

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**OUTSIDE ACTIVITIES OF  
SENIOR-LEVEL NIH EMPLOYEES**



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Inspector General

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# *Office of Inspector General*

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## OBJECTIVES

1. To describe the nature of outside activities for which senior-level National Institutes of Health (NIH) employees received approval between 2001 and 2003.
2. To determine the extent to which senior-level NIH employees provided key information on their outside activity forms and supporting documentation between 2001 and 2003.
3. To assess NIH's process for reviewing outside activity requests between 2001 and 2003.

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## BACKGROUND

In general, employees of the Department of Health and Human Services (HHS) are allowed to work privately with non-Federal entities on their personal time through outside activities, which in some cases require prior approval. Examples of outside activities include consulting, teaching, speaking, and writing related to official duties. These activities must not conflict with employees' official duties, and may or may not involve financial compensation. Outside activities must be approved in accordance with regulations issued by the Office of Government Ethics and supplemental rules issued by HHS.

In December 2003, an investigative report in the Los Angeles Times raised concerns about the ethics program at NIH. This article alleged that certain approved outside activities (i.e., consulting arrangements) of several NIH employees had created serious conflicts of interest that may have biased agency decisions. In response to these allegations, several internal and external groups have conducted reviews of NIH's ethics program.

NIH takes a decentralized approach to implementing and overseeing its ethics program. NIH has 27 institutes and centers, as well as a central Office of the Director, Office of Research Facilities, and Office of Research Services (all hereafter referred to as institutes). Each institute has its own ethics staff.

When an employee seeks to participate in an outside activity, he or she submits an outside activity request (the HHS-520 form) and supporting documentation (which often includes two additional forms, the NIH-2657 and the unnumbered supplemental form) to his or her supervisor. The supervisor makes a recommendation regarding

whether the activity should be approved and then forwards the request on to the appropriate ethics official, who makes a final determination.

We conducted a retrospective review of all outside activity requests and supporting documentation that senior-level employees submitted to NIH ethics officials between January 1, 2001, and December 31, 2003. We defined senior-level employees to be those employees who were required to file Standard Form (SF)-278 public disclosure financial forms as of February 2004. We also interviewed the ethics staff at each NIH institute. Finally, we reviewed institutes' written procedures related to outside activities.

We conducted this review prior to February 2005, when HHS issued an interim final rule that placed several new restrictions on the types of outside activities in which NIH employees are allowed to participate.

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## NATURE OF OUTSIDE ACTIVITIES

Forty percent of senior-level employees at NIH received approval for 319 outside activities between 2001 and 2003. Of the 174 senior-level employees at NIH, 78 requested approval for 355 outside activities between 2001 and 2003. NIH approved 90 percent, or 319, of these requests for 69 senior-level employees.

About half of these outside activities involved teaching or consulting and most were compensated. Thirty-three percent of the approved activities were for teaching/lecturing. Twenty percent of the approved activities were for consulting, of which almost half involved pharmaceutical or biotechnology companies. Eighty-eight percent of the approved outside activities involved some type of compensation.

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## VULNERABILITIES

### **Limited information submitted by employees inhibits NIH's ability to effectively review outside activity requests**

- Thirty-two percent of the approved outside activity requests were missing at least 1 required piece of information: reviewing officials' signatures were missing from 67, the unnumbered supplemental form was missing or incomplete for 19, and the NIH-2657 form was missing or incomplete for 34. Both the supplemental form and the NIH-2657 form provide NIH with additional information regarding the nature of the activity; this

information is critical in determining whether an activity should be approved.

- Twenty-two percent of the outside activities were not disclosed as required by regulations on annual financial disclosure forms.
- Ten of the sixty-three consulting activities contained a copy of the consulting contract and 54 percent of all the activities contained a letter of invitation. Although NIH requires neither, consulting contracts and letters of invitation can provide important information on the nature of an outside activity.
- Position descriptions and job billets that employees provided were too general to demonstrate that employees' official duties would not overlap with proposed outside activities.

**Inadequacies in the review process inhibit NIH's ability to effectively review outside activity requests**

- Twenty-eight percent of outside activity requests were approved after the scheduled start dates for those activities, which violates HHS regulations.
- Written recusals were present for 19 percent of the activities. Recusals disqualify employees from general or particular matters in their official duties so that conflicts of interest are avoided. All employees who engage in outside activities are required to recuse themselves from official duty matters that may create actual or apparent conflicts of interest; however, recusals are not necessarily required in writing. Written recusals are important because they inform supervisors and co-workers of potential conflicts of interest and increase awareness among employees.
- Nine institutes do not routinely notify employees' supervisors of final decisions on requests, and four others notify supervisors only of disapproved requests.
- Six institutes do not follow up on ongoing outside activities to determine whether the nature and time commitment associated with activities have changed. NIH policy regarding the frequency and the nature of followup of ongoing activities is unclear.
- Ethics work is a collateral duty for about three-quarters of the ethics officials at NIH, which means it may be difficult for staff to maintain ethics expertise.

- Lack of training for supervisors and employees is a major challenge. Although NIH trained all employees and provided training specifically geared towards supervisors in 2004, there is currently no requirement that supervisors attend regular training in how to review outside activity requests, and there is no requirement that all other employees attend regular training sessions on outside activities.

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## RECOMMENDATIONS

HHS and NIH have already undertaken a variety of initiatives to address inadequacies in the review and approval process for outside activities. NIH has increased training and has centralized the review of certain types of outside activity requests. Furthermore, in February 2005, HHS issued an interim final rule that placed several restrictions on the types of outside activities in which NIH employees are allowed to participate. (For a complete list of HHS and NIH initiatives, see Appendix C attached to the main body of this report.) We offer the following recommendations to NIH.

### **Improve the quality and extent of information for outside activities**

- Require all employees to submit additional details on the nature of their proposed outside activities and their current official duties.
- Ensure that employees fill out their outside activity requests completely.
- Ensure that institutes cross-check financial disclosure forms with employees' outside activities records for the previous year.

### **Address the inadequacies in the review process for outside activities**

- Ensure that institutes approve outside activities before their scheduled start dates.
- Require recusals, if needed, to be made in writing and disseminated to immediate supervisors and other key personnel for all outside activities that are related to employees' official duties.
- Ensure that ethics officials notify supervisors of all approvals and disapprovals.
- Ensure annual followup of ongoing outside activities.

## E X E C U T I V E   S U M M A R Y

- Enhance training related to outside activities.
- Consider centralizing some or all aspects of the review process for outside activities.

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### AGENCY COMMENTS

NIH concurred with our findings and recommendations. However, it indicated a need for caution regarding written recusals for outside activities in certain circumstances. Further, NIH noted that it has already taken many steps to address the vulnerabilities identified in this report, and has further initiatives planned. For NIH's complete comments, see page 24 of this report.

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### OIG RESPONSE

We appreciate NIH's comments and the steps that NIH has taken and has planned to address vulnerabilities in its review process for outside activities.

In response to NIH's concerns about recusals, we reiterate that written recusals, when needed, are protective of employees who are participating in outside activities because they allow for the establishment of screening and gate-keeping practices that help to ensure employees do not encounter conflicts between their official duties and outside activities. Thereby, they can help prevent conflicts of interest from arising. Recent guidance from the Office of Government Ethics also suggests that recusals can help to prevent conflicts from arising.

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3. To assess NIH's process for reviewing outside activity requests between 2001 and 2003.

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## BACKGROUND

Federal employees hold positions of public trust and are accountable for the responsible use of public funds. As such, the public expects Federal employees' actions and decisions to demonstrate integrity and objectivity. Therefore, pursuant to congressional mandate, the Office of Government Ethics (OGE) has put into place an ethics program that addresses a broad array of topics, including employees' outside activities. Each department in the executive branch is responsible for implementing its ethics program.

In general, employees of the Department of Health and Human Services (HHS) are allowed to work or interact privately with non-Federal entities on their personal time through outside activities, which in some cases require prior approval. Examples of outside activities include consulting, teaching, speaking, and writing related to employees' official duties. These activities must not conflict with employees' official duties, and may or may not involve financial compensation.

Outside activities are not necessarily related to employees' professions, but some outside activities provide scientists at NIH with opportunities to work with industry, academia, hospitals, and nonprofit foundations to help translate important scientific and biomedical research into practice. Outside activities can also be sources of professional gratification by allowing NIH scientists to build and maintain their professional expertise. Further, the compensation from outside activities may help NIH attract and retain staff.

However, outside activities may create actual or apparent conflicts of interest for employees. Pursuant to 18 U.S.C. § 208(a), an actual conflict of interest arises when an employee personally and

substantially participates, in an official capacity, in a particular matter in which he or she has a personal or imputed financial interest, if the matter will otherwise have a “direct and predictable effect” on that interest. Additionally, pursuant to 5 CFR § 2635.502, the appearance of a loss of impartiality arises when an employee participates in an official capacity in a matter in which he or she has certain defined associations or interests that would “cause a reasonable person [...] to question his impartiality in the matter.”

### **Recent concerns regarding outside activities**

In December 2003, an investigative report in the Los Angeles Times raised concerns about NIH’s ethics program.<sup>1</sup> The article alleged that certain approved outside activities (i.e., consulting arrangements) for several employees at NIH had created serious conflicts of interest that may have biased agency decisions.<sup>2</sup> The article also raised questions about the lack of public disclosure regarding the compensation that scientists received for these outside activities.

In response to these allegations, several internal and external groups have launched reviews of both the overall system for reviewing outside activity requests at NIH and the questionable outside activities in which NIH employees participated. The following is a summary of those reviews:

- NIH is in the process of reviewing all compensated outside activities involving consulting with pharmaceutical and biotechnology companies in which employees participated between 1999 and 2003 to ensure that they met pertinent requirements.
- Several hearings by the Senate Appropriations Committee and the House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations examined consulting arrangements that NIH employees maintained with pharmaceutical and biotechnology companies.
- A blue ribbon panel of outside advisors convened by NIH evaluated the agency’s policies for outside activities.
- A routine program review by OGE assessed the procedures and administrative systems in place for outside activities at four NIH institutes.

