report, and OGE was careful in its own regulations not to impose any greater mandatory documentation obligations than the statute requires. OGE was mindful of the need to preserve agencies’ flexibility to respond to a very wide range of situations and exigencies.” OGE GC Letter at 2.

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descriptive elements which OGE strongly recommends, but took issue with the Draft Report's interpretation of those recommendations. OGE aptly observed that the Draft Report errs principally as a result of two faulty assumptions: (1) "that there is an objective standard of specificity that can readily be applied to judge waivers in various circumstances, when in fact OGE has recognized considerable discretion in such matters," and (2) "that the only sources of information (and guidance) available to employees and their agencies concerning the scope, limits and rationales for waivers are the actual certifications themselves, which is not the case." OGE Director Letter at 3.

Applying the authoritative OGE interpretation of the recommendations contained in the OGE waiver regulations, OGC reviewed each of the 50 waiver documents included within OEI's sample. None of the waivers failed to meet legal requirements. And as to those descriptive elements recommended for inclusion in waivers, the documents contained language consistently acknowledged by OGE as appropriate, accepted descriptions.

Assuredly, although any written product can be improved—and some waivers in the cohort would have benefitted from editorial assistance—the sampled waivers, nevertheless, were "documented as recommended in provisions of selected Governmentwide Federal ethics regulations." OEI's contrary conclusion is simply incorrect and premised on several fundamental errors that are described more fully in the attached statement prepared by the OGC Ethics Division (copy attached as Tab 3 and incorporated herein by reference). Summarizing that analysis, as well as the concerns articulated by OGE, the Draft Report:

- Applies a simplistic analytic technique that fails to evaluate documents in their entirety (for example, faulting a waiver for particular phrasing without acknowledging other textual information that explains the terminology or describes the context);
- Evinces a basic misunderstanding of the duties of special Government employees (SGE) who serve as members of advisory committees chartered under the Federal Advisory Committee Act (FACA) (for example, although an individual member's duties are legally defined by, coextensive with, and indistinct from those of the committee as a whole—due to the FACA requirement that a committee render collective advice as a group, the Draft Report, nevertheless, classified 34 of the 42 sampled waivers granted to SGEs as lacking an adequate description of the matters to which the waiver applied if the "waiver explained the general duties of the employee's committee . . . without describing the employee's responsibilities within that committee");
- Citing a need to inform the public, seeks a level of specificity for waivers granted to SGE advisory committee members under 18 U.S.C. § 208(b)(3) that by law would need to be redacted prior to public release of such waivers;

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- Does not distinguish between the level of specificity appropriate for those rare waivers granted to regular employees under 18 U.S.C. § 208(b)(1) and those granted to advisory committee members under the less exacting standard of 18 U.S.C. § 208(b)(3); thereby improperly positing the former as a model for the latter;
- Does not distinguish between the level of specificity appropriate for those waivers granted under 18 U.S.C. § 208(b)(3) to SGEs on FACA advisory committees that focus on discrete commercial products (most commonly, but not exclusively, at the Food and Drug Administration) from those granted to SGEs serving on committees with broader, more policy-oriented missions;
- Reaches findings that are contradicted generally by OGE oversight of language in comparable documents and specifically by an OGC Ethics Division analysis of the same 50 waivers reviewed for the Draft Report;
- Makes broad policy recommendations based on its findings, notwithstanding that the Draft Report specifically states that the findings are not derived from a statistically valid sample and are not generalized to all HHS waivers granted in 2009; and
- Citing a need to ensure notice of waiver terms and conditions, recommends that waivers must be signed and dated by employees although other means are available to achieve this objective without the consequent administrative burdens and processing delays.

OEI properly may review waiver documents for clarity, observe that further elaboration and illustrative examples could improve the written products, and state its opinions about best practices. However, OGC disagrees with the finding that the sampled documents were not documented as recommended in OGE regulations. Accordingly, OGC responds as follows to OEI's request that we indicate our concurrence or non-concurrence with the five recommendations to OGC for implementation throughout the HHS Departmental Ethics Program. OGC concurs conditionally with two of the five recommendations, as noted below.

Recommendation (1): Require OPDIVs and STAFFDIVs to document conflict of interest waivers as recommended in Governmentwide Federal ethics regulations.

NON-CONCUR. OPDIVs and STAFFDIVs currently document conflict of interest waivers as recommended in Governmentwide Federal ethics regulations. Compelling the heightened level of specificity that OEI would prefer would deprive the Departmental components of the requisite flexibility to address a "very wide range of situations and exigencies" and impose requirements which OGE has expressly declined to mandate.

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Recommendation (2): Develop additional guidance and training to assist OPDIVs and STAFFDIVs in documenting conflict of interest waivers as recommended in Governmentwide Federal ethics regulations.

CONCUR. OGC disagrees with the Draft Report's interpretation of the waiver documentation recommendations in Federal ethics regulations, but agrees that guidance and training based on the correct interpretation will benefit the HHS waiver process.

Recommendation (3): Take action to revise the conflict of interest waivers in [the OEI] review that were not documented as recommended in Governmentwide Federal ethics regulations.

NON-CONCUR. Because the Draft Report reaches incorrect conclusions about the adequacy of descriptions contained in the waiver documents, OGC does not concur with the recommendation. Modification of extant waivers is not warranted.

Recommendation (4): Expand the review of conflict of interest waivers for special Government employees (SGEs) on HHS advisory committees.

CONCUR, although no further action is necessary to meet this recommendation. Before OEI conducted the fieldwork for this Draft Report, OGC revised its review and oversight process for waivers in a manner that is more expansive than those actions recommended by the Draft Report.

Recommendation (5): Require all employees to sign and date, or similarly document, their conflict of interest waivers.

NON-CONCUR. Current practices in each component provide employees notice of any waiver issued and afford each agency the means to document that notice so that employee accountability can be ensured. Although some components use a dated employee signature to meet these goals, requiring a "one size fits all" approach unnecessarily limits components from using existing procedures that meet the goals of this recommendation through other means.

The reasons for OGC's disagreement and non-concurrence with certain recommendations are described more fully in the attached statement at Tab 3. If you have any questions concerning these comments, please feel free to contact me or Edgar M. Swindell, Associate General Counsel for Ethics and Designated Agency Ethics Official.

Attachments

cc: Edgar M. Swindell, HHS DAEO

TAB 1



United States
Office of Government Ethics
1201 New York Avenue, NW, Suite 500
Washington, DC 20005-3917

MAR 9 2011

Edgar M. Swindell
Associate General Counsel for Ethics
and Designated Agency Ethics Official
Department of Health and Human Services
700-E Humphrey Building
200 Independence Ave., SW 20201

Dear Mr. Swindell,

We have reviewed the "OIG Draft Report: Conflict-of-Interest Waivers Granted to HHS Employees in 2009, OEI-04-10-00010," which you recently forwarded to my office. While the recommendations in the Draft Report support good documentation practices, in some areas, the Draft Report confuses items that are mandatory for legal sufficiency with ones that are merely desirable. OGE was mindful to distinguish between these categories in drafting the regulations implementing waiver provisions under 18 U.S.C. § 208. As discussed below, maintaining this delineation is essential.

The Draft Report examines a sample of waivers issued by HHS and concludes that a seemingly high level of HHS waivers do not comply with documentation requirements. In particular, the Draft Report notes the absence of sufficiently specific information in many of the waiver documents concerning: (1) the employee's financial interest, (2) the particular matter(s) which the waiver covers, and (3) any limitations regarding particular matter(s) in which the employee remains prohibited from participating. Draft Report at 1. The Report states that "waivers for both SGEs and all other HHS employees must describe" these three items. *Id.* at 8 (emphasis added). In support of these mandatory obligations to document information in a waiver, the Report cites several provisions in OGE's waiver regulations. *See id.* at fn. 37, citing 5 C.F.R. §§ 2640.301(a)(3), 2640.302(a)(4), (5).

However, as OGE has stated in its own interpretative guidance, the documentation of these three items in a waiver is not mandated by law, but rather is a practice that "OGE recommends." DO-07-006, sec. IV.¹ It is important to remember that the operative verb in each

¹ http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2007/do07006.html.

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of the three regulatory provisions cited in the Draft Report is "should," rather than "must" or "shall." OGE used this language advisedly, with the understanding that "should" denotes discretion and is not to be construed as "shall." Singer & Singer, 3 Sutherland Statutory Construction 30 (2008).² Section 208 does not impose the three documentation elements identified in the Draft Report, and OGE was careful in its own regulations not to impose any greater mandatory documentation obligations than the statute requires. OGE was mindful of the need to preserve agencies' flexibility to respond to a very wide range of situations and exigencies. This is because agencies and employees may have more or less information available to them concerning the particular matters in which certain employees might participate, their role in such matters, and the actual or potential financial impact of such matters.

Indeed, the broader in scope an employee's responsibilities, the more difficult it is to identify all the particular matters in which an official might be called upon to participate. The need to describe matters more generally may arise more frequently with more senior officials who may have very broad responsibilities and with advisory committee members where the advisory committee charter is quite broad. OGE also has recognized that there is a diversity of agency practices with regard to the level of detail and the location of such detail, e.g., in the actual waiver document itself as opposed to ancillary memoranda and other sources.³ In other words, the support for a waiver—and the explanation of the waiver provided to the employee—may be found outside the four corners of the waiver itself, even though it is generally a good practice to include such detail in the waiver if possible.

For these reasons, OGE also provided a textual "Note" in the regulations stating that "[t]he disqualifying financial interest, the particular matter of matters to which the waiver applies, and the employee's role in such matters do not need to be described with any particular degree of specificity." 5 C.F.R. § 2640.301(a)(Note) (emphasis added). The preamble to the proposed rule explained: "There is no requirement in the rule as proposed that the disqualifying financial interest, the particular matter to which the waiver applies, or the employee's role in the matter be described with any specific degree of particularity. This would, for example, permit the agency issuing the waiver to describe the employee's duties in a general way or to describe a class of matters to which the waiver would apply." 60 FR 47207, 47222 (Sept. 11,

² See also *U.S. v. Rogers*, 14 Fed. Appx. 303 (6th Cir. 2001) ("should" is usually precatory, not mandatory); *U.S. v. Nichols*, 661 F.Supp. 507 (W.D.Mich. 1987) (same); *Emory v. Sec. of Navy*, 708 F.Supp. 1335 (D.D.C. 1989) (distinguishing between "should" and mandatory terms such as "shall" and "must").

³ OGE has recognized, for example, that some agencies include greater detail in separate decision memoranda than in the actual waiver document. DO-07-006, sec. IV. OGE also has encountered a variety of transmittal documents, employee counseling documents, ethics agreements and other items that pertain to the agency decision to grant a waiver, any of which may contain more or less detail than the actual waiver document that constitutes the formal legal certification under 18 U.S.C. § 208(b)(1) or (3).

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1995)(emphasis added).⁴ The preamble then adds, in precatory language describing a best practice toward which agencies should strive: "Of course, agencies should endeavor to formulate waivers with enough specificity that a member of the public would have a clear understanding of the circumstances to which the waiver applies." *Id.*

OGE continues to believe that it is a best practice to draft waivers that are descriptive enough that both the employees and the public can readily appreciate the scope and rationale. Nevertheless, OGE is aware that agencies have other means, besides the waiver documents themselves, of informing employees about the scope and any limits of their waivers. These may include ancillary memoranda, ethics agreements, training and individual counseling. Moreover, it is essential to remember that waivers are, first and foremost, legal documents. That is, the waiver is the legal certification that operates to remove a statutory disqualification. While it is desirable that such documents, to the extent feasible, should also serve to inform employees and the public, those are decidedly secondary benefits that do not affect the legal sufficiency of the waiver.

Finally, we have particular concerns about certain statements in the Draft Report indicating that it is insufficient detail for a waiver to permit participation in "general matters" while requiring recusal from more "specific" matters that "uniquely" affect the employee's financial interests.⁵ In fact, it has long been common for agencies to grant waivers that generally permit employees to participate in a broadly defined class of particular matters of general applicability, with a similarly broadly defined proviso that the employees may not participate in any particular matter that involves specific parties or otherwise uniquely affects the employee's financial interest. The earliest guidance provided to the Executive Branch concerning waivers under section 208 used language of this type.⁶ OGE's written guidance on waivers states that a "common limitation is that the employee may be prohibited from working on particular matters

⁴ As we stated in our most comprehensive written guidance on waivers: "The specificity of such information can vary greatly from waiver to waiver. It may be as broad as including any particular matter affecting the financial interest or as limited as describing only a single particular matter." DO-07-006, sec. IV.2.

⁵ Draft Report at 17 (not sufficient to include language stating waiver "would allow this individual to participate in the general matters that may affect [the HHS employ's] financial interests" and "would allow him to participate in general matters before the committee that may directly affect his financial interest"); *id.* (insufficient description of waiver limitation to include "broad statement that the employees must not participate in specific matters related to their conflicts of interest"); *id.* at 18 (not sufficient for limited waiver to state that it "would allow this individual to participate in general matters that may directly affect [the HHS employee's] financial interest, but not uniquely affecting the employee's financial interest").

⁶ President Kennedy, Memorandum to the Heads of Executive Departments and Agencies, 28 FR 4539, (May 2, 1963)(the disqualification requirement of section 208 is "not limited to those [particular matters] involving a specific party," but the power to waive the disqualification may be exercised "if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization").

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where a conflicting entity is a party, but may work on broader policy matters affecting the entity as part of a class or group." DO-07-006, sec. IV.3. Moreover, where a waiver is so limited, it is natural to expect less specific detail, in some cases anyway, than if the agency were permitting the employee actually to participate in particular matters involving specific parties that might pose a more acute conflict of interest; it has long been understood that the desirability for specificity can vary depending on the magnitude and seriousness of the conflict.⁷

In conclusion, it is critical to distinguish the legal requirements for a waiver under 18 U.S.C. 208 from practices that may be desirable because they enhance clarity and transparency but which do not impact the legal sufficiency of the underlying waiver. Great care and precision must be taken to not confuse the two because to do so could create the erroneous impression that agency and individual employee actions have violated the law.

If OGE may be of further assistance in this matter, or if you have any questions, please contact me at 202-482-9292.

Sincerely,

/S/

Don W. Fox
General Counsel and
Principal Deputy Director

⁷ In fact, the Office of Legal Counsel, Department of Justice, specifically advised a component of HHS to this effect concerning certain advisory committee members, over 30 years ago: "Although by its literal terms §208(b)(1) would appear to require the appointing official to issue a separate exemption for each particular matter in which a given financial interest may arise, we have consistently taken the position that a blanket exemption covering a given financial interest may be issued in appropriate circumstances if the appointing official concludes that the financial interest will not be so substantial as to affect the integrity of the employee's services in whatever context it arises." 2 Op. O.L.C. 151, 156 n.5 (1978)(emphasis added). Note that this advice was rendered explicitly concerning HHS advisory committee members participating in particular matters of general applicability with respect which the members render "advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization." *Id.* at 156 (quoting former Federal Personnel Manual).

TAB 2



United States
Office of Government Ethics
1201 New York Avenue, NW, Suite 500
Washington, DC 20005-3917

April 20, 2011

The Honorable Daniel Levinson
Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Mr. Levinson:

The United States Office of Government Ethics (OGE) appreciates the opportunity to comment on your office's Draft Report, "Conflict-of-Interest Waivers Granted to HHS Employees in 2009" (OEI-04-10-00010), which you forwarded to me by letter dated April 12, 2011. As you know, my General Counsel previously provided written comments on an earlier version of your Draft Report to the Designated Agency Ethics Official (DAEO) at the Department of Health and Human Services (HHS). Although I have been advised that the DAEO provided a copy of those comments to your office, I am also enclosing a copy, which is incorporated by reference herein.

OGE appreciates the Office of the Inspector General's interest in the quality of the written waivers issued by the Department of Health and Human Services. As a general matter, OGE believes that the recommendations in the Draft Report support good documentation practices that the Office of Government Ethics itself strongly recommends. OGE also appreciates that your office has made certain changes to the Draft Report in response to earlier comments about the distinction between legal requirements and recommended practices. OGE remains concerned, however, that the report does not recognize that, by regulation and policy, OGE has afforded agencies certain latitude to craft waivers that both are legally sufficient and meet agencies' legitimate policy objectives.

Specifically, several points in our earlier comments do not appear to have been addressed in the current Draft Report:

First, there is no discussion in the Draft Report of the language in our waiver rule, which was highlighted at page 2 of our earlier comments, stating that "[t]he disqualifying financial interest, the particular matter or matters to which the waiver applies, and the employee's role in such matters do not need to be described with any particular degree of specificity." 5 C.F.R. § 640.301(a)(Note)(emphasis added). Nor is there mention of the preamble language, also quoted on page 2 of OGE's earlier comments, to the effect that "[t]his would, for example, permit the agency issuing the waiver to describe the employee's duties in a general way or to describe a class of matters to which the waiver would apply." 60 FR 47207, 47222 (Sept. 11, 1995)(emphasis added). Moreover, the Draft Report does not reflect, in our view, the OGE

The Honorable Daniel Levinson
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guidance, quoted at page 3 fn. 4 of our earlier comments: "The specificity of such information can vary greatly from waiver to waiver. It may be as broad as including any particular matter affecting the financial interest or as limited as describing only a single particular matter." DO-07-006, sec. IV.2.