### **Requirements for outside activities at NIH**

Office of Government Ethics. OGE was established in the Ethics in Government Act of 1978 to oversee ethics programs at all executive

branch agencies. In October 1992, OGE promulgated governmentwide Standards of Ethical Conduct for Employees of the Executive Branch, which became effective on February 3, 1993, and include Subpart H on outside activities.<sup>3</sup> OGE regulations require employees to comply with 18 U.S.C. § 209, which prohibits employees from accepting outside compensation for work conducted in an official capacity. OGE regulations also prohibit employees from engaging in outside activities, both compensated and uncompensated, that would conflict with those employees' official duties to such a degree that they would have to be disqualified from performing essential parts of their jobs. Further, employees are required to endeavor to avoid actions that would create the appearance of violating the standards of ethical conduct.<sup>4</sup>

*Department of Health and Human Services.* Agencies may impose, with OGE concurrence, additional limitations on outside activities. In 1996, HHS promulgated the Supplemental Standards of Ethical Conduct, which provide additional ethics rules.<sup>5</sup> During the period covered by our review, these supplemental regulations prohibited all HHS employees from engaging in any compensated employment regarding HHS-funded activities, or providing consultative or professional services for compensation in preparing grant applications, contract proposals, and certain other documents for submission to HHS. In addition, the regulations required, and continue to require, employees to request and receive prior written approval from their supervisors and ethics officials for certain outside activities. The types of activities that trigger the prior approval requirement include: (1) providing consultative or professional services; (2) teaching, speaking, writing, or editing that relates to official duties or results from contact with certain sources; or (3) serving on certain boards or advisory bodies.<sup>6</sup>

In February 2005, HHS issued an interim final rule that revised the Supplemental Standards of Ethical Conduct and placed additional restrictions on the types of outside activities in which NIH employees are allowed to participate.<sup>7</sup>

At the time of this review, regulation stipulated that outside activities shall be approved unless they violate a statutory or regulatory requirement.<sup>8</sup>

*National Institutes of Health.* In its NIH Manual, NIH maintains policies and procedures for outside activities that elaborate on HHS and OGE regulations.<sup>9</sup> The NIH Manual reiterates and clarifies the basic rules for outside activities as stated in OGE regulations and HHS

supplemental regulations. The NIH Manual stipulates that outside activities may draw on employees' general scientific or professional expertise and may be compensated, but they may not be conducted on Government time or using Government resources, and they may not be related to any matter that an employee has been assigned as an official duty in the past 12 months.<sup>10</sup>

### **Outside activity approval process at NIH**

NIH takes a decentralized approach to implementing and overseeing its ethics program. It has 27 institutes and centers, as well as a central Office of the Director, Office of Research Facilities, and Office of Research Services (all hereafter referred to as institutes). Each institute has its own Deputy Ethics Counselor (DEC), and sometimes additional ethics staff, who oversee its ethics program. Among their ethics duties, the DEC's ensure that institute employees abide by NIH's requirements for outside activities and answer employees' questions regarding ethics. Typically, DEC's are the Deputy Directors or executive officers of their institutes, so they have other job responsibilities in addition to ethics. The DEC for the Office of the Director also serves as the head NIH DEC and the Deputy Director of NIH.

While the process for approving an outside activity in every institute reflects the policies delineated in the NIH Manual, institutes may develop their own procedures for executing those policies so long as those procedures do not contradict HHS, OGE, or NIH policies or rules.

*Outside Activity Requests.* In general, the official process for approval begins when an employee submits a Request for Approval of Outside Activity (HHS-520) and, often, one or more NIH supplements to his or her supervisor. Each of these forms collects information on particular aspects of a proposed outside activity and is used in determining whether an outside activity may pose a conflict of interest.

- The *HHS-520* is required for all outside activity requests. It collects information on the employee's position, the nature of the outside activity, the length of time over which the outside activity will be performed, and the method of compensation. As of January 2004, the amount of compensation must also be disclosed.<sup>11</sup>
- The *NIH Unnumbered Supplemental Information Form to Accompany the HHS-520* is required for all compensated outside activities.<sup>12</sup> It documents the employee's official duties, how the outside activity does or does not relate to those official duties, and

the nature of the relationship, if any, between the organization sponsoring the outside activity and NIH.

- The *Supplemental Information to the HHS-520 Form (NIH-2657)* is required for outside activities involving consulting and private clinical and legal practice. It contractually binds the employee to avoid certain situations that could create an actual or apparent conflict of interest.

The employee's supervisor reviews these forms and makes a recommendation to the appropriate DEC about whether an activity should be approved. The DEC then reviews these forms and makes a final decision about whether to approve the outside activity request. At this point, the need for any recusals would be determined. A recusal disqualifies an employee from a general or particular matter in his or her official capacity to avoid a conflict of interest. It is a protective measure that aims to ensure that employees do not face conflicts of interest.

*Annual Financial Disclosure.* Certain executive branch employees, including some NIH employees, must also disclose their compensated outside activities through an annual financial disclosure form. By statute, officials for whom the minimum base pay in their pay band is equal to or greater than 120 percent of the minimum rate of base pay for the GS-15, and certain other designated officials such as presidential appointees and members of the uniformed services above a certain pay grade, must file the annual public financial disclosure, the Standard Form (SF)-278, with their DEC's.<sup>13</sup> The SF-278 captures all outside sources of assets worth at least \$1,000, income, and liabilities along with the financial value for each source; compensated outside activities for which the income is greater than \$200; and certain compensated and uncompensated positions.

Other employees who do not file the SF-278 but who hold positions of significant decisionmaking authority as determined by NIH in conjunction with OGE are required to file the annual confidential financial disclosure form, the OGE-450, with their DEC's. The OGE-450 captures certain outside sources of assets worth at least \$1,000, income, and liabilities—including compensated outside activities above \$200—but does not require the disclosure of the financial value from any source. This form requires the disclosure of certain compensated and uncompensated positions.

Employees who do not meet the criteria for filing the SF-278 or the OGE-450 do not file any annual financial disclosure forms.

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## METHODOLOGY

Our review is based on three data sources: (1) a file review, (2) interviews, and (3) a procedure review. (For a complete description of our methodology, see Appendix A.) We conducted this review prior to February 2005, when HHS issued an interim final rule that placed several new restrictions on the types of outside activities in which NIH employees are allowed to participate.

For our file review, we conducted a retrospective review of all outside activity requests that senior-level employees submitted to NIH ethics officials between January 1, 2001, and December 31, 2003. We defined senior-level employees to be those employees who were required to file SF-278 public disclosure forms as of February 2004. NIH provided us with a list of 176 employees who met that criterion. We excluded from our review the Director of NIH and the Director of the National Cancer Institute, both of whom are presidential appointees and are therefore overseen by ethics officials outside of NIH. Therefore, our final population was 174 employees. The population of senior-level employees included, but was not limited to: (1) institute directors, (2) institute deputy directors, (3) institute scientific directors, and (4) institute clinical directors.

Our file review included three methodologies: (1) a descriptive review, (2) a completeness review, and (3) a compliance review.<sup>14</sup> For the descriptive review, we tallied the number and nature of the outside activity requests overall and conducted trend analyses of the approved activities. One limitation of this review is that it may have been subject to underreporting, as we did not assess whether employees conducted any additional outside activities between 2001 and 2003 that were not reported to NIH in outside activity requests. For the completeness review, we calculated the extent to which the required documentation was filled out completely and correctly.

For the compliance review, two analysts, and when necessary a third, independently assessed each approved outside activity using a set protocol and documented whether the activity appeared to be allowable under existing requirements. A limitation of this review is that we made our assessments based solely on the documentation provided by

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

NIH and did not follow up with employees or ethics officials for further details on the outside activities.

For our interviews, we interviewed the DECAs, and any ethics staff they chose to include, at all institutes. We used a structured questionnaire to conduct the interviews. The questionnaire addressed topics such as the institutes' procedures for reviewing outside activity requests and challenges that ethics officials experience in reviewing outside activity requests.

Finally, we requested operating procedures related to outside activities from all institutes. We assessed the nature of these documents and identified common themes and best practices.

We conducted this inspection in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

In this section we provide a summary of the number and types of outside activities in which NIH senior-level employees participated between 2001 and 2003. We conducted this review prior to February 2005, when HHS issued an interim final rule that placed several new restrictions on the types of outside activities in which NIH employees are allowed to participate. For more information see Appendix B.

**Forty percent of senior-level NIH employees received approval for 319 outside activities between 2001 and 2003**

**Senior-level employees received approval for 90 percent of the outside activity requests they submitted**

- Of the 174 senior-level employees at NIH, 78 requested approval for 355 outside activities between 2001 and 2003. NIH approved 319 of these outside activity requests for 69 senior-level employees. It is not surprising that most activities were approved. At the time of our review, departmental supplemental regulations required that outside activity requests be approved unless they violated statute or regulation.<sup>15</sup>

**Most senior-level employees participated in 1 or 2 approved outside activities, but a few participated in more than 20**

- Fifty-seven percent (39) of the sixty-nine senior-level employees participated in only one or two approved outside activities between 2001 and 2003.
- Eight senior-level employees participated in 10 or more approved outside activities during this 3-year period, and 3 senior-level employees participated in 20 or more approved outside activities.

**Senior-level intramural employees accounted for 76 percent of the approved outside activities**

- Intramural employees coordinate and conduct research within their institutes at NIH, whereas extramural employees administer grants and contracts with outside entities.

**Senior-level employees at three institutes accounted for 52 percent of the approved activities**

- Senior-level employees at the National Institute of Mental Health participated in 77 approved outside activities between 2001 and 2003. Senior-level employees at the National Human Genome Research Institute participated in 45 approved outside activities,

and senior-level employees at the National Heart, Lung and Blood Institute participated in 44 approved outside activities.

**About half of these activities involved teaching or consulting and most were compensated**

**Fifty-three percent of the approved outside activities involved teaching or consulting, commonly with universities and pharmaceutical companies, respectively**

- Thirty-three percent (105) of the approved activities were for teaching/lecturing. Forty-four percent (46) of these teaching/lecturing activities were with universities. It is important that NIH review activities with universities carefully as NIH funds scientific research at universities, and certain outside activities may inappropriately influence the employee's or the agency's decisions with respect to future funding decisions. Extramural employees, who administer grants and contracts with universities, may pose greater risks for conflicts of interest if they engage in outside activities with universities and other potential grantees.
- Twenty percent (63) of the approved activities were for consulting. Forty-nine percent (31) of these consulting arrangements were with pharmaceutical or biotechnology companies. It is vital that NIH review activities with these companies carefully to ensure that they are not receiving inappropriate access to Government data and that the employee's and the agency's decisions are not influenced by industry.

**Eighty-eight percent of the approved outside activities involved some type of compensation**

- For those activities for which the information was available, senior-level employees reported earning on average \$869 in expenses, \$1,500 in honoraria, and \$2,000 in fees, per activity. Honoraria and fees ranged from \$150 to \$18,000 and \$500 to \$30,000, respectively, per activity.<sup>16</sup> For those activities for which the information was available, no relationship appeared to exist between the amount of time an employee spent on an outside activity and the amount of compensation he or she received for that activity.
- Fifty-seven percent of approved activities involved some amount of time off and 7 percent required a week or more of time off.

## ► V U L N E R A B I L I T I E S

### **Limited information submitted by employees inhibits NIH's ability to effectively review outside activity requests**

#### **Of the 319 approved outside activities, 101 were missing at least 1 required piece of information in the documentation**

Of the 101 activities that were missing information, 82 percent were missing 1 item of information, 15 percent were missing 2 items, and 3 percent were missing 3 items.

Foremost among the missing items were signatures on the HHS-520, which is the main outside activity request form and is required for all employees submitting requests. Of the 319 approved outside activities, 67 were missing a signature by the reviewing official. The reviewing official, typically the employee's supervisor, is responsible for verifying that a proposed outside activity does not overlap with the employee's official duties and recommending to the ethics official whether a request should be approved. One approved outside activity request lacked an employee signature testifying that the information provided on the HHS-520 was true and complete, and one approved outside activity request lacked a signature of the final approving official.

For 19 of the 279 approved outside activity requests that required unnumbered supplemental forms, the forms were either missing or incomplete. The unnumbered supplemental form is the NIH form that is required for all compensated activities. These missing and incomplete forms are of particular concern as this form solicits details about an employee's official duties, the proposed outside activity, and the difference between the two. It is essential for ethics officials to have this information in determining whether proposed outside activities could create real or apparent conflicts of interest.

NIH requires employees to attach position descriptions or job billets along with unnumbered supplemental forms. Of the 279 approved requests that required unnumbered supplemental forms, 66 percent lacked position descriptions or job billets.

It is also of concern that NIH does not require unnumbered supplemental forms and position descriptions for all outside activity requests, regardless of compensation amount.<sup>17</sup> These documents provide information that is relevant to determining whether or not activities should be allowed.

Furthermore, for 34 of the 205 approved outside activity requests that required NIH-2657 forms, the forms were either missing or incomplete. The NIH-2657 is the supplemental form that, in certain situations, contractually binds employees who participate in consulting activities or private clinical or legal practice to avoid real or apparent conflicts of interest.