All of these comments were intended to emphasize the fundamental flexibility of agencies in drafting waivers, provided of course that all legal requirements are satisfied. As stated at page 2 of the earlier OGE comments: "In this connection, OGE was mindful of the need to preserve the flexibility of agencies to respond to a very wide range of situations and exigencies, including situations in which agencies and employees may have more or less information available to them concerning the particular matters in which certain employees might participate, their role in such matters, and the actual financial impact of such matters." OGE also emphasized that it is well established that the level of detail may be less in the case of "limited" waivers that do not apply to the more problematic category of matters that involve specific parties. "[W]here a waiver is so limited, it is natural to expect less specific detail, in some cases anyway, than if the agency were permitting the employee actually to participate in particular matters involving specific parties that might pose a more acute conflict of interest: it has long been understood that the desirability for specificity can vary depending on the magnitude and seriousness of the conflict."¹ In sum, the current Draft Report still appears to OGE to assume that there is an objective standard of specificity that can readily be applied to judge waivers written in various circumstances, when in fact OGE has recognized considerable discretion in such matters.

Second, the current Draft Report does not account for the OGE comments concerning the location or availability of information in places other than the actual waiver certification document. As stated on page 2 of OGE's earlier comments: "OGE also recognized that there is a diversity of agency practices with regard to the level of detail and the location of such detail, e.g., in the actual waiver document itself as opposed to ancillary memoranda and other sources." Similarly, on page 3, OGE stated: "OGE is aware that agencies have other means, besides the waiver documents themselves, of informing employees about the scope and any limits of their waivers, such as ancillary memoranda, ethics agreements, training and individual counseling." The current Draft Report appears to OGE to assume that the only sources of information (and guidance) available to employees and their agencies concerning the scope, limits and rationales for waivers are the actual certifications themselves, which is not the case.

This point is extremely important in the case of waivers issued under 18 U.S.C. § 208(b)(3) for advisory committee members. That is because there are legal limits on the extent of the information that may be contained or publicly disclosed in those waiver documents, which the Draft Report does not reflect. As provided in 18 U.S.C. § 208(d)(1): "For purposes of determinations under subsection (b)(3), the information describing each financial interest shall be

¹ OGE invites your attention to the Office of Legal Counsel opinion discussing "blanket" waivers, which is quoted at footnote 7 on page 4 of the earlier OGE comments. That this OLC opinion was directed specifically to a component of HHS seems all the more relevant to the present discussion.

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no more extensive than that required of the individual in his or her financial disclosure report under the Ethics in Government Act of 1978." Further, any such financial information beyond what is required to be reported must be withheld from the public. 5 C.F.R. § 2640.304(b)(2).

In this connection, certain statements in the Draft Report, to the effect that financial interests should be described with more detail in waivers, are problematic. For example, the Draft Report (pp. 9-10) states that waivers should describe the market value of stock owned by advisory committee members. However, many advisory committee members file the OGE 450 financial disclosure report, which does not require valuation information about stock or other assets or income. In those cases, an agency should not include such information in a publicly available waiver document. While the OGE regulation cited in the Draft Report does state that agencies "may consider . . . [t]he dollar value of the disqualifying financial interest, if it is known or can be estimated," 5 C.F.R. § 2640.302(b)(5)(emphasis added), that regulation does not, contrary to the assertion on page 9 of the Draft Report, "recommend[]" that waivers describe the . . . value (e.g., current market value of the stock) of the interest." Essentially, the Draft Report blurs the crucial distinction between the information on which an agency may base its determination and the information that may be included in a publicly available waiver certification under 208(b)(3). In order to make informed waiver decisions while remaining faithful to the requirements of sections 208(d)(1) and 2640.304(b)(2), many agencies obtain relevant information through various methods (including interviews of advisory committee members), but document such information in various deliberative materials that are separate from the publicly available waiver certifications.

Third, OGE continues to have the concerns expressed in its earlier comments (pp. 3-4) regarding the purported insufficiency of detail in waivers that permit participation in more general matters but require recusal from matters that more specifically affect the employee's interests. Rather than restating the entire discussion contained in those earlier comments, OGE would add only that similar language describing limitations has been used in waivers for decades and that OGE itself has used similar language to describe limitations in its own "regulatory" waivers, issued under 18 U.S.C. § 208(b)(2). *See, e.g.*, 5 C.F.R. §§ 2640.102(m)(distinguishing particular matters of "general applicability" and particular matters involving "specific parties"); 2640.201(c)(2)(regulatory waiver applying only to particular matters of general applicability as opposed to specific party matters); 2640.201(d)(same); 2640.202c(same); 2640.203(b)(same); 2640.203(g)(same); 2640.203(d)(regulatory waiver does not apply to certain matters that "individually or specially relate to or affect" certain interests). OGE is concerned, therefore, that the Draft Report could be read as casting doubt on the clarity and enforceability of similar limiting language that has long been in use in the Executive Branch.

Finally, although the earlier comments did not address this, OGE does have one observation about the recommendation in the Draft Report with respect to individuals signing and acknowledging their own waivers. In order to avoid confusion on the part of anyone who reads the final report, OGE believes it is critical to draw a clear distinction between what the Office of the Inspector General may view as desirable and what OGE, as the agency responsible

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for oversight and implementing regulations in this area, has determined is either legally required or a best practice. OGE's regulations or policy guidance do not require employees to sign and acknowledge their waivers and do not suggest that this practice would add value to the process. As described above, agencies have various means, apart from the actual waiver certification, to apprise employees of the scope of their permitted duties and any continuing recusal obligations. In some cases, for instance, OGE could envision that a pro forma acknowledgment signature might have less value than oral counseling, particularly where the employee has questions or doubts about the contents and meaning of the waiver.

OGE has long provided expert advice to inspectors general in a wide variety of ethics-related matters. If you have any questions about waivers under 18 U.S.C. § 208 or how to interpret the applicable regulations or policy in this area, please contact me or my General Counsel, Don Fox, at 202-482-9292.

Sincerely,

/S/

Robert I. Cusick
Director

Enclosure: (Letter from Don W. Fox, General Counsel, OGE,
to Edgar M. Swindell, DAEO, HHS, March 9, 2011)

cc: Edgar M. Swindell, Designated Agency Ethics Official

TAB 3

OGC ANALYSIS OF OIG DRAFT REPORT: *CONFLICT-OF-INTEREST WAIVERS GRANTED TO HHS EMPLOYEES IN 2009*, OEI-04-10-00010 (March 2011)

The Draft Report Misinterprets OGE Regulations that Recommend the Inclusion of Certain Descriptive Elements within Conflict of Interest Waivers

The Federal conflict of interest statute disqualifies employees from participating personally and substantially in an official capacity in any particular matters that would have a direct and predictable effect on their individual or imputed financial interests, unless an authorized official makes a written determination or certification that certain criteria have been satisfied. 18 U.S.C. § 208. These legal instruments, commonly referred to as “waivers” of the disqualification, grant employees permission to participate in potentially conflicting matters. Citing Office of Government Ethics (OGE) regulations at 5 C.F.R. §§ 2640.301(a)(3), 2640.302(a)(4), (5), the Office of Evaluation and Inspections (OEI) Draft Report claims that three elements should be described in precise detail in these conflict of interest waiver documents: (1) the employee’s specific financial interest; (2) the particular matter(s) in which the employee is permitted to participate; and (3) any limitations regarding the particular matter(s) in which the employee remains prohibited from participating. Draft Report at 1, 8-9.

From this premise, OEI examined 50 sampled waivers issued by the Department of Health and Human Services (HHS) in 2009, claimed that a significant percentage lacked adequate textual descriptions for one or more of these elements, and concluded that the waivers were not documented as “recommended in provisions of selected Governmentwide Federal ethics regulations.” The Draft Report, in particular, finds fault with textual references to broad categories of interests, general descriptions of an employee’s duties that may affect those interests, and utilization of legal terms of art that delineate classes of matters to which the waiver would apply. Draft Report at 16-19.

The fundamental flaw in OEI’s analysis is that OGE disclaims any intent in its regulations to require any particular degree of specificity when describing the recommended elements. As OGE has emphasized repeatedly in guidance documents and in a recent letter from the OGE General Counsel to the HHS Designated Agency Ethics Official (DAEO), “documentation of these three items in a waiver is *not* mandated by law, but rather is a practice that ‘OGE recommends.’” Letter from Don W. Fox, General Counsel and Principal Deputy Director, Office of Government Ethics, to Edgar M. Swindell, Associate General Counsel for Ethics and Designated Agency Ethics Official, Department of Health and Human Services (March 9, 2011) (OGE GC Letter) (emphasis in original); OGE Informal Advisory Opinion 07 x 4; OGE DAEOgram DO-07-006, sec. IV. When OGE discussed this recommended practice in its proposed regulations, the preamble clearly explained: “There is no requirement in the rule as proposed that the disqualifying financial interest, the particular matter to which the waiver applies, or the employee’s role in the matter be described with any specific degree of particularity. This would, for example, permit the agency issuing the waiver to describe the employee’s duties in a general way or to describe a class of matters to which the waiver would apply.” 60 Fed. Reg. 47207, 47222 (September 11, 1995). When the final rule was issued without substantive change, OGE included a note to the same effect within the text of the regulation. 5 C.F.R. § 2640.301(a) (Note).

OGE reiterated this position when it reviewed an earlier version of the Draft Report. OGE GC Letter at 2. Most recently, in a second OGE letter that addressed the revised March 2011 Draft Report, the OGE Director quoted with emphasis the language from the note and observed that OEI's analysis appears to "assume that there is an objective standard of specificity that can readily be applied to judge waivers written in various circumstances, when in fact OGE has recognized considerable discretion in such matters." Letter from Robert I. Cusick, Director, Office of Government Ethics, to Daniel Levinson, Inspector General, Department of Health and Human Services (April 20, 2011) (OGE Director Letter) at 1-2.

To provide background, OGE regulations specify that individual waivers granted pursuant to 18 U.S.C. § 208(b) must meet the following requirements for issuance:

- (1) the waiver must be issued in writing by the appropriate appointing official;
- (2) the waiver must be issued prior to any participation by the employee in a particular matter covered by the waiver; and
- (3) the waiver must be issued based on the determination that it meets the appropriate statutory standard.

5 C.F.R. §§ 2640.301(a)(2), (a)(4), (a)(5); 2640.302(a)(2), (a)(3), (a)(6).

For waivers granted under 18 U.S.C. § 208(b)(1), in addition to these three requirements, the disqualifying financial interest and the nature and circumstances of the particular matter must be fully disclosed to the employee's appointing official or other individual with delegated authority to grant the waiver. 5 C.F.R. § 2640.301(a)(1). Any waivers granted under 18 U.S.C. § 208(b)(3) must meet the three requirements above; must be issued to a special Government employee (SGE) serving on an advisory committee within the meaning of the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2; and must be issued after a review of the SGE's financial disclosure report. 5 C.F.R. §§ 2640.302(a)(1), (a)(2); *see generally* OGE 07 x 4; OGE DAEOgram DO-10-005 (April 22, 2010). These requirements address how, by whom, when, and on what basis a waiver may be issued. None of these provisions addresses what descriptions should be included in the waiver document itself.

To that end, OGE strongly recommends, but does not require, that an adequate description of certain items be included in conflict of interest waivers.¹ These include:

¹ HHS policy specifies, as conditions to be satisfied prior to granting a waiver, that the waiver must fully describe the potential conflict and the basis for its issuance, reflect an individualized assessment of the requestor's circumstances, and narrowly draw the categories of official actions to which the waiver applies to ensure that participation is appropriately limited. Memorandum from the Secretary, HHS, *Delegation of Authority to Grant Conflict of Interest Waivers Under 18 U.S.C. §§ 203(d), 205(e) and 208(b)* (January 16, 2009) (Delegation Memorandum). These procedural conditions do not articulate additional substantive legal requirements for waiver content. As OEI recognized, they are not intended to define any

- (1) the disqualifying financial interest;
- (2) the particular matter or matters to which the waiver applies and the employee's role in the matters; and
- (3) any limitations on the employee's ability to act in the particular matters involved.

OGE 07 x 4. *See also* 5 C.F.R. §§ 2640.301(a)(3); 2640.302(a)(4), (a)(5).

OGE guidance concerning these regulatory recommendations suggests, for example, that an adequate description of the interest should include not only the type of interest (stock, mutual fund, outside employment, etc.) but also an approximation of the value of the interest. OGE 07 x 4. Even in making this recommendation, however, OGE makes it clear that:

The disqualifying financial interest, the particular matter or matters to which the waiver applies, and the employee's role in such matters do not need to be described with any particular degree of specificity. For example, if a waiver were to apply to all matters which an employee would undertake as part of his official duties, the waiver document would not have to enumerate those duties. The information contained in the waiver, however, should provide a clear understanding of the nature and identity of the disqualifying financial interest, the matters to which the waiver will apply, and the employee's role in such matters.

5 C.F.R. § 2640.301, Note to Paragraph (a).

OGE further advises, "The specificity of such information can vary greatly from waiver to waiver. It may be as broad as including any particular matter affecting the financial interest or as limited as describing only a single particular matter." OGE GC Letter at 3, fn. 4, *quoting* OGE DAEOgram DO-07-006, sec. IV.2.; OGE Director Letter at 2. OGE counsels that the "desirability for specificity can vary" depending upon context and rejects OEI's inelastic approach that considers waivers lacking in sufficient detail simply because they "permit

particular level of descriptive specificity. Draft Report at 9 ("Neither OGE regulations nor the HHS Secretary's January 2009 memorandum defines how specific these requirements must be when they are documented in waivers."). The Delegation Memorandum signed by the Secretary was prepared by, and issued at the request of, the DAEO within OGC. As the drafter and official charged with implementation of its directives, the DAEO speaks authoritatively as to the Memorandum's intent, and, under well-settled legal principles, is to be accorded deference with respect to any interpretive questions concerning that document that may require resolution of ambiguity, such as whether in a given context a potential conflict has been fully described. The DAEO has reviewed the sampled waivers, determined that they contain descriptions that satisfy the OGE recommendations, and found them to be consistent with the conditions stated in the Delegation Memorandum.

participation in ‘general matters’ while requiring recusal from more ‘specific matters’ that ‘uniquely’ affect the employee’s financial interests.” OGE GC Letter at 3-4.

OGE further recognizes that although it is a desirable practice, to the extent feasible, to draft waivers in a manner descriptive enough to instruct the employee and inform the public, such goals are secondary and can be accomplished through other means, such as transmittal documents, ancillary memoranda, ethics agreements, training, individual counseling, statements at public meetings, and electronic posting of summaries. *Id.* at 2, n. 3, and 3.

Contrary to the expressed views of the agency that promulgated the regulations, the Draft Report transforms a baseline recommendation to provide a “clear understanding” into an inflexible, heightened descriptive standard that fails to accommodate the need for “flexibility to respond to a very wide range of situations and exigencies” that OGE intended to preserve. OGE GC Letter at 2.

The Draft Report Assesses the Descriptive Clarity and Adequacy of Waivers
Using a Faulty Analytic Approach to Measure Conformity with Three Stated Criteria

A series of analytic errors—(1) neglecting to evaluate documents in their entirety, (2) failing to appreciate the degree of specificity appropriate in different contexts, (3) failing to understand the drafting implications of confidentiality laws, (4) misunderstanding the nature of advisory committee members’ duties, and (5) ignoring the descriptive latitude OGE has provided for drafting waivers—led ineluctably to the mistaken conclusions that pervade the report. These errors are addressed in more detail under each of the three criteria that the Draft Report uses to determine whether an individual waiver was documented as “recommended in provisions of selected Governmentwide Federal ethics regulations.”

Criterion 1: Description of the Disqualifying Financial Interest

OEI concluded that a waiver did not clearly or adequately describe the employee’s disqualifying financial interests if it contained general language describing broad categories of interests. Draft Report at 14, 17. The Draft Report also states that the “OGE regulation recommends that waivers describe the type (e.g., stock) and value (e.g., current market value of the stock) of the interest.” Draft Report at 9.² Type and value information generally is included in waivers

² The Draft Report incorrectly cites 5 C.F.R. §§ 2640.301(b)(3) and 2640.302(b)(5) to support this statement. The cited sections list considerations that the official responsible for granting a waiver may consider in determining whether a prospective waiver meets the applicable statutory standard. There is nothing in either section that indicates that this level of specificity should be included in the waiver document itself. OGE guidance recognizes that agencies may address these factors outside of the waiver document, such as through an internal decision memorandum that accompanies the waiver. OGE 07 x 4. For the proposition that OGE

granted to HHS regular employees under 18 U.S.C. § 208(b)(1).³ The Draft Report finds that all the sampled section 208(b)(1) waivers sufficiently described the financial interest in question. Draft Report, Appendix D. Such waivers are rare, constituting just 2.3 percent (8 of 342) of all waivers granted by HHS in 2009. Draft Report, Appendix A.