**Even when the forms were complete, they often provided limited information**

Because of the limited information provided on the forms, ethics officials must routinely follow up with employees for additional details or clarification, which consumes valuable staff time. Ethics officials at 22 institutes commented that they always or often follow up with employees for additional information as they review outside activity requests. Ethics officials indicated that the most common reason for followup with employees is to obtain more information on the difference between an outside activity and an employee's official duties.

NIH does not require certain additional documents that could be useful for reviewers. For example, NIH does not require employees to submit letters of invitation or any descriptions of the outside activities from outside entities, although 12 institutes require letters of invitation in their written procedures for outside activities. Fifty-four percent (172) of approved outside activity requests contained letters of invitation.

Furthermore, NIH does not require ethics officials to collect or review copies of contracts for consulting activities. Ten of the sixty-three consulting activities had copies of the contracts, with the terms and conditions of the activity, on file. Previously, NIH counsel would occasionally review contracts for outside activities. However, they no longer do so because such reviews may have led to NIH lawyers providing legal advice to Government employees in their private capacities. Currently, NIH requires employees who are participating in outside activities to insert a standard clause in all contracts so that outside employers recognize that Federal employees must adhere to certain laws and standards of ethical conduct.<sup>18</sup>

In addition, the position descriptions and job billets that employees provided were typically too general to demonstrate that employees' official duties would not overlap with proposed outside activities. Position descriptions do not commonly list employees' current research projects and affiliations.

In our compliance review, our reviewers found that information on outside activities was limited in 81 percent of the approved outside

activities. This limitation included insufficient detail regarding the nature of the outside activities, the nature of employees' official job duties, the differences between the outside activities and their official job duties, the outside organizations, and any NIH funding or partnerships with the outside organizations. For example, in describing the differences between their official duties and proposed outside activities, employees provided vague responses such as, "The activity is not appropriate as an official duty."

To address these concerns, the HHS Designated Agency Ethics Official (DAEO) has reminded ethics officials throughout the Department of the importance of performing due diligence when reviewing ethics forms.<sup>19</sup> The DAEO has authority, delegated from the Secretary, to oversee the HHS ethics program.

**Twenty-two percent of the approved outside activities were not disclosed as required on annual financial disclosure forms**

Employees who file the annual public financial disclosure form (SF-278) must disclose all sources of income over \$200, certain outside positions, and all reimbursement for travel expenses greater than \$260. All disclosures on the SF-278 must include the amount of compensation, if applicable. Senior-level employees who were public filers did not disclose 20 of the 95 approved outside activities that required disclosure on their SF-278 forms in 2001 or 2002. In addition, senior-level employees did not disclose 22 of the 93 approved outside activities that required disclosure in 2003; however, NIH had not completed its final review and authorization of the 2003 SF-278 forms at the time of our review, and some of the deficiencies for 2003 may have been later identified and corrected by ethics officials.<sup>20</sup>

Employees who file the confidential financial disclosure form (OGE-450) must disclose all sources of income over \$200, certain outside positions, and reimbursement for travel expenses greater than \$285. However, confidential filers are not required to report the *amount* of compensation in all cases. Senior-level employees who filed the confidential financial disclosure at any point during the period of our review did not disclose 30 of the 141 approved outside activities that required disclosure on the OGE-450.<sup>21</sup> At the time of our review, NIH had already completed its final review and authorization of the OGE-450 forms for 2003.

## **Inadequacies in the review process inhibit NIH's ability to effectively review outside activity requests**

### **Approvals after the start date**

Twenty-eight percent of outside activity requests were approved after the start dates provided on the request forms. HHS regulations mandate that outside activities must be approved in advance.<sup>22</sup> A recent OGE review of outside activities at NIH also found a significant number of late approvals: in its sample of 155 approved activities at 4 institutes, 25 percent were approved after their scheduled start dates.<sup>23</sup>

In our review, some approvals after the scheduled start dates were due to late submissions. For 40 percent of the late approvals, employees submitted their outside activity requests after the activities had begun. Late approvals may also occur if ethics officials need to follow up with employees for additional information on requests. Ethics officials noted that followup can add weeks to the time it takes to review requests.<sup>24</sup>

Fifteen institutes set specific deadlines for the submission of outside activity requests in their procedures. Eleven institutes require requests to be submitted at least 6 weeks prior to start dates; the remaining institutes have shorter deadlines or call for “reasonable advance.”

### **Limited use of written recusals for outside activities**

Written recusals specific to outside entities were present for 19 percent of the approved activities. Pursuant to the prohibitions of the Federal conflict of interest statute (18 U.S.C. § 208) and OGE regulations, all employees who participate in outside activities are obligated to recuse themselves, in other words disqualify themselves, from any official duty matters that may create an actual conflict of interest or an appearance of loss of impartiality in the performance of official duties.<sup>25</sup> However, ethics officials generally leave recusals to employees to carry out. Recent OGE guidance suggests that recusals can help to prevent conflicts of interest from arising.<sup>26</sup>

It is unclear what NIH's expectations with regard to written recusals are. The NIH Manual continues to call for written recusals in all cases.<sup>27</sup> However, NIH officials have indicated that recusals are not necessarily required in writing. All employees participating in outside activities receive two forms, the “Notice to Applicants for Prior Approval of Outside Activities” and the “Excerpts from the Standards of Ethical

Conduct for Employees of the Executive Branch and the Department of Health and Human Services Supplemental Agency Ethics Regulations,” which mention the expectation that employees must recuse themselves, but do not include further details.

Although ethics officials at 28 of the 30 institutes indicated that when they require recusals they require them in writing, ethics officials at only 8 of these institutes indicated that they always or often require recusals for outside activities. Only four institutes mention the need for recusals in their written procedures. Written recusals are important because they inform supervisors and coworkers of potentials for conflicts of interest and thereby help to prevent those conflicts from arising.

Ethics officials at five institutes indicated that they have no mechanisms for determining whether or not recusals are being observed, and ethics officials at other institutes rely on oversight by supervisors, verbal reminders, and the annual review of financial disclosure statements to ensure that employees are observing recusals.

#### **Inadequate notification of supervisors**

Nine institutes do not routinely notify employees’ supervisors of final decisions on requests, and four others notify supervisors only of disapproved requests. Although employees’ supervisors are required to review and sign off on outside activity requests before sending them to the appropriate DEC, they are frequently not aware of the final approval decisions made by the DECs. When supervisors are unaware of ongoing outside activities, they may not be able to monitor employees’ assignments to avoid conflicts of interest. However, NIH ethics staff commented that supervisors typically assume that all outside activity requests are approved unless they hear otherwise.

#### **Inadequate followup of ongoing outside activities**

Six institutes do not follow up on ongoing outside activities to determine whether the nature and time commitments of activities are in line with the specifications of the requests, or whether ethics rules are being observed. Although ethics officials at 22 institutes stated that they perform varying levels of followup, ethics officials at only 14 institutes said that they review outside activities annually.<sup>28</sup> Six institutes mention the importance of annual review for ongoing activities in their written procedures.<sup>29</sup>

It used to be that NIH required employees to annually submit the HHS-521 form, which collects updated information on ongoing outside activities, for all ongoing activities. The requirement for followup still

exists in the NIH manual.<sup>30</sup> At the time of this report, filing of the HHS-521 was no longer required. However, the February 2005 interim final rule stipulates that employees who engage in outside activities must file annual reports on their activities.<sup>31</sup>

OGE also found that followup of outside activities was problematic. None of the four institutes it examined appeared to be conducting followup consistently.<sup>32</sup> OGE found examples of institutes following up only once, at sporadic intervals over the course of a multiyear activity, or not at all.

### **Varying levels of staffing and training**

Ethics work is a collateral duty for about three-quarters of institute ethics officials, and only two institutes have full-time DEC's. The DEC's report spending 27 percent of their time on ethics issues, on average, and other key ethics staff reported spending an average of 59 percent of their time on ethics issues.

Ethics officials at 14 institutes cited staffing as a major or moderate challenge. Although it may be efficient for ethics staff to perform their ethics function as a collateral duty, this arrangement may make it difficult for ethics officials to cultivate the set of skills and experience necessary for handling outside activities, especially at smaller institutes that receive fewer requests. In addition, when ethics offices are understaffed, ethics officials may have less time to train employees.

Ethics officials at 18 institutes reported providing no training on outside activities specifically geared toward supervisors. Currently, there is no requirement for supervisor training that addresses the review of outside activities. However, in 2004 NIH distributed to supervisors a memorandum that provided guidance on reviewing outside activities.<sup>33</sup>

Training supervisors is crucial to ensuring that they understand their role in the outside activity approval process and vet requests adequately. Ethics officials at 12 institutes noted that insufficient training of supervisors posed a major or moderate challenge in the outside activity approval process, and 1 official said that supervisors are currently "flying blind" with regard to their outside activities duties.

Moreover, ethics officials at 11 institutes noted that insufficient training for employees posed a major or moderate challenge in the outside activity approval process. Currently, there is no requirement for annual ethics training for all employees. Annual ethics training is required for employees who file financial disclosure reports, as well as for other

employees designated by institute directors or DECs.<sup>34</sup> This training is generally done through a computer-based module and includes one section on outside activities and official duties. Face-to-face training typically happens once every 3 years, although several ethics officials noted opportunities for informal face-to-face training exist whenever they answer employees' questions. NIH required all employees to attend face-to-face training in 2004, but there is no requirement for annual training.

**These vulnerabilities may have led to possible violations of ethics rules**

We conducted this review prior to February 2005, when HHS issued an interim final rule that placed several new restrictions on the types of outside activities in which NIH employees are allowed to participate. Our review, therefore, only addresses activities that may have been inappropriate under the previous version of the regulations. The new regulations impose substantially greater restrictions on the types of activities that are appropriate for NIH employees.

Determining whether any outside activity adhered to the regulations involved a judgment call on our part. To minimize subjectivity, two reviewers independently reviewed each outside activity. A final reviewer was consulted to resolve cases in which the two initial reviewers disagreed.

Our review included all available NIH documentation regarding these activities. However, these documents do not necessarily include all the facts known to or considered by the NIH ethics reviewers at the time of their reviews. Ethics officials indicated to us that they often do additional research to get information about proposed activities.

In no instance was the documentation we reviewed adequate for us to make a definitive determination regarding whether an activity was appropriate. As demonstrated above, the information contained in the documentation for outside activity requests is often inadequate to make determinations. Therefore, we cannot state with absolute certainty that any activity was or was not allowable. Instead, we made one of three determinations for each activity: (1) appears to be allowable, (2) appears not to be allowable, and (3) cannot determine.

In cases for which the documentation did not suggest any violation of the regulations, our reviewers identified activities as "appears to be allowable," even if more information would be necessary to definitively determine that they were in fact allowable. Our reviewers only identified an activity as "appears *not* to be allowable" if the

documentation suggested a violation of the regulations. Finally, our reviewers identified activities as “cannot be determined” when the information available was so incomplete that they were unable to make a determination, or when the information raised concerns that the activity may have violated the regulations.

Ultimately, our reviewers could not determine the appropriateness of eight activities, and they also determined that two of the activities appeared to violate regulations. However, it is quite possible that, due to the approach taken in this review, we have underestimated the number of activities that should not have been approved. Inadequate documentation for outside activities can, intentionally or unintentionally, hide potential violations. If ethics officials conduct additional research on requests, they may uncover and resolve those potential problems before they become violations, but this may not happen in every case.

Our reviewers were unable to make determinations on the appropriateness of eight activities; it was unclear whether or not these activities may have posed a variety of potential violations. In some cases, it was unclear whether activities violated 5 CFR § 2635.802, which prohibits employees from engaging in outside activities that conflict with their official duties. Other activities appeared to potentially violate various stipulations of the NIH Manual. In some instances, it was unclear whether employees had received compensation for outside activities that related to their official duties. In other cases, it was unclear whether employees had used Government time or facilities to conduct outside activities. In still other cases, it was unclear whether employees had been properly recused from official duties that may have related to their outside activities. NIH reviewed these activities and determined that no violations had occurred.

The two outside activities that appeared not to be allowable may have violated 5 CFR § 5501.106(c)(1) of the HHS supplemental standards, which prohibits employees from providing consultative or professional services for compensation to assist in the preparation of any grant application intended for submission to HHS.<sup>35</sup> We referred these two cases to NIH for further review and copied the HHS DAEO. NIH reviewed both of these outside activities and agreed that they appeared to violate HHS supplemental regulations and therefore should not have been approved. NIH also reported that the employees who performed these activities had disclosed all relevant details to their DEC.<sup>36</sup>



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HHS and NIH recognize the importance of reviewing outside activities and have proposed several major changes to NIH's process for reviewing outside activities. (See Appendix C for a list of these initiatives.) Most notably, in February 2005, HHS issued an interim final rule that established new requirements for outside activities of NIH employees, as well as of other Federal employees.<sup>37</sup> The interim final rule addresses many of the vulnerabilities identified in this report.

The changes made by HHS and NIH reflect a commitment to addressing concerns regarding outside activities, and these changes appear to be moving in the right direction. We encourage HHS and NIH to continue their efforts to improve the NIH ethics program.

We offer the following recommendations to NIH on how to improve its review process for outside activities. (For lists of recommendations offered by OGE and the NIH blue ribbon panel, see Appendixes D and E, respectively.)

### **Improve the quality and extent of information for outside activities**

#### ***Require all employees to submit additional details on the nature of their proposed outside activities and their current official duties.***

Determining whether an outside activity is appropriate or whether it conflicts or overlaps with an employee's job duties depends on the employee's specific job duties and the nature of the outside activity. In 2005, HHS revised the HHS-520 to ensure that it provides substantive information.<sup>38</sup> We recommend that NIH amend its NIH Manual to require that several additional pieces of information be submitted for all outside activity requests. NIH should require:

- Statements, written by employees, that carefully, accurately, and substantively describe the work that will be performed for outside entities, and also describe the differences between outside activities and official duties. The interim final rule calls for supervisors to prepare statements “. . . addressing the extent to which the employee's duties are related to the proposed outside activity . . . .”<sup>39</sup>
- Detailed descriptions of employees' current job-related activities, in addition to copies of their position descriptions, to accompany all outside activity requests. Position descriptions are often vague and lack information on specific research projects or organizations that employees work with as part of their official duties. A list of

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employees' specific job duties would help reviewers in making decisions about appropriateness. This information would be especially valuable for ethics officials, who may not always be fully aware of the scope of employees' work. NIH has already begun to supplement request packets with employees' current publications and performance plans. The interim final rule requires employees to submit additional information about their official duties and any relationships between their official duties and outside activities.<sup>40</sup>

- Written letters of invitation to accompany all requests for approval. These letters can provide important information on the sponsoring organization, the location of the activity, and the nature of the activity.
- All consulting contracts and other confidentiality agreements to be submitted with outside activity requests, when applicable. These agreements can provide important information on the nature of proposed activities. We recognize that Government lawyers cannot provide personal legal advice to employees who are requesting approval for outside activities. Therefore, we recommend that these contracts be used as tools to provide additional information on the type and scope of work in which employees will be engaging with outside entities. If reviewers find that contract terms violate regulation or policy, activities should be disapproved. However, Government lawyers should not negotiate contract terms on behalf of NIH employees.

*Ensure that employees fill out their outside activity requests completely.* We found that not only were required forms incomplete, but also answers were sometimes too vague to be meaningful. To assist employees in filling out these forms properly, NIH could develop a standardized checklist for employees to ensure that all proper documentation is submitted. This type of checklist would serve as an aid in filling out and gathering forms and would help to verify that all appropriate forms and questions are completed. The checklist's use should be limited to ensuring that forms are administratively complete; it should not be used to determine the appropriateness of any activity.

*Ensure that institutes cross-check financial disclosure forms with employees' outside activities records for the previous year.* We found that outside activities were not always properly disclosed, as required by OGE regulations, on the applicable financial statements.<sup>41</sup> Ensuring disclosure

on these forms promotes transparency in employees' outside affiliations and earnings and makes the employees publicly accountable for avoiding real or apparent conflicts of interest. NIH should make this requirement more explicit in its NIH Manual.

**Address the inadequacies in the review process for outside activities**

Currently, institutes have differing procedures for reviewing outside activity requests. The following recommendations serve to address the variation that currently exists across institutes in the review process for outside activity requests.

Ensure that institutes approve outside activities before their scheduled start dates. HHS and OGE regulations, as well as the NIH Manual, require that all approvals occur prior to outside activities' scheduled start dates.<sup>42</sup> However, we found that some outside activities are being approved after the start dates provided on request forms. NIH should reemphasize its expectation that institutes comply with these regulations and policies and ensure that institutes are in compliance.

It is important for all institutes to continue to collect information when employees come forward to disclose outside activities after the fact, as doing so provides a record of employees' noncompliance and the nature of activities conducted. However, this does not mean that activities should necessarily be approved when they are disclosed after they have begun. In fact, if ethics officials discover that completed outside activities are inappropriate, the DEC and/or supervisor should take appropriate disciplinary action (e.g., counseling, verbal or written reprimands, requiring the employee to return any compensation, prohibiting participation in future outside activities, and, in the most extreme circumstances, removing the employee).

To help ensure that reviewers have adequate time to review requests prior to their start dates, NIH should consider amending its NIH Manual to establish an appropriate timeframe for the submission of requests for outside activities. This timeframe should allow adequate time for supervisors and ethics officials to conduct their reviews and follow up with the employees, if necessary, for clarification. We recognize that such a timeline may not always be feasible, but we encourage NIH to use deadlines whenever possible.

Require recusals, if needed, to be made in writing and disseminated to immediate supervisors and other key personnel for all outside activities that are related to employees' official duties. Regulations do not require recusals to be in writing, although NIH policy appears to require

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written recusals.<sup>43</sup> Recusals are protective of employees who participate in outside activities, as they allow for the establishment of screening and gate-keeping practices that help to ensure that employees do not encounter conflicts between their official duties and outside activities.<sup>44</sup> Having recusals in writing is important because recusals inform supervisors and subordinates of disqualifications and their scopes. Recusals also serve as points of accountability. Supervisors who are aware of recusals can work to ensure that employees meet their recusal obligations. NIH's blue ribbon panel recommended that written recusals be submitted to immediate supervisors.<sup>45</sup>

We recognize that if recusals are very widely disseminated, there are implications for employee privacy. However, at the very least, employees' immediate supervisors should be aware of any recusals. Supervisors can serve as gatekeepers who ensure that information implicated in employees' recusals does not reach them.

*Ensure that ethics officials notify supervisors of all approvals and disapprovals.* We found that supervisors were not always notified of the final decisions on outside activity requests, especially for activities that were approved. It is important for the integrity of the process that all relevant parties are informed of final decisions, regardless of outcome. Supervisors can play an important role in ensuring that their employees' work continues to remain free of conflicts, even after activities are approved, as job duties change over time. NIH has already issued a training memorandum for supervisors and has added the ethics function to the performance plans of all supervisors.<sup>46</sup>

*Ensure annual followup of ongoing outside activities.* We found that not all institutes are conducting annual followup of ongoing outside activities. Following up on continuing outside activities is important because over time job duties and the nature of outside activities can change and new conflicts can arise. We recommend that NIH reestablish the expectation, already set forth in the NIH Manual, that information on continuing activities be collected on an annual basis.

The NIH blue ribbon panel also recommended annual followup of ongoing outside activities.<sup>47</sup> OGE recommended that NIH either improve its procedures for collecting updated information or eliminate the requirement altogether.<sup>48</sup> The interim final rule calls for employees to submit annual reports on any ongoing outside activities.<sup>49</sup>

*Enhance training related to outside activities.* Existing OGE regulations and the NIH Manual require annual ethics training for

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those employees who file financial disclosure forms, but not for all employees.<sup>50</sup> We recommend that NIH require all employees, regardless of whether they file financial disclosure forms, to attend annual ethics training that covers outside activities. NIH has taken an important first step by providing ethics training to all of its employees in 2004, and we encourage NIH to continue this into the future.

NIH's blue ribbon panel also recommended that NIH enhance its training program. It recommended that NIH disseminate user-friendly documents to explain ethics rules in straightforward language. It also recommended that NIH issue regular agency-side reports on anonymous case studies and general issues related to outside activities to help foster a common understanding of the ethics rules.<sup>51</sup>

NIH should require all supervisors to receive training on how to review outside activity requests. Ethics officials commented that a lack of training for supervisors posed a significant challenge. Supervisors play a critical role in the review process, and therefore they should know how to conduct these reviews effectively. NIH has already taken important first steps toward holding supervisors more accountable by adding their ethics functions to their performance plans and by issuing a memorandum to supervisors that elaborated on how to review outside activity requests. Ethics training for supervisors could be accomplished by modifying existing Web-based training modules or videos.

NIH's blue ribbon panel called for additional training for supervisors, but not specifically regarding the review of outside activities.<sup>52</sup>

*Consider centralizing some or all aspects of the review process for outside activities.* NIH is in part moving in this direction with the implementation of its NIH Ethics Advisory Committee (NEAC), a group comprised of senior employees from across NIH that reviews certain outside activity requests.<sup>53</sup> NIH could centralize several facets of the process for outside activities, including:

- Standardized criteria and procedures;
- Training for ethics officials, supervisors, and employees;
- Audits of prior outside activity request reviews; and
- Decisionmaking regarding the approval of outside activities.

We recognize that institutes vary in size and mission and that taking steps toward centralization may be challenging to implement. Centralization may involve removing ethics officials from the

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institutes. Ethics officials at several institutes told us that by being easily accessible to employees, they are able to better monitor employees' outside activities. Furthermore, the mere presence of ethics offices in the institutes serves as a reminder to employees that ethics play an important role in the day-to-day business of NIH.

However, centralization could also offer several important advantages. First and foremost, it would allow NIH to develop a cadre of full-time ethics officials who, over time, could develop expertise in all ethics matters, including the review of outside activities. Currently, many ethics officials perform ethics functions as a collateral duty. Centralization could help ensure the independence of the decisionmaking process, since ethics officials would be more removed from the employees in the institutes. No longer would ethics officials be making decisions regarding their immediate colleagues.

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### AGENCY COMMENTS

NIH concurred with our findings and recommendations. However, it indicated a need for caution regarding written recusals for outside activities in certain circumstances. Further, NIH noted that it has already taken many steps to address the vulnerabilities identified in this report and has further initiatives planned.

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### OIG RESPONSE

We appreciate NIH's comments and the steps that NIH has taken and has planned to address vulnerabilities in its review process for outside activities.

In response to NIH's concerns about recusals, we reiterate that written recusals, when needed, are protective of employees who are participating in outside activities because they allow for the establishment of screening and gate-keeping practices that help to ensure employees do not encounter conflicts between their official duties and outside activities. Thereby, they can help prevent conflicts of interest from arising. Recent OGE guidance also suggests that recusals can help to prevent conflicts from arising.<sup>54</sup>

Finally, based on the revised HHS-520 form released by HHS in April 2005, we made minor edits to our recommendation concerning the quality and extent of information that NIH collects for outside activities.