The vast majority, 97.66 percent (334 of 342), of the waivers issued by the Department in 2009 were granted to SGE members of FACA advisory committees under 18 U.S.C. § 208(b)(3). *Id.* The Draft Report finds that seven of the 42 sampled waivers granted to SGEs serving on Federal advisory committees did not meet the stated criterion. Draft Report, Appendix D. Obscuring the distinction between requirements and recommendations, the Draft Report claims that including within such waivers a detailed description—identification of the disqualifying asset, income source, or relationship, and an approximation of value—is necessary so that the public does not question the integrity of the employee’s services to the Government. Draft Report at 21. The Draft Report asserts that this level of disclosure should be provided in the waiver document so that the public understands the nature and identity of the specific interest. Draft Report at 23.

Section 208(b)(3) waivers typically do not include the same level of specificity found in section 208(b)(1) waivers due to important distinctions that the Draft Report fails to acknowledge. Unlike section 208(b)(1) waivers that are based on publicly available information, section 208(b)(3) waivers are largely based on confidential information reported by SGE FACA advisory committee members on the OGE 450 Confidential Financial Disclosure Report or its equivalent. (Ironically, the disclosure forms themselves do not require the specificity of reporting that the OEI appears to expect in the waiver documents based on them.) Prior to public disclosure of a waiver granted under 18 U.S.C. § 208(b)(3), an agency must withhold from disclosure any information concerning an individual’s financial interest that is more extensive than that required to be disclosed by the individual in his or her financial disclosure report, or which is otherwise subject to a prohibition on public disclosure under the law. 18 U.S.C. § 208(d)(1); 5 C.F.R. § 2640.304(b)(2). Requiring a section 208(b)(3) waiver to reflect asset valuations and income amounts that are not required to be reported on the OGE 450 or equivalent forms would be counterproductive because ultimately such information would have to be redacted upon public release.

recommends that a waiver describe the financial interest involved, including the type of interest (stock, mutual fund, etc.) and an approximation of value, the correct citations are to 5 C.F.R. §§ 2640.301(a)(3), 2640.302(a)(4); and OGE 07 x 4, Part IV.1.

³ The standard for granting section 208(b)(1) regular employee waivers requires an evaluation of the relative “substantiality [in terms of value] of the disqualifying financial interest” in order to assess whether that interest is likely to affect the integrity of the services expected of the employee. Section 208(b)(3) waivers granted to SGE members of FACA advisory committees—which constitute the most numerous category—must satisfy a different test that focuses predominately on the individual’s expertise and the consequent need for the SGE’s services. Accordingly, specific asset valuations play a less determinative role in granting section 208(b)(3) waivers. Moreover, the SGEs to which these waivers are issued are not required to report values on their confidential financial disclosure forms.

The Draft Report essentially equates the failure to include recommended information more suitable for section 208(b)(1) waivers with an alleged failure in section 208(b)(3) waivers to contain a clear and adequate description. There is considerable irony in the Draft Report's insistence on a level of specificity for section 208(b)(3) waivers based on the need for public understanding, given the legal requirement that such information be removed prior to public disclosure.

The Draft Report also concludes that the seven section 208(b)(3) waivers did not satisfy this criterion because they included broad categories of interest *even though the waiver also provided examples of those interests relevant for the SGE receiving the waiver*. As an example of language that was viewed as lacking sufficient specificity because of inclusion of broad categories of interests, the Draft Report cites the following:

[e]mployment with honoraria or other compensation from the health care industry, research institutions, state and local government, health care product manufacturers, insurance companies, hospitals, medical management delivery organizations, or other organizations . . . ; and

[e]xpert witness, litigation, or advocacy services . . .

Draft Report at 17. This language is only used in two of the waivers reviewed for the Draft Report. The full text of each of those two waivers actually included the specific sources of compensation within the broad category relevant to the SGE. However, in the excerpt contained in the Draft Report, those specific income sources were omitted.

One waiver included the language "such as earnings received from [a county-level health service provider from which the SGE had received compensation]." The other stated "such as earnings received from [a University from which the SGE had received compensation] and [the name of a company that paid the SGE]."⁴ Three other waivers reviewed for the Draft Report also included similar broad categories of interest but always with specific examples relevant to the SGE being granted the waiver. As noted above, these examples were quite specific to the SGE; one included not only the names of the SGE's employers but the site locations where the SGE had worked that were relevant to the committee's deliberations. The other two included, under the broad category of grants or other research funding, not just the names but the grant numbers of the funding sources relevant to the SGEs and the committee's deliberations. According to the Draft Report, this level of specificity was not only insufficient, but was not even considered relevant enough to justify inclusion in the excerpt used in the report, i.e., the key descriptive language cited above was omitted in the ellipsis.

⁴ Although otherwise factually accurate, legally sufficient, and adequately documented, these two waivers did include information not relevant to the SGEs in question, such as language referring to service as an expert witness when there was no indication that the individual had consulted in this manner. OGC reminds components, when warranted, to eliminate inapplicable illustrative statements.

The Draft Report goes on to state “[i]n contrast, most waivers clearly described the employee’s specific interests that posed conflicts” and cites an example that includes the names of the companies in which the employee held stock, identifies the number of shares of stock held by the employee in each company, and provides the value of those shares. Draft Report at 17-18. This language was taken from a waiver granted to an SGE serving with the Food and Drug Administration (FDA). Although the waiver was disclosed prior to the meeting in question as required under the Food and Drug Administration Amendments Act of 2007 (FDAAA), 21 U.S.C. § 379d-1, much of the language excerpted in the Draft Report was in fact redacted from the waiver prior to public disclosure based on the confidentiality requirements under the Ethics in Government Act and the Privacy Act. Indeed, current FDA practice is to describe financial holdings generically (e.g., “a pharmaceutical company that makes cholesterol-lowering drugs”) and to state valuations only within broad categories, so that waivers can be posted as required under the 2007 amendments without violating the confidentiality requirements of Federal law. Inclusion of the level of detail excerpted from the FDA waiver in the Draft Report for all waivers granted under 18 U.S.C. § 208(b)(3) would be an unavailing attempt at transparency because such information must be redacted prior to public disclosure.⁵

Use of the FDA waiver as an example brings up another important point. The FDA waivers are not necessarily a model for the rest of the Department because the FDA has a specific regulatory mission. This mission means that most FDA committees work on product-specific matters, which in turn makes it much easier to define both the affected financial interest and the particular matter to which the waiver applies. HHS committees that do not evaluate product-specific matters cannot be expected to have the same level of specificity as the FDA waivers.

Criterion 2: Description of the Particular Matters in which the Employee is Permitted to Participate

OEI considered a waiver to have satisfied this second criterion if the waiver adequately described the “matters being waived” and the “employee’s official duties.” Draft Report at 14. OEI determined that a waiver did not meet this criterion if it either: (1) “contained only a broad statement that the employee may participate in general matters related to the conflict of interest;” or (2) “explained the general duties of the employee’s committee or office without describing the employee’s responsibilities within that committee or office.” *Id.* On this basis, OEI found that 35 of the 50 waivers sampled did not adequately describe the particular matter in which the employees were permitted to participate, including one of eight waivers sampled that were

⁵ Because of this requirement, the Draft Report must remove or redact the information in question prior to making any final report available to the public, unless there is specific authority permitting disclosure. The Draft Report withholds only the company names and not the number of shares or valuation amounts.

granted under 18 U.S.C. § 208(b)(1)⁶, and 34 of 42 waivers sampled that were granted under 18 U.S.C. § 208(b)(3). Draft Report, Appendix D.

Test 1: Detailed Description of Matters Being Waived. The Draft Report cites as a paradigmatic matter description the detailed statements typically found in FDA advisory committee waivers:

For example, one employee was permitted to participate in “[d]iscussion and recommendations on the safety and efficacy of [X] THERAPY, sponsored by [Y] Technologies, Inc. (formerly [Z] Technologies, Inc.) for moderate to severe nasolabial fold wrinkles. This is determined to be a particular matter involving specific parties.”

Draft Report at 18.