▶ A G E N C Y C O M M E N T S



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Institutes of Health  
Bethesda, Maryland 20892

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MAY 23 2005

TO: Daniel R. Levinson  
Acting Inspector General

FROM: Director  
National Institutes of Health

SUBJECT: Office of Inspector General Draft Report "Outside Activities of  
Senior-Level NIH Employees," OEI-01-04-00150

We appreciate the opportunity to review and comment on this draft report. Please see our comments on the attached pages.

In general, we concur with your findings, conclusions, and recommendations. As noted in your report and elucidated in our response, we have taken significant steps to address the identified vulnerabilities, and we have implemented several corrective actions.

Should your staff have any questions, please ask them to contact Ms. Holli Beckerman Jaffe, Director, NIH Ethics Office, at 301-402-6628.

Again, thank you for the opportunity to review and comment.

Elias A. Zerhouni, M.D.

Attachment

**Response of the National Institutes of Health (NIH) to the Office of  
Inspector General (OIG) Draft Report, "Outside Activities of Senior-Level  
NIH Employees, OEI-01-04-00150, March 31, 2005**

**Recommendations to improve the quality and extent of information for outside activities.**

OIG Recommendation:

1. Require all employees to submit additional details on the nature of their outside activities and their current official duties.

NIH Response:

We concur. In the new supplemental regulations, HHS revised the requirement for outside activity approval. For requests for prior approval to engage in an outside activity, HHS now requires the submission of additional information such as: a description of how the employee's official duties will affect the interests of the person for whom the proposed activity will be performed; and--for activities involving teaching, speaking, or writing--a syllabus, outline, summary, synopsis, draft or similar description of the content and subject matter involved in the course, speech, or written product (including, if available, a copy of the text of any speech). See 5 C.F.R. § 5501.106 (d)(3)(ii).

Furthermore, HHS issued a revised Form 520 which requires an employee to include the following information in his or her package: (1) a discussion of the employee's official duties, including a description of any of the employee's official duty assignments that involve the outside employer; and (2) documentation of supervisory review, which must include a description of the extent to which the employee's official duties are related to the proposed outside activity. While the regulations do not specifically require submission of written letters of invitation or copies of consulting contracts and confidentiality agreements,<sup>1</sup> an employee is required to describe fully the nature of the proposed outside activity, including a full description of the specific duties or services to be performed. It is our experience that employees often voluntarily include letters of invitation. We believe that implementing the new regulations and using the corresponding approval forms meet and fulfill the intent of this recommendation and also replace the need for the unnumbered supplemental form.

In addition to the written submission required of the employee, NIH's internal review process adds significantly to information that will be considered with respect to an

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<sup>1</sup> We note that NIH Deputy Ethics Counselors and, on request, HHS OGC used to review consulting contracts and confidentiality agreements for employees engaged in outside activities. However, it was determined that since employees were participating in these activities in their private, non-governmental capacities, it was not appropriate for OGC to review these documents. OGC developed standard language for inclusion into consulting contracts and currently advises employees to seek private counsel for legal advice regarding these documents.

outside activity request. As noted in this draft report, NIH has begun to supplement request packets with employees' current publications, performance plans, or recent research projects. Also, for all senior OD Staff, IC Directors, and direct reports to IC Directors, these packets will be reviewed by the NIH Ethics Advisory Committee (NEAC), which is composed of a broad range of senior employees. Often, a member personally knows of the requesting employee's work and is able to inform the other members of such. This first-hand knowledge significantly adds to the thoroughness of the review.

As OIG evaluation staff is aware, the regulations were published in an interim final form. HHS stated in the preamble that it "intends to evaluate certain provisions in the rule, particularly on outside activities and financial holdings, within the next year." 70 Fed. Reg. 5543, 5543 (Feb. 3, 2005). We feel it is premature to re-issue the Outside Activity manual chapter until the rule is published as a final rule. This will occur after comments are fully considered. We will, of course, train employees on any new submission requirements.

OIG Recommendation:

2. Ensure that employees fill out the outside activity request forms completely.

NIH Response:

We concur. During a review of previously approved outside activities, the NIH noticed that many prior approval request packages were incomplete. We agree that that is an unacceptable situation and have already taken corrective actions. Both the Institute and Center (IC) ethics officials and the NIH Ethics Office review packages for completeness before the package is considered by the deciding official. If a deficiency is found, the package is either sent back to the employee with instructions regarding the missing information, or the ethics staff obtains the information. Only complete packages are put forward for decision.

OIG Recommendation:

3. Ensure that institutes check financial disclosure forms with the employees' records for outside activities for the previous year.

NIH Response:

We concur. Starting with the October 2004 Confidential Financial Disclosure Report filing cycle, we have reminded ethics officials to cross check outside activities and financial disclosure reports. Our review process requires that ethics officials confirm that all approved outside activities are properly disclosed on the reports (i.e., that both the position and income (if any) are reported) and, if a disclosure report contains entries for an outside activity, ensure that an approved outside activity packet is on file with the ethics office.

**Recommendations to address the inadequacies in the review process for outside activities.**

OIG Recommendation:

4. Ensure that ICs approve outside activities before the start date.

NIH Response:

We concur. We have taken several steps to ensure that the prior approval requirement will be adhered to throughout the NIH. First, employees have been told repeatedly that prior approval must be given before they may engage in an activity. Furthermore, they have been informed that it is their responsibility to secure such approval before starting the activity. Also, supervisors have been made aware of this requirement and we have added an ethics component to supervisors' performance plans. We believe this measure will help to increase compliance with the prior approval requirement.

Second, ethics officials and supervisors have been told that they cannot retroactively approve an outside activity request. If the activity start date reported on the HHS 520 has already past, the supervisor and/or ethics official either returns the request to the employee unsigned (they will then find out if the employee engaged in the activity without prior approval and take further appropriate action, if necessary), or approves the activity for any date after the approval date. Because activity requests often do not list true start dates, a new start date for the activity can be assigned after the approval date.

OIG Recommendation:

5. Require all recusals to be made in writing and disseminated to immediate supervisors for all outside activities.

NIH Response:

We concur in principle that supervisors should be made aware in writing if an employee cannot participate in a matter because to do so would create a real or apparent conflict. However, we want to be cautious of situations in which an outside activity with a particular company does not require disqualification from any matters because the employee is not currently assigned to any matters involving that company. As noted in previous meetings with OIG staff, a written recusal could give the false impression that a conflict exists where in fact it does not.

OIG Recommendation:

6. Ensure that ethics officials notify supervisors of all approvals and disapprovals.

NIH Response:

We concur and have already instituted this procedure. Supervisors are given copies of the prior approval form after the Deputy Ethics Counselor (DEC) has rendered his or her decision with respect to the request for approval.

OIG Recommendation:

7. Ensure annual follow-up of ongoing outside activities.

NIH Response:

We concur. Section 5502.102 of the interim final regulations requires employees to file an annual supplemental report of outside employment, the Form HHS 521, by February 28 of each year. (For this initial year, the report due date was extended to April 25, 2005, and then again to June 13, 2005.) Furthermore, the new rules only permit an activity to be approved for at most one year. 5 C.F.R. § 5501.106(d)(5). Between the annual report of outside employment and the relatively short approval period, we are confident that the NIH will have current information regarding both the employee's official duties and the outside activity in order to make an accurate decision with respect to the approval request.

OIG Recommendation:

8. Enhance training related to outside activities.

NIH Response:

We concur. As noted in this draft report, the Office of Government Ethics' government-wide regulations only require financial disclosure report filers to attend annual ethics training. Nevertheless, in 2004, the NIH mandated ethics training for all NIH employees, and incorporated into that training session was a discussion of outside activities. In February 2004, the NIH issued a memorandum to supervisors to give them guidance on what to consider when reviewing outside activity approval requests. We have discussed outside activities at training sessions on the new regulations and have issued a summary statement and a question-and-answer sheet on the new regulations. In addition, we will hold more classes on the new outside activity approval and annual reporting forms.

We appreciate that the outside activity portion of our ethics program has been at the center of many of the issues raised regarding our ethics program. We also know that comprehensive training of both employees and supervisors regarding outside activities provides assurances that identified issues will not again surface. The new regulations prohibit many of the activities that have been brought into question. These prohibitions may be re-evaluated, in whole or in part, but only after the NIH creates an adequate oversight system. Any new system will be coupled with an extensive training plan

because employees and supervisors need to be able to identify conflicts in order to properly manage them.

OIG Recommendation:

9. Consider centralizing some or all aspects of the review process for outside activities.

NIH Response:

We concur. In early 2004, the NIH DEC became the approving official for outside activity requests that fell within the NEAC's jurisdiction. The NEAC reviews and makes recommendations regarding activities submitted by all of NIH's senior employees, for those activities with pharmaceutical and biotechnology companies, and where compensation for the activity was greater than \$10,000 or paid with stock or stock options. The majority of the activity requests fall within these categories. Also, the NEAC's jurisdiction has been expanded since the interim final regulations were put into place. The NEAC now makes recommendations regarding exceptions to the new prohibitions. Hence, most of NIH's outside activities approval requests now undergo a centralized review process. Last, at the monthly DEC meetings (which since the new regulations were issued are now being held weekly), guidance is often issued to the IC ethics staff with respect to outside activities. Through these meetings, we are ensuring that consistent review of similar activities occurs.

5/19/05

▶ E N D N O T E S

- <sup>1</sup> Wilman, D. December 7, 2003. Stealth Merger: Drug Companies and Government Medical Research. The Los Angeles Times: A1, A32-33.
- <sup>2</sup> Of the six employees mentioned in the Los Angeles Time article on December 7, 2003, only one was included in our review.
- <sup>3</sup> 5 CFR Part 2635.
- <sup>4</sup> 5 CFR § 2635.801(c).
- <sup>5</sup> 5 CFR Part 5501.
- <sup>6</sup> 5 CFR § 5501.106(c). These requirements remain the same in the February 2005 interim final rule.
- <sup>7</sup> 70 Fed. Reg. 5,543, Feb. 3, 2005.
- <sup>8</sup> 5 CFR § 5501.106(d)(4). At the time this review was conducted, the regulation stipulated that: “Approval shall be granted unless it is determined that the outside employment or other outside activity is expected to involve conduct prohibited by statute or Federal regulation . . .” In the February 2005 interim final rule, the standard of approval is higher: “Approval shall be granted *only upon a determination* that the outside employment or other outside activity is not expected to involve conduct prohibited by statute or Federal regulation . . .” [emphasis added].
- <sup>9</sup> NIH Manual 2300-735-4–Outside Work and Related Activities with Outside Organizations, release date February 17, 1998.
- <sup>10</sup> NIH Manual 2300-735-4–Outside Work and Related Activities with Outside Organizations, release date February 17, 1998, pp. 7-8.
- <sup>11</sup> Department of Health & Human Services memorandum to Deputy Ethics Counselors and Ethics Contacts, January 27, 2004.
- <sup>12</sup> NIH Manual 2300-735-4–Outside Work and Related Activities with Outside Organizations, release date February 17, 1998.

<sup>13</sup> 5 CFR § 2634.202.

<sup>14</sup> We first determined that 319 of the 355 outside activities in our population had been approved by NIH. All remaining analysis was performed on the 319 approved activities.

<sup>15</sup> 5 CFR § 5501.106(d)(4). At the time this review was conducted, the regulation stipulated that: “Approval shall be granted unless it is determined that the outside employment or other outside activity is expected to involve conduct prohibited by statute or Federal regulation . . . .” In the February 2005 interim final rule, the standard of approval is higher: “Approval shall be granted *only upon a determination* that the outside employment or other outside activity is not expected to involve conduct prohibited by statute or Federal regulation . . . .” [emphasis added].