OGC examined the 37 non-FDA advisory committee waivers as part of its audit of the 50 waivers sampled for the Draft Report. Only three waivers from this subset appear to have met OEI’s heightened descriptive standard. Not surprisingly, all three involved SGEs serving on committees that, like FDA committees, had meetings that focused on very limited, specific issues. One such waiver, for example, was granted to an SGE serving on the Advisory Board on Radiation and Worker Health (ABRWH) at the Centers for Disease Control and Prevention (CDC). The mission of the ABRWH focuses not only on specific entities, but often focuses on specific employers and work sites; such precision with respect to committee responsibilities is not representative of the vast majority of HHS advisory committees.

OEI used FDA waivers as models—despite differences in programmatic functions that would counsel otherwise—and found that the remaining 34 non-FDA SGE waivers did not meet OEI’s articulated standard. OGC believes that what the Draft Report purports to identify as inexact descriptions instead reflects a failure to appreciate that context necessarily dictates the manner in which waivers are crafted. The descriptive standard expected of waivers issued to members of committees that do not work on limited, specific issues by necessity must differ. In layman’s terms, the Draft Report examines the thick peel of an orange and then disparages apples for their thin skin.

The level of specificity appropriate for waivers issued by a component with a regulatory mission that focuses on discrete commercial products, such as many program offices at the FDA, is necessarily different than that which may be used for those waivers granted by program offices

⁶ The OGC Ethics Division audit of the 50 waivers sampled for the Draft Report was not able to determine with certainty which waiver granted under 18 U.S.C. § 208(b)(1) was determined by the Draft Report not to meet this standard. The OGC Ethics Division believes that all such waivers granted did in fact comport with OGE guidance, but will specifically review the waiver in question if OEI provides a list of individual findings; that list was not made available to OGC for the purposes of submitting these comments.

whose mission is more policy-oriented. The latter generally employ SGEs that advise on “particular matters of general applicability,” such as proposed regulations, programs, initiatives, and policies, where the exact impact on the SGE’s individual or imputed financial interests that may result from the agency’s resolution of the matter often cannot be anticipated with precision. These circumstances necessarily call for a more generic description in the waiver document.

OGE expressly recognizes that agencies must retain the “flexibility to respond to a very wide range of situations and exigencies” and “may have more or less information available to them concerning the particular matters in which certain employees might participate, their role in such matters, and the actual or potential financial impact of such matters.” OGE GC Letter at 2. OGE aptly observes that “the broader in scope an employee’s responsibilities, the more difficult it is to identify all the particular matters in which an official might be called upon to participate” and the “need to describe matters more generally may arise more frequently . . . with advisory committee members where the advisory committee charter is quite broad.” *Id.*

As an example of a broad statement that OEI deemed insufficient under the first test under this second criterion, the Draft Report uses an excerpt from a waiver that “would allow this individual to participate in the general matters that may affect [the HHS employee’s] financial interests.” Draft Report at 18.⁷ This language is virtually identical to an example used to illustrate a waiver that purportedly did not meet the third criterion. Draft Report at 19.⁸ For the reasons discussed more fully below in our comments on the third criterion, the sampled waivers that contained a broad statement of the kind quoted in the Draft Report contained information sufficient to describe the matters to which the waiver applies.

In issuing its regulations, OGE made it clear that an agency issuing a waiver could describe an employee’s duties in a general way, or describe a class of matters to which the waiver would

⁷ In auditing the 50 waivers selected for the Draft Report, the OGC Ethics Division was unable to identify the waiver quoted here. However, waivers that contain a plain language term such as “general matters” typically refer to “particular matters of general applicability,” a legal term of art. Use of the shorthand reference reflects an effort by HHS components to enhance readability and to assist waiver recipients in understanding the matters from which the employee must refrain from participating. Indeed, the language omitted by the ellipsis on page 18 of the Draft Report further described the meaning of “general matters” by comparing and contrasting a general matter to those other types of matters from which the waiver recipient would still be required to recuse, i.e., those that would have a specific or unique effect on the employee’s financial interest as a party.

⁸ Where the Draft Report concludes that a limited waiver did not satisfy the third criterion, that waiver likely failed the second criterion as well. Compare Draft Report, Appendix D (20 limited waivers were found not to have adequately described matters in which employees were prohibited from participating), and Appendix E (21 waivers were found not to have been documented in accordance with two or three of the criteria analyzed).

apply. 60 Fed. Reg. 47207, 47221-22 (September 11, 1995) (Proposed Rule); 61 Fed. Reg. 66830, 66841 (December 18, 1996) (Final Rule). Indeed, OGE notes that the specificity of such information can vary greatly from waiver to waiver. OGE 07 x 4. OGE recommends that a waiver “should explain in enough detail the types of matters in which the employee is likely to participate that might affect the financial interests concerned.” *Id.* at 8. OGE goes on to state that the language “may be as broad as including any particular matter affecting the financial interest,” while noting that in such cases the waiver “should include a reasonably detailed description of those responsibilities.” *Id.*

When OGE reviewed a previous version of the Draft Report, the General Counsel expressed “particular concerns about certain statements in the Draft Report indicating that it is insufficient detail for a waiver to permit participation in ‘general matters’ while requiring recusal from more ‘specific’ matters that ‘uniquely’ affect the employee’s financial interests.” OGE GC Letter at 3. Citing guidance that dates back to the Kennedy Administration, OGE confirmed that “it has long been common for agencies to grant waivers that generally permit employees to participate in a broadly defined class of particular matters of general applicability, with a similarly broadly defined proviso that the employees may not participate in any particular matter that involves specific parties or otherwise uniquely affects the employee’s financial interest.” *Id.*

In the most recent OGE letter, the Director expressed concern that the revised March 2011 Draft Report continues to claim that such language provides insufficient descriptive detail. OGC Director Letter at 3. Reiterating the longstanding use and acceptance of such language, the Director emphasized that OGE itself has used similar language in its own “regulatory” waivers, issued under 18 U.S.C. § 208(b)(2). OGC Director Letter at 3. The Director provided several examples including 5 C.F.R. §§ 2640.102(m) (definition distinguishing between particular matters of “general applicability” and particular matters involving “specific parties”); 2640.201(c) (regulatory waiver applying only to particular matters of general applicability as opposed to specific party matters); and 2640.203(d) (regulatory waiver that does not apply to certain matters that “individually or specially relate to or affect” certain interests). *Id.*

Test 2: Specific Delineation of Employee’s Official Duties. The first test enunciated by OEI under the second criterion ignores the broad latitude that OGE guidance provides when describing matters. The second test similarly errs by faulting general descriptions of an employee’s official duties. Incorporating text that precisely delineates those duties that potentially may have an impact on the employee’s financial interests is not required. *See* OGE GC Letter at 2 *citing* 60 Fed. Reg. at 47222 (agency issuing the waiver permitted to “describe the employee’s duties in a general way”) (emphasis in original). Organizational titles, context, or information external to the document itself suffice to supply the understood connection between the exercise of those duties and the potential effect on the employee’s financial interests.

The Draft Report, however, inexorably insists upon form over substance. A particularly telling example—upon which the Draft Report builds its statistical predicate—is the classification of 34 of the 42 sampled waivers granted to SGEs as having described inadequately the matters to

which the waiver applied because the “waiver explained the general duties of the employee’s committee . . . without describing the employee’s responsibilities within that committee.” Draft Report at 14, Appendix D.

This supposed inadequacy is premised on a false distinction between the functions of a Federal advisory committee chartered under the FACA, on the one hand, and the duties of an individual SGE serving on the committee, on the other. In fact, the assigned functions of the committee dictate the duties of the members; describing the former perforce describes the latter as they are one and the same. Conflict of interest waivers granted to SGEs serving on advisory committees invariably include not only the statutory or regulatory authorization for the committee but a summary of the committee’s charter, mission, and duties. For SGEs, a description of the duties and mission of the advisory committee describes the duties of the members, inasmuch as the duties of any individual member are not distinguishable from the group as a whole. Indeed, providing group advice rather than individual advice is one of the definitional aspects of a FACA committee. *See* 41 C.F.R. Part 102-3, Subpart A, Appendix A. For most committees, there is simply no meaningful way to create a more individualized assessment of one member’s duties.

Criterion 3: Description in Limited Waivers of the Particular Matter(s) in which the Employee Is Prohibited from Participating

OEI designated conflict of interest waivers as being limited waivers:

if they were documented as limited waivers (i.e., they contained language such as, “This is a limited waiver . . .”) and/or contained any reference to matters in which the employee must not participate. Then [OEI] classified a waiver as describing the limitations on the employee’s participation if it provided any explanation of the types of matters on which the employee must not participate. [OEI] classified a waiver as not containing this description if it contained only a broad statement that the employee must not participate in particular matters related to the conflict of interest and did not provide any detail about these matters.