<sup>16</sup> Prior to January 2004, employees were not required to report the amount of compensation on the HHS-520. Therefore, when possible, we obtained this information from annual public disclosure forms (for those employees required to file the SF-278) and from employees who voluntarily disclosed the amount of compensation on their HHS-520 or supporting documentation. We only obtained information from the SF-278 when the employee reported the exact amount of compensation, rather than a range.

In January 2004, HHS required compensation information for all activities to be provided on the HHS-520 form. Department of Health & Human Services memorandum to Deputy Ethics Counselors and Ethics Contacts, January 27, 2004.

Furthermore, the interim final rule calls for disclosure of compensation information for all outside activity requests. 5 CFR § 5501.106(d)(3)(ii).

<sup>17</sup> Forty approved outside activity requests for senior-level employees between 2001 and 2003 did not require unnumbered supplemental forms.

<sup>18</sup> The required statement reads: “Notwithstanding any other provisions of this agreement, the rights of Consultant’s employer, the National Institutes of Health (NIH), shall not be abrogated by any commitment

or obligation Consultant has incurred hereunder. Company recognizes that as a Federal employee, Consultant is bound by Federal laws, regulations and policies, including those governing conflicts of interest, standards of conduct, and intellectual property, including 45 C.F.R. Part 7.”

<sup>19</sup> “Performing ‘due diligence’ that is appropriate to the circumstances should be a standard operating procedure. Conduct Internet searches, make phone calls to the entities involved, talk to the employees, elicit responses from them . . . .” Department of Health & Human Services memorandum to Deputy Ethics Counselors and Ethics Contacts, August 13, 2004, p. 1.

<sup>20</sup> Although senior-level employees submitted outside activity requests for 319 outside activities during our timeframe, only 290 of those activities actually had start dates between January 1, 2001, and December 31, 2003, which would require disclosure on the SF-278 or OGE-450 for those years. However, we reported that 188 outside activities should have been disclosed on the SF-278 forms in those 3 years and 141 outside activities should have been disclosed on the OGE-450 forms; this adds up to 329 outside activities. The explanation for the excess is that the 329 outside activities include 43 activities that senior-level employees reported on both the SF-278 and OGE-450 in a given year (typically because a change in their employment status or the equal classification determination required that they switch from confidential filer to public filer within the course of a year) and that were therefore double-counted. The 329 figure also does not account for 4 outside activities for which employees were not required to file either the SF-278 or the OGE-450 in the year in which they performed the outside activity (because their employment status was not in one of the categories that required filing an annual disclosure form).

<sup>21</sup> Many of the senior-level employees who were required to file the SF-278 as of February 2004 had been required to file the OGE-450 at some point between 2001 and 2003.

<sup>22</sup> 5 CFR § 5501.106(d). This expectation remains the same in the February 2005 interim final rule.

- <sup>23</sup> U.S. Office of Government Ethics, memorandum to the Director of NIH, July 26, 2004, p. 9.
- <sup>24</sup> On average, it took ethics staff 17 calendar days from the time senior-level employees submitted their outside activity requests to final approval. Senior-level employees submitted 14 outside activity requests 17 days or less prior to the start of the activity between 2001 and 2003.
- <sup>25</sup> 5 CFR § 2635, Subpart D (for conflicting financial interests) and 5 CFR § 2635, Subpart E (for appearances of a loss of impartiality). The exception to the recusal obligation is when an employee is granted a waiver or authorization.
- <sup>26</sup> U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials, General Counsels and Inspectors General, June 1, 2004, p. 1.
- <sup>27</sup> The NIH Manual states that “. . . [a] disqualified employee [should sign] a written statement reflecting the scope of the disqualification and the precise nature of the conflicting interest or activity. The disqualification should also identify the individual who will deal with the matters from which the employee is disqualified.” NIH Manual 2300-275-1–Avoiding Conflicts of Interest, release date June 19, 1998, p. 15.
- <sup>28</sup> The other eight institutes indicated that they rely on annual financial disclosure reports to verify whether activities are ongoing or have ended, but not all employees are required to file annual disclosures, and those who do file may not always disclose their outside activities.
- <sup>29</sup> One of these six also provides specific instructions about the tracking system that the institute uses to monitor ongoing activities and the timeframe for the annual review.
- <sup>30</sup> NIH Manual 2300-735-4–Outside Work and Related Activities with Outside Organizations, release date February 17, 1998, p. 11.
- <sup>31</sup> 5 CFR § 5502.102.

- <sup>32</sup> U.S. Office of Government Ethics memorandum to the Director of NIH, July 26, 2004, p. 9.
- <sup>33</sup> National Institutes of Health memorandum to Supervisors, April 12, 2004.
- <sup>34</sup> 5 CFR § 2638.704(a) for public filers; 5 CFR § 2638.705(a)(3) for confidential filers.
- <sup>35</sup> This prohibition remains the same in the February 2005 interim final rule.
- <sup>36</sup> At the time of NIH's review, both of these employees were retired from Federal service.
- <sup>37</sup> 70 Fed. Reg. 5,543, Feb. 3, 2005.
- <sup>38</sup> Department of Health & Human Services memorandum to the Acting Director of OGE, October 22, 2004.
- <sup>39</sup> 5 CFR § 5501.106(d)(3).
- <sup>40</sup> 5 CFR § 5501.106(d)(3).
- <sup>41</sup> 5 CFR Part 2634.
- <sup>42</sup> 5 CFR § 2635.803; 5 CFR § 5501.106(d); NIH Manual 2300-735-4—Outside Work and Related Activities with Outside Organizations, release date February 17, 1998, p. 10. The requirement for prior approval remains in the February 2005 interim final rule.
- <sup>43</sup> NIH Manual 2300-275-1—Avoiding Conflicts of Interest, release date June 19, 1998, p. 15.
- <sup>44</sup> U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials, General Counsels and Inspectors General, June 1, 2004, pp. 1-2.
- <sup>45</sup> Blue Ribbon Panel Report on Conflict of Interest Policies, Report of the National Institutes of Health, June 22, 2004, p. 66.

- <sup>46</sup> National Institutes of Health, Department of Health & Human Services memorandum to Designated Agency Ethics Office, October 22, 2004, and National Institutes of Health, Department of Health & Human Services memorandum to Supervisors, February 16, 2004.
- <sup>47</sup> Blue Ribbon Panel Report on Conflict of Interest Policies, Report of the National Institutes of Health, June 22, 2004, p. 62.
- <sup>48</sup> U.S. Office of Government Ethics memorandum to the Director of NIH, July 26, 2004, p. 19.
- <sup>49</sup> 5 CFR § 5502.102 and 5 CFR § 5502.103.
- <sup>50</sup> 5 CFR § 2638 Subpart G, February 14, 2000, and NIH Manual 2300-735-1, p. 20.
- <sup>51</sup> Blue Ribbon Panel Report on Conflict of Interest Policies, Report of the National Institutes of Health, June 22, 2004, p. 67.
- <sup>52</sup> Blue Ribbon Panel Report on Conflict of Interest Policies, Report of the National Institutes of Health, June 22, 2004, p. 65.
- <sup>53</sup> In its recent report, OGE also raised concerns regarding the appropriateness of NEAC since it is not comprised of ethics officials. OGE recommended that the HHS DAEO establish a set of clear guidelines to help NEAC determine if an activity is allowable, and that the NEAC not have final approving authority over outside activity requests. U.S. Office of Government Ethics memorandum to the Director of NIH, July 26, 2004, p. 11.
- <sup>54</sup> U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials, General Counsels and Inspectors General, June 1, 2004, p. 1.

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## METHODOLOGY

We conducted this review prior to February 2005, when HHS issued an interim final rule that placed several new restrictions on the types of outside activities in which NIH employees are allowed to participate.

### **File reviews**

We conducted a retrospective review of all outside activity requests that senior-level employees submitted to NIH ethics officials between January 1, 2001, and December 31, 2003. We defined senior-level employees to be those employees who were required to file SF-278 public financial disclosure forms as of February 2004. NIH provided us with a list of 176 employees who met that criterion. This group of employees included, but was not limited to: (1) institute directors, (2) institute deputy directors, (3) institute scientific directors, and (4) institute clinical directors. We excluded from our review the Director of NIH and the Director of the National Cancer Institute, both of whom are presidential appointees and as such are overseen by ethics officials outside of NIH. Therefore, our final population was 174 employees.

We focused our review on senior-level employees because these employees may be most likely to engage in outside activities that involve substantial influence and compensation, and therefore they may pose the greatest risk for NIH in terms of potential conflicts of interest. However, restricting our review to employees in this group presents some limitations. During 2004, while this review was taking place, NIH designated over 600 additional employees as public financial disclosure filers to create consistency across NIH in terms of the categories of positions that require public financial disclosure. Additionally, it may be the case that employees who do not hold senior-level positions are more likely to engage in high-risk, high-compensation outside activities.

We requested outside activity request forms (HHS-520s) and supporting documentation for all outside activities performed by these 174 senior-level employees during the timeframe of our review.

Supporting documentation that we received included:

- NIH Unnumbered Supplemental Information Forms to Accompany the HHS-520;
- Supplemental Information to the HHS-520 Forms (NIH-2657);
- Written waivers, authorizations, and recusals;

- Public Financial Disclosure Reports (SF-278);
- Confidential Financial Disclosure Reports (OGE-450);
- Correspondence;
- Reviewer notes;
- Position descriptions;
- Letters of invitation;
- Consulting contracts; and
- Confidentiality agreements.

We received 355 outside activity requests from NIH. We considered requests to be within the timeframe of our review if the dates on which employees signed the requests fell between January 1, 2001, and December 31, 2003. Employees' signature dates served as proxies, as the dates on which forms were submitted were typically not documented in the files. We did not assess whether employees conducted any additional outside activities between 2001 and 2003 that were not reported in the requests we reviewed, which represents a potential limitation of our review. However, the responsibility for submitting outside activity requests rests with employees.

Our review included initial requests, revised requests, and renewed requests. An initial request occurs when an employee submits an HHS-520 for the first time for a particular activity. A revised request would be submitted if an employee had to change information on an initial request. A renewed request is submitted if an activity continues beyond the end date originally specified in the initial request. Our population of approved outside activities included 249 initial requests, 53 renewals, 6 revised requests, and 11 outside activity requests for which request types were not specified.

Because we intended to analyze all outside activity requests submitted between 2001 and 2003, we needed to include all types of requests. However, we may have double-counted some activities if they were approved as initial requests and later resubmitted and approved as revised or renewed requests. At most, we estimate that we may have counted 17 outside activities in our population more than once because employees may have submitted 1 or more renewals for already approved activities between 2001 and 2003. Based on the documentation we received from NIH, we cannot verify whether these 17 outside activity

requests are actual duplicates. However, none of the revised requests appeared to match with initial requests in our timeframe.

Our file review included three methodologies: (1) a descriptive review, (2) a completeness review, and (3) a compliance review.

*Descriptive review.* For each outside activity request in our timeframe, we extracted the details of the outside activity from the HHS-520 and supporting documents into a database. If the amount of compensation for the activity was listed on the HHS-520, the applicable financial disclosure form, or any other documentation in the file, we recorded that. Finally, we noted any additional documentation that the employee submitted as part of the outside activity request.

After entering the data into a Microsoft® Access® database, we verified the data accuracy for a random sample of 10 percent of the 355 outside activity requests in the database. Because we identified data entry errors regarding the start and end dates of outside activities and the types of compensation received for activities, we subsequently reviewed the accuracy of those data fields for all records in our database.