Draft Report at 14.

Applying these criteria, OEI found that 19 of the 50 waivers sampled were not limited waivers.⁹

⁹ Using the criteria cited in the Draft Report, the six conflict of interest waivers granted for participation in FDA advisory committee meetings—five were granted to SGEs under 18 U.S.C. § 208(b)(3), and the other was granted to an employee under 18 U.S.C. § 208(b)(1), but also concerned participation in a meeting of an FDA advisory committee—may be fairly said not to be limited in the context of the actions of the relevant committees. Of the remaining 44 waivers, all were limited in some fashion, whether in scope (for example, a waiver that permitted an employee to participate in a bid protest meeting) or to certain types of matters, such as

Of the 31 remaining waivers, 20 were considered lacking in detail about the limitations other than that contained in a broad statement, and thus were found to be insufficiently specific. Draft Report at 18-19.

The Draft Report uses a more exacting descriptive standard for limited waivers than is expected under OGE guidance. OGE observes that a common limitation in a waiver is that the waiver permits employee participation in “matters affecting a conflicting entity only as a member of a class or group, but prohibiting the employee from working on particular matters where a conflicting entity is a party.” OGE 07 x 4. The Draft Report acknowledges that “[a]ll of the limited waivers in [OEI’s] review contained broad statements that the employees must not participate in specific matters related to their conflicts of interest.” Draft Report at 18. Notwithstanding that this broad, shorthand admonition to avoid participation in “particular matters involving specific parties” was taken directly from OGE guidance, the Draft Report views such statements as lacking in sufficient detail and clarity to constitute documentation as “recommended in provisions of selected Governmentwide Federal ethics regulations.”

A conflict of interest waiver granted to an SGE serving on an advisory committee will often have a broad statement in the final summary paragraph. In one such waiver, for example, the recommendation to the authorizing official has the following statement:

This waiver would be expressly limited as described above, and would not allow participation relating to specific party matters in which he has a direct or imputed financial interest. As to these matters, [the SGE] will recuse . . . from participation.

But this statement generally is not the only relevant information provided for the SGE in the waiver. The Draft Report focuses on particular phrasing rather than holistically appraising the entire document. Waivers issued by most components within HHS contain more detail in the body of the waiver. In the waiver quoted above, for example, the text explains the terms being used:

Matters of general applicability include evaluation of the development and effectiveness of program-related activities, evaluation of new scientific knowledge and technological developments in program-related areas, and consideration of program goals in relation to the agency’s public health mission. General matters do not include particular matters involving specific parties, such as specific grants, contracts, or recommendations regarding a specific product. These matters

particular matters of general applicability. It is possible that OEI found that eleven of the waivers granted under 18 U.S.C. 208(b)(3) to SGEs serving at the National Institutes of Health were not limited, as the addendum document associated with each waiver did not explicitly refer to limitations. These addenda, however, essentially add to previously granted waivers that contained the applicable limitations.

are not anticipated to have a unique and distinct impact on any of [the SGE's] personal or imputed financial interests, but may affect classes of similarly situated entities to the same extent.

And the waiver goes on to state:

Upon [the authorizing official's] approval, [the SGE] will be granted a waiver for general matters only. [The SGE] will not be permitted to participate in any matters involving specific parties that may affect [the SGE's] financial interests, or any person or organization described above. Should the work of [the advisory committee] move from general matters to more specific matters which could specifically affect [the SGE's] personal and imputed interests, [the Designated Federal Official] will examine [the SGE's] interests in relation to the particular matter, and either obtain a specific waiver allowing [the SGE] to participate, or exclude [the SGE] from participating in the specific party matter.

This level of detail in fact exceeds that recommended by OGE. When the OGC Ethics Division conducted an audit of the 50 waivers reviewed for the Draft Report, waivers issued by most HHS components included a broad statement that included a similar level of explanation of the waivers' limitations. This level of explanation provides guidance to the SGE serving on an advisory committee with a very broad portfolio while not attempting to anticipate every possible matter that may come before the committee.¹⁰ This is appropriate because a waiver issued to an SGE serving on an advisory committee with a broad subject matter area is very different from a conflict of interest waiver issued to a regular employee, and any analysis of HHS waivers should take these distinctions into account.

Returning to the apples and oranges analogy, the Draft Report denigrates limited waivers granted to SGEs under 18 U.S.C. § 208(b)(3) by contrasting them with text from a waiver granted to a regular employee under 18 U.S.C. § 208(b)(1):

[T]his waiver is intended to be limited in scope in that it does not apply to certain actions. You must have no involvement in any HHS grants, contracts, or other official actions that generate financial support to the [X], such as the procurement of [X] publications or approving expenditures for [X]-sponsored training for [HHS] staff. Likewise, you will have no involvement in HHS decisions to

¹⁰ The OGC Ethics Division audit of the 50 waivers sampled for the Draft Report showed that certain components within NIH had issued waivers that included broad general language similar to that quoted at page 18 of the Draft Report. While this language comports with OGE guidance, OGC does believe that providing additional detail may be useful depending on the scope of the committee's work. OGC has been working with the NIH Office of Federal Advisory Committee Policy (OFACP) on revising the model waivers that OFACP provides to NIH committee management officials.

provide speakers or other support to [X] events. You also will recuse yourself from all charitable solicitation activities by [X] ...

Draft Report at 19. That waiver permitted a high level HHS official to hold a fiduciary board position with an organization outside of the Government as a part of his official Government duties and implicated management concerns peculiar to the fact pattern at issue.¹¹

For most waivers, however, a general statement that tracks OGE’s guidance on limiting waivers to particular matters of general applicability suffices. The Draft Report notes that all the limited waivers that OEI reviewed included this language. Most HHS components issuing waivers to SGEs serving on advisory committees go beyond this standard by using the term “particular matter of general applicability,” contrasting that term with “particular matter involving a specific party or parties,” and providing explanations of those terms. Although OGC regards this as a best practice and has worked and continues to work with components on appropriate language to use, OGC has not prevented components from using simpler language to communicate the distinction. In the advisory committee context, where the waiver document provides details concerning the scope and mission of the advisory committee, this level of detail also provides sufficient specificity to enable a reader to determine the general scope of the waiver.

Comparing the Draft Report with Prior OGE Oversight

Another means of illustrating the Draft Report’s misapprehension of Federal ethics regulations and the resulting analytical errors is to compare the Draft Report’s results with those of OGE. In keeping with OGE regulations, copies of all 342 waivers granted by the Department in 2009 were forwarded to OGE. 5 C.F.R. § 2640.303. This necessarily included the 50 waivers sampled in the Draft Report. OGE did not express a concern in response to these submissions. As part of its oversight role, OGE also conducts regular reviews of agency ethics programs. Since the 1996 publication of the regulations governing conflict of interest waivers, OGE has conducted a number of program reviews of HHS components. In that time OGE reviewed the National Institutes of Health (NIH) in 2000, the FDA in 2005, the Health Resources and Services Administration (HRSA) in 2009, and the HHS Office of the Secretary and the OGC Ethics Division, also in 2009. These reviews included reviews of advisory committee issues and conflict of interest waivers.

In conducting these reviews, OGE at times has made suggestions to improve conflict of interest waivers. For example, OGE’s program review of certain NIH components in 2000 noted a concern about overinclusive descriptions of financial interests in certain conflict of interest

¹¹ This quote was initially difficult to locate in the OGC audit of the 50 conflict of interest waivers because the Draft Report does not make it clear that the first sentence quoted is from the paragraph previous to the remainder of the quoted text.

waivers that had been granted to SGEs.¹² The language currently used for drafting waivers granted to SGEs serving on NIH advisory committees—to describe the disqualifying financial interest, the particular matters in which the employee is permitted to participate, and (for limited waivers) the scope of the limitations of the waiver—is the same as that which was used in 2000 when OGE conducted its review, yet OGE interposed no objection to the language which the Draft Report now finds deficient. Moreover, in none of the OGE reviews of HHS ethics programs conducted in 2009 did OGE express concerns over any of the aspects of the conflict of interest waivers identified in the Draft Report.

The Draft Report's Recommendation that Employees Must Sign and Date Waivers Unnecessarily Limits Components in Providing Notice and Ensuring Accountability Through Alternative Means

Although the Draft Report acknowledges that having the employee who is granted a conflict of interest waiver sign and date the waiver is not a Federal ethics requirement, the Draft Report recommends that HHS revise its practices to require that all employees sign and date, or similarly document, their conflict of interest waivers. Draft Report at 24. In finding that 38 of the 50 waivers had not been signed or dated, the Draft Report expresses:

- (1) concern that the employees granted the waivers were not aware that the waivers existed;
- (2) apprehension that even if the employees are aware of the existence of their waivers, the employees may not understand the waivers' contents or their effect on the employees' official duties; and
- (3) belief that requiring employees to sign and date their waivers may assist in ensuring that they are held accountable for complying with the waivers' terms.

Draft Report at 4, 20, 24-25.

According to the Draft Report, by revising current policy to require all employees to sign and date, or similarly document, their waivers, employees would do this in order to: (1) acknowledge the waivers; (2) document that they understood any limitations on their participation in official

¹² The waivers in question listed every asset, income source, or affiliation shown by the SGE on his or her financial disclosure report, regardless of whether those interests created a potential conflict. OGE believed that such over inclusion, although added in an excess of caution, might mislead a reader as to what constitutes a conflict of interest under Federal ethics laws and regulations. OGC concurred; and after that report was issued, NIH revised its procedures so that waivers granted to SGEs only refer to those interests and affiliations that may create a potential conflict of interest.

Government duties;¹³ and (3) confirm that the waivers accurately describe their specific circumstances and conflicts of interest. Draft Report at 24-25. The report goes on to state that obtaining these signatures would also “demonstrate that OPDIVs or STAFFDIVs presented the waivers to the employees and that the employees had a chance to review and understand them.” *Id.* at 25. The report further states that the signatures “may also assist in ensuring that [employees] are held accountable for complying with the waivers’ terms.” *Id.*

This finding and recommendation constitute, quite simply, a solution in search of a problem.¹⁴ The Draft Report produces no data showing that employees were unaware of a waiver granted to them; no information indicating that employees failed to understand any limitations on what they were permitted to do as part of their official responsibilities; and no facts (with one possible exception) demonstrating that a waiver was issued based on inaccurate information.¹⁵ In terms of ensuring employee accountability for compliance with a waiver, the Draft Report uses the example of seven SGEs serving with the Centers for Disease Control and Prevention (CDC) mentioned in a previous OEI report.¹⁶ Draft Report at 4. According to the Draft Report, one

¹³ OGC questions whether a dated signature is a meaningful indicator of employee understanding of the terms of a conflict of interest waiver.

¹⁴ In December 2010, the OGC Ethics Division conducted an e-mail survey of all HHS components that had issued waivers in 2009. Among other questions, this survey asked component ethics officials whether they had ever encountered a situation where an employee was unaware that a waiver had been issued to the employee, or whether there had ever been a situation where an employee had acted improperly in any matter because the employee did not understand the scope of a waiver that had been granted. All components responded to the survey in the negative.

¹⁵ The Draft Report states that one waiver was issued based on a finding that the employee’s spouse’s employment posed a potential conflict of interest, but that the employee’s financial disclosure report indicated that the employee’s spouse was unemployed. Draft Report at 17. There are a number of possible explanations for this seeming discrepancy (e.g., disclosure reports elicit from the filer only a “snapshot” of information that is current as of a specific date and do not reflect subsequent changes; the term “employment” as used in different contexts may or may not distinguish among consulting relationships, self-employment, or independent contractor status), but OGC cannot completely evaluate this lone assertion without receiving the specific data from OEI concerning its findings.

¹⁶ *CDC’s Ethics Program for Special Government Employees on Federal Advisory Committees*, OEI-04-07-00260 (December 2009). Although not directly relevant to the point being made here, OGC notes that footnote 19 on page 5 of the report should be revised to indicate that OGC’s determination (that although the SGEs in question may have failed to adhere to the terms of their waivers, the SGEs did not violate 18 U.S.C. § 208 because the relevant interests did not actually present a conflict and thus should not have been included in a waiver) was only reached after OGC consulted with OGE and OGE concurred in OGC’s determination.

aspect of the lack of oversight on the part of the CDC was a failure to obtain the SGEs' signatures on their waivers (which were issued in 2007 and not subject to the current report).

The concerns expressed in the Draft Report with regard to employee awareness indicate a lack of detailed familiarity with the conflict of interest waiver processes at HHS. Granting a waiver to an SGE serving on an advisory committee or any other employee is the result of an extensive process that begins with information provided by the employee being granted the waiver. While the waiver is being drafted, the employee is regularly contacted for a variety of reasons (to confirm information that goes into the waiver, etc.). Once a waiver is issued, all HHS components have processes in place to ensure that employees are aware of their waivers, have an opportunity to familiarize themselves with those waivers, and that the agency can document these facts.

Like CDC, HRSA requires employees to provide a dated signature on their waivers. At FDA, every employee granted a waiver for participation at an advisory committee meeting must sign and date an Acknowledgment of Financial Interest form before the waiver is granted, and the employee is not permitted to attend a meeting if the employee has not done so. At NIH, every SGE who has been granted a waiver is issued an individual recusal list prior to attending a meeting. This document not only reminds the SGE of the existence of a waiver, it reminds the SGEs of their specific responsibilities under those waivers, including any limitations to the waiver. At the Agency for Healthcare Research and Quality (AHRQ), conflict of interest waivers for SGEs serving on advisory committees are granted by the Deputy Ethics Counselor and mailed to respective employees with an attached acknowledgment and confirmation letter. The SGEs are required to print their name, sign and date, and return the letter to the ethics program via a pre-paid envelope for subsequent inclusion in their official ethics folder. Mailed waivers are tracked to ensure return of the acknowledgment and confirmation of waiver. Through these means, HHS employees granted conflict of interest waivers are well aware when a waiver has been granted to them, and the agency components can document this awareness.

Moreover, the Draft Report's recommendation that the *employee* sign and date, or similarly document, his or her conflict of interest waiver is unnecessarily limiting. As noted in the Draft Report, the vast majority of waivers are granted to SGEs serving on advisory committees. In addition to the logistical difficulties created by attempting to obtain dated signatures from widely scattered individuals—who may only engage in their Government duties for a handful of days in a calendar year, placing the burden of responding on an SGE already overloaded with paperwork may discourage some individuals from serving, thus depriving the Government of needed expertise.

The logistical issues may be exacerbated for components with specific requirements or issues. For example, pursuant to the FDAAA, the FDA is required to disclose any conflict of interest waiver that was issued pursuant to either 18 U.S.C. § 208(b) or Section 712 of the Federal Food, Drugs and Cosmetic Act (a parallel waiver provision that requires a determination of "essential expertise" before a conflict can be waived) on its public web site at least 15 days in advance of

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each advisory committee meeting (unless the financial interest became known to the agency less than 30 days before the meeting, in which case the waiver must still be disclosed no later than the meeting date). In addition, the statute requires the public record and transcript of each advisory committee meeting to include the same disclosure of waivers. The statutory requirement that waivers be posted on the public web site and placed in the public record and transcript of the committee hearing ensures that both the public and the SGEs are aware of any waivers related to the meeting. Additional procedural requirements, such as requiring a dated employee signature, would create a redundancy and potentially interfere with the agency's ability to meet the statutory deadlines and requirements established by Congress.

What is important are the underlying goals of documenting notice and ensuring accountability. Where an agency can meet those goals through other means (such as using e-mail with read receipts, publishing the waivers online and notifying the employee, or providing an SGE with an individual recusal list prior to the meeting), the needs of the program can be addressed without additionally burdening the individual SGE. This also may avoid confusion concerning whether an employee must concur with the issuance of a waiver. Issuance of a waiver is at the sole discretion of the agency; an employee's signature is irrelevant to the effectiveness of the waiver, and an employee may not disqualify himself or herself from a matter on conflict of interest grounds where an agency has issued a waiver. *See, e.g.*, 5 C.F.R. § 2635.502(d) (where an agency designee determines that an employee's participation is authorized, the employee may not thereafter disqualify himself from participation in the matter on the basis of an appearance problem involving the same circumstances that have been considered by the agency designee).

Finally, as OGE emphasized in its comments on the revised March 2011 Draft Report, "OGE's regulations or policy guidance do not require employees to sign and acknowledge their waivers and do not suggest that this practice would add value to the process." OGE Director Letter at 4. Concluding that "agencies have various means, apart from the actual waiver certification, to apprise employees of the scope of their permitted duties and any continuing recusal obligations, OGE observed that "[i]n some cases . . . a pro forma acknowledgment signature might have less value than oral counseling, particularly where an employee has questions or doubts about the contents and meaning of the waiver." *Id.*

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Ethics Division
Department of Health and Human Services
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A C K N O W L E D G M E N T S

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