We tallied the number and nature of outside activities overall, as well as by year, activity type, compensation type, institute, employee type, and time commitment.<sup>1</sup> (When employees provided estimated ranges for time commitments, we used the midpoints in our analysis.) We performed our analyses using SAS® version 8.0 (a statistical software package).

*Completeness review.* We calculated the extent to which forms were filled out completely and correctly. For each outside activity request in our timeframe, we documented in our database the dates on which the employee, reviewing official, and final approving official signed off on the outside activity request. We also recorded whether the employee had completed the unnumbered supplemental form and the NIH-2657, if applicable, and whether the employee had listed the outside activity on his or her financial disclosure form (SF-278 or OGE-450) for that year.

We counted the number of missing signatures, missing or incomplete supplemental forms, and missing outside activity disclosures on annual disclosure forms.

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<sup>1</sup> We first determined that 319 of the 355 outside activities in our population had been approved by NIH. All remaining analysis was performed on the 319 approved activities.

*Compliance review.* We reviewed all approved outside activity requests that senior-level employees submitted between January 1, 2001, and December 31, 2003, to determine whether activities complied with the pertinent requirements for avoiding conflict of interest.

We used the following statutes, regulations, and policies as our criteria:

- Federal ethics laws regarding conflict of interest (18 U.S.C. § 205, 18 U.S.C. § 208, and 18 U.S.C. § 209),
- Governmentwide Standards of Ethical Conduct for Employees of the Executive Branch (codified in 5 CFR § 2635),
- HHS Supplemental Standards of Ethical Conduct (codified in 5 CFR § 5501), and
- NIH Manual chapter on Outside Work and Related Activities with Outside Organizations (section 2300-735-4).

It is important to note that these criteria do not explicitly prohibit certain types of outside activities (e.g., consulting arrangements). Therefore, determining whether an outside activity adhered to the regulations involved a judgment call on our part. In order to minimize subjectivity, two reviewers used a standardized protocol to independently review each outside activity request and all supporting documentation. A final reviewer was consulted to resolve cases in which the two initial reviewers disagreed. A third reviewer was required for 92 outside activities. In the cases where the two initial reviewers agreed, no third reviewer was used.

Our review included all available NIH documentation regarding these activities. However, these documents do not necessarily include all facts known to or considered by NIH ethics reviewers at the time of their reviews. Ethics officials indicated to us that they often perform additional research to obtain information on proposed activities.

In no instance was the documentation we reviewed adequate for our reviewers to make a definitive determination regarding the appropriateness of any activity. As demonstrated in the *Vulnerabilities* section of this report, the information contained in the documentation for outside activity requests is often inadequate, which limits reviewers' abilities to make determinations on the appropriateness of proposed activities. Therefore, we could not state with absolute certainty that any activity was or was not allowable. Instead, we made one of three

determinations for each activity: (1) appears to be allowable, (2) appears not to be allowable, and (3) cannot determine.

In cases where the documentation contained enough information and did not appear to violate any regulations, our reviewers identified it as “appears to be allowable,” even if more information would have been necessary to definitively determine that the activity was in fact allowable. Our reviewers only identified an activity as “appears *not* to be allowable” if the documentation indicated a violation of the regulation. Finally, our reviewers identified activities as “cannot be determined” when the available information was so incomplete that they were unable to make a determination, or when the information raised concerns that the activity may have violated the regulations.

Ultimately, our reviewers could not determine the appropriateness of eight activities, and they determined that another two activities appeared to have violated the regulations. However, it is quite possible that, due to the approach taken in this review, we have underestimated the number of activities that should not have been approved.

Inadequate documentation for outside activities can, intentionally or unintentionally, hide potential violations. If ethics officials conduct additional research on requests, they may uncover and resolve those potential problems before they become violations, but this may not happen in every case.

In general, we did not seek additional information beyond what was provided in the files. For example, we did not speak with any employees or ethics officials at NIH or research the outside organizations involved in outside activities. As a result, an important limitation of this review is that we cannot comment on whether NIH ethics officials considered additional facts during their reviews of outside activity requests.

As part of our assessment, we recorded whether additional pieces of information would have been helpful in making determinations. These pieces of information included: (1) greater detail on the nature of an outside activity, (2) greater detail on the nature of an employee’s job duties, (3) greater detail regarding the difference between an outside activity and an employee’s job duties, (4) greater detail on the outside organization, and (5) whether the outside organization received or was in the process of negotiating NIH funding.

#### **Interviews with NIH ethics officials**

We interviewed the DEC’s and ethics staff they chose to include at all 27 institutes, the Office of Director, the Office of Research Services, and

the Office of Research Facilities Development and Operations. Additional staff included, but was not limited to, the ethics coordinator for the institute, the executive officer for the institute, and management analysts within the ethics office. Five institutes (Office of Research Services, Office of Research Facilities, National Institute on Aging, National Institute on Biomedical Imaging and Bioengineering, and Center for Information Technology) share an ethics coordinator and three of those (Office of Research Services, Office of Research Facilities, and Center for Information Technology) share a DEC; we conducted three interviews with these institutes, one with each of the DECs and the ethics coordinator.

Prior to each interview, we provided ethics officials with a preinterview questionnaire. This questionnaire captured the number of outside activity requests their institutes reviewed in calendar years 2001, 2002, and 2003, and the job duties of all ethics staff at their institutes.

We used a structured questionnaire to conduct the interviews. The questionnaire addressed: (1) institutes' procedures for reviewing outside activity requests; (2) the training that institutes provide to employees, supervisors, and ethics staff on outside activities; (3) institutes' approaches to enforcing ethics violations regarding outside activities; (4) challenges institutes face in reviewing outside activity requests; and (5) recommendations for improving the system for outside activities. We conducted all interviews by telephone.

We also spoke with staff in the NIH Ethics Office to learn of initiatives to improve the NIH process for outside activities that are planned or under way. Staff in the NIH Ethics Office served as a resource for clarifying our questions on NIH ethics policy throughout our review.

#### **Institute procedure review**

We requested operating procedures related to outside activities from all 27 institutes, the Office of Director, the Office of Research Services, and the Office of Research Facilities Development and Operations. NIH allows, but does not require, its institutes to develop written operating procedures for implementing NIH policies on outside activities. Nineteen institutes provided us with written procedures. These included: (1) standard operating procedures, (2) checklists, (3) routing slips, (4) Web site printouts, and (5) memoranda. We counted the number of institutes that maintained these documents and compared them to one another.

**NATURE OF OUTSIDE ACTIVITIES**

We conducted this review prior to February 2005, when HHS issued an interim final rule that placed several new restrictions on the types of outside activities in which NIH employees are allowed to participate.

**Forty percent of senior-level employees at NIH received approval for 319 outside activities between 2001 and 2003**

*Senior-level employees received approval for 90 percent of the outside activity requests they submitted.* Of the 174 senior-level employees at NIH, 78 requested approval for 355 outside activities between 2001 and 2003. (See Table 1 below.) NIH approved 319 of these outside activity requests for 69 senior-level employees.<sup>2</sup> The remaining outside activity requests were either disapproved, cancelled, conducted as part of the employee’s official duties, or did not have a final action documented.

<b>Table 1. NIH's Decisions Regarding Outside Activity Requests Submitted by Senior-Level Employees, 2001 - 2003.</b>		
<b>Final Actions Taken</b>	<b>Number of Outside Activity Requests</b>	<b>Percent of Outside Activity Requests</b>
Approved	319	90
No Final Action Specified	19	5
Cancelled	12	3
Conducted as Official Duty	3	1
Disapproved	2	1
<b>Totals</b>	<b>355</b>	<b>100</b>

Source: Office of Inspector General analysis of NIH data, 2005.

<sup>2</sup> For the period covered by this review, HHS supplemental regulations called for outside activity requests to be approved unless they clearly violated statute (5 CFR § 5501.106). The interim final rule calls for a higher standard of approval, where activities are only to be approved “. . . upon a determination that [activities are not] expected to involve conduct prohibited by statute or Federal regulation . . . .” Further, NIH employees often confer with ethics officials before formally submitting requests to ensure that their proposals are approvable.

An *approved* outside activity is an activity for which both the requesting employee's supervisor and the institute's DEC determined that it met the pertinent requirements and did not pose a potential conflict of interest. Approval allows the employee to conduct the activity.

*No final action specified* means that the DEC did not check the box on the HHS-520 that indicated whether the outside activity was approved or disapproved. Without a mark in that checkbox, we could not determine the status of the outside activity request.

A *cancelled* outside activity is an activity that was approved and then terminated before the end date designated on the outside activity request form. From the documentation in the employees' files we could not generally determine the dates of cancellation or whether decisions to cancel the activities were made by employees or ethics officials.

An activity was *conducted as an official duty* if, after being approved as an outside activity, an employee's supervisor or ethics official identified overlap between the employee's proposed outside activity and his or her current job duties that could pose a potential conflict of interest. In these cases, the employee converted the activity to an official duty. When an employee conducts an activity as an official duty, NIH excuses the employee from his or her job duties for the allotted time and covers the costs of travel. In return, the employee conducts the work as an NIH representative and receives no outside compensation.

Typically, when supervisors identify overlap between proposed outside activities and employees' official duties, they disapprove the requests and ask employees to request permission to perform the activities in their official capacities. However, this process was not followed in the activities we reviewed that were conducted as official duties.

A *disapproved* activity is one that the DEC did not consider to be allowable given the pertinent requirements. Between 2001 and 2003, NIH disapproved only two outside activity requests for the senior-level employees in our population. Both were disapproved because of overlap between the activities and the employees' official duties.

One disapproved request involved an employee who wished to give a speech to a foreign audience on aspects of disease distribution in the United States. The supervisor recommended approval for the activity, but the DEC ultimately disapproved the request, writing on the HHS-520: "After discussions with [the institute Deputy Director], we do not feel that the lecture to be delivered can be separated from your

official role . . . .” The DEC recommended resubmission for approval as an official duty.

The second disapproved request involved an employee who submitted a renewal request to continue serving on a scientific advisory board of an organization that raises funds and awards grants for scientific research. Although the employee had received approval for the outside activity in the past, the institute ethics official indicated that the activity appeared closely related to the employee’s research area and suggested that it instead be done as an official duty. The employee agreed to perform the activity as an official duty.

The distribution of employee submissions was virtually constant across the 3-year period. The number of employees who submitted 1 or more outside activity requests that were approved was 39 in 2001, 40 in 2002, and 41 in 2003.<sup>3</sup>

*Most senior-level employees participated in 1 or 2 outside activities, but a few participated in more than 20.* Fifty-seven percent of the sixty-nine senior-level employees participated in only one or two approved outside activities between 2001 and 2003. (See Table 2 on the following page.) However, 8 senior-level employees participated in 10 or more approved outside activities during this 3-year period, and 3 senior-level employees participated in 20 or more approved outside activities. The maximum was 37 approved outside activities for 1 employee.

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<sup>3</sup> If one were to sum up the 39 senior-level employees in 2001, 40 in 2002, and 41 in 2003, the total would add up to more than the 69 senior-level employees who submitted outside activity requests in that 3-year period. This is because senior-level employees may have submitted outside activity requests in two or more of the years in that period, meaning some employees are counted more than once. The distribution of approved outside activities is also virtually constant across the 3-year period. The 39 senior-level employees in 2001 accounted for 31 percent of all approved outside activities in our timeframe. The 40 employees in 2002 accounted for 37 percent of the approved outside activities in our timeframe. And the 41 employees in 2003 accounted for 32 percent of the approved outside activities in our timeframe.

<b>Table 2. Number of Approved Outside Activities for Senior-Level NIH Employees, 2001 - 2003.</b>		
<b>Number of Approved Activities</b>	<b>Number of Participating Employees</b>	<b>Percent of Participating Employees</b>
1	21	30
2	18	26
3	6	9
4	4	6
5	6	9
6	4	6
7	1	1
8	1	1
10	1	1
11	1	1
15	1	1
16	1	1
17	1	1
20	1	1
33	1	1
37	1	1
<b>Totals</b>	<b>69</b>	<b>*</b>

\* Column does not sum to 100 due to rounding.  
 Source: Office of Inspector General analysis of NIH data, 2005.

*Senior-level intramural employees accounted for 76 percent of the approved outside activities.* Intramural employees coordinate and conduct research within their institutes at NIH. Intramural senior-level employees comprise 39 percent of all senior-level employees at NIH. However, they accounted for more than half of the senior-level employees who received approval for outside activities between 2001 and 2003, and for more than three-quarters of the approved outside activities during this time. (See Table 3 below.)

<b>Table 3. Number of Approved Outside Activities for Senior-Level NIH Employees, by Employee Type, 2001 - 2003.</b>			
<b>Employee Types</b>	<b>Number of Approved Activities</b>	<b>Percent of Approved Activities</b>	<b>Number of Employees</b>
Intramural	243	76	40
Extramural	37	12	12
Other *	39	12	17
<b>Totals</b>	<b>319</b>	<b>100</b>	<b>69</b>

\* Includes institute directors and deputy directors, who are neither intramural nor extramural.  
 Source: Office of Inspector General analysis of NIH data, 2005.

OGE noted in its recent NIH ethics program review that “. . . the potential for conflicts among intramural researchers may be at least as great, if not greater . . .” than for extramural employees.<sup>4</sup> Extramural employees oversee and provide technical support for NIH-funded research at external institutions, which includes administering grants and contracts with outside entities. OGE further noted:

Many of the very consulting activities that have become the subject of public controversy have involved intramural researchers . . . Overall, it appears to us that intramural researchers are more likely to have official duties that directly involve drug companies—for example, cooperative research and development agreements or other arrangements with a particular company’s products – than do extramural officials.

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<sup>4</sup> U.S. Office of Government Ethics memorandum to the Director of NIH, July 26, 2004, p. 13.

OGE cautioned NIH against imposing less restrictive limits on intramural employees than extramural employees. However, these two groups of employees have different functions, have little contact within NIH, and may pose different kinds of risks in terms of conflicts of interest. Extramural employees may be more likely to pose risks when they engage in activities with universities and other potential or actual grantees. Intramural employees may be more likely to pose risks when they engage in activities where there is scientific overlap between their official, Government-sponsored research and the work they are performing for outside entities.

*Senior-level employees at three institutes accounted for 52 percent of the approved activities.* Senior-level employees at the National Institute of Mental Health participated in 77 approved outside activities between 2001 and 2003. Senior-level employees at the National Human Genome Research Institute participated in 45 approved outside activities, and senior-level employees at the National Heart, Lung, and Blood Institute participated in 44 approved outside activities. (See Table 4 on the following page.)

The primary explanation for the volume of approved outside activities at these three institutes seems to be that one employee at each institute was engaging in many outside activities over the 3-year period, thereby increasing the numbers for the institute as a whole. In addition, demand may be particularly high for certain types of scientific expertise in which these institutes specialize. Moreover, institutes with large numbers of employees may be likely to receive more outside activity requests than smaller institutes.<sup>5</sup>

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<sup>5</sup> The National Institute of Mental Health and the National Heart, Lung, and Blood Institute are two of the larger institutes at NIH.

**Table 4. Approved Outside Activities for Senior-Level NIH Employees, by Institute, 2001 - 2003.**

Institutes	Number of Approved Outside Activities	Percent of Approved Outside Activities	Number of Senior-Level Institute Employees Participating	Percent of Senior-Level Institute Employees Participating
National Institute of Mental Health	77	24	7	54
National Human Genome Research Institute	45	14	4	80
National Heart, Lung, and Blood Institute	44	14	9	56
National Institute of Neurological Disorders and Stroke	25	8	4	67
NIH Clinical Center	16	5	4	67
National Library of Medicine	16	5	4	44
National Institute on Drug Abuse	15	5	3	43
National Institute of Diabetes and Digestive and Kidney Diseases	12	4	3	60
National Cancer Institute	10	3	4	31
National Institute on Aging	9	3	4	50
National Institute of Child Health and Human Development	9	3	5	71
National Institute on Deafness and Other Communications Disorders	9	3	3	60
Center for Scientific Review	5	2	2	40
National Eye Institute	4	1	2	25
National Institute on Alcohol Abuse and Alcoholism	4	1	1	14
National Institute of Allergy and Infectious Diseases	4	1	1	25
National Institute of Environmental Health Sciences	4	1	3	60
National Center for Complementary and Alternative Medicine	3	1	1	50
Office of the Director *	3	1	2	12
National Center on Minority Health and Health Disparities	2	1	1	50
National Institute of Arthritis and Musculoskeletal and Skin Diseases	2	1	1	33
National Institute of Dental and Craniofacial Research	1	<1	1	17
Center for Information Technology	0	0	0	0
Fogarty International Center	0	0	0	0
National Center for Research Resources	0	0	0	0
National Institute of Biomedical Imaging and Bioengineering	0	0	0	0
National Institute of General Medical Sciences	0	0	0	0
National Institute of Nursing Research	0	0	0	0
<b>Totals</b>	<b>319</b>	<b>**</b>	<b>69</b>	<b>-</b>

\* Includes Office of Research Facilities and Office of Research Services.

\*\* Column does not sum to 100 due to rounding.

Source: Office of Inspector General analysis of NIH data, 2005.

**About half of these outside activities involved teaching or consulting and most were compensated**

*Fifty-three percent of the approved outside activities involved teaching or consulting.* Thirty-three percent (105) of the approved activities were for teaching/lecturing. (See Table 5 below.) Forty-four percent (46) of these teaching/lecturing activities were with universities. Of the 46 activities with universities, only 8 appeared to involve teaching regular classes. It is important that NIH review activities with universities carefully as NIH funds scientific research at these universities and certain outside activities may inappropriately influence the employee's or the agency's decisions with respect to future funding decisions. Extramural employees who work with universities may pose potential risks in terms of conflicts of interest because they may oversee university funding decisions. Other common venues for lecturing were hospitals (19 activities), industry (10 activities), professional societies (13 activities), and continuing education courses (9 activities).

<b>Table 5. Nature of Approved Outside Activities for Senior-Level NIH Employees, 2001 - 2003.</b>		
<b>Types of Outside Activities</b>	<b>Number of Approved Outside Activities</b>	<b>Percent of Approved Outside Activities</b>
Teaching/Lecturing	105	33
Consulting	63	20
Other *	51	16
Speaking	41	13
Serving on Advisory Boards **	29	9
Writing/Editing	19	6
Clinical/Private Practice	6	2
Consulting with Law Firms	5	2
<b>Totals</b>	<b>319</b>	<b>***</b>

\* Includes primary task forces, boards, and committees that were not scientific or consultory in nature.

\*\* In addition, seven consulting arrangements included advisory board memberships as part of the approved activities.

\*\*\* Column does not sum to 100 due to rounding.

Source: Office of Inspector General analysis of NIH data, 2005.

Twenty percent (63) of the approved activities involved consulting. (See Table 5 on the previous page.) Forty-nine percent (31) of these consulting activities took place with pharmaceutical or biotechnology companies. It is vital that NIH review activities with these companies carefully to ensure that they are not receiving inappropriate access to Government data and that the employee's and the agency's decisions are not influenced by industry.

Moreover, NIH approved 29 additional outside activities in which senior-level employees participated on scientific advisory boards, which can be considered a type of consulting. Forty-eight percent of these advisory board memberships were with pharmaceutical or biotechnology companies.

The NIH Manual acknowledges that outside activities with pharmaceutical or biotechnology companies pose special concerns.<sup>6</sup> In particular, if employees sign consulting agreements with these companies that contain confidentiality clauses, information sharing may be restricted in ways that interfere with employees' official duties. For example, confidentiality clauses that prevent consultants from engaging with an outside entity's competitors could inhibit future NIH research partnerships or programs. In fact, the HHS Office of the General Counsel has prepared a statement addressing this concern that employees are required to include in all consulting agreements.<sup>7</sup> Previously, Government lawyers occasionally reviewed contracts for outside activities. However, they no longer do so because such reviews may have led to Government lawyers providing legal advice to Government employees in their private capacities. Currently, although employees are not required to submit contracts with their activity requests and NIH will not review them, some employees do submit those contracts in order to provide additional information about their activities. Nineteen approved consulting or advisory board activity requests in our review included consulting arrangements. Thirteen of those included confidentiality agreements.

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<sup>6</sup> NIH Manual 2300-735-4–Outside Work and Related Activities with Outside Organizations, release date February 16, 1998, Appendix 7, p. 2.

<sup>7</sup> The required statement reads, "Notwithstanding any other provisions of this agreement, the rights of Consultant's employer, the National Institutes of Health (NIH), shall not be abrogated by any commitment or obligation Consultant has incurred hereunder. Company recognizes that as a Federal employee, Consultant is bound by Federal laws, regulations and policies, including those governing conflicts of interest, standards of conduct, and intellectual property, including 45 C.F.R. Part 7."

Eighty-eight percent of the approved outside activities involved some type of compensation. Employees must report on their HHS-520s the types of compensation they plan to receive for outside activities. Approved outside activities may involve one or more forms of compensation; employees may also perform activities for no compensation. The NIH Manual does not impose any limits on the types or amounts of compensation that employees may receive.<sup>8</sup>

Types of Compensation	Number of Approved Activities Involving This Type	Percent of Approved Activities Involving This Type *
Expenses	202	63
Honoraria	176	55
Fees	50	16
None	37	12
Other **	19	6
Per Diem Payments	13	4
Per Annum Payments	2	1
Royalties	2	1

\* Column sums to more than 100 because some outside activities involved more than 1 type of compensation.

\*\* Includes a copy of a textbook, a subscription to a publication, and a cruise.

Source: Office of Inspector General analysis of NIH data, 2005.

Expenses and honoraria were the most common types of compensation that senior-level employees reported. (See Table 6 above.) Sixty-three percent of approved outside activities involved compensation for expenses, and 55 percent received compensation in the form of honoraria.

We obtained information on the exact amount of compensation for 134 approved outside activities. (See Table 7 on the following page.)

<sup>8</sup> NIH Manual 2300-735-4—Outside Work and Related Activities with Outside Organizations, release date February 17, 1998, p. 7.

For those 134 approved activities, senior-level employees reported earning on average \$869 in expenses, \$1,500 in honoraria, and \$2,000 in fees, per activity. Honoraria and fees ranged from \$150 to \$18,000 and \$500 to \$30,000, respectively, per activity.

<b>Types of Compensation</b>	<b>Number of Activities Disclosing Compensation Amount</b>	<b>Median Compensation Amount</b>	<b>Range of Compensation Amounts</b>
Expenses	41	\$ 869	\$ 125 - \$ 3,000
Honoraria	97	\$ 1,500	\$ 150 - \$ 18,000
Fees	15	\$ 2,000	\$ 500 - \$ 30,000
Per Annum Payments	1	\$ 5,500	N/A
Per Diem Payments	0	N/A	N/A
Royalties	0	N/A	N/A

Source: Office of Inspector General analysis of NIH data, 2005.

For those activities where information was available, there did not appear to be a relationship between the amount of time an employee spent on an outside activity and the amount of compensation he or she received for that activity.

Prior to January 2004, employees were not required to report the amount of compensation on the HHS-520. Therefore, when possible, we obtained this information from annual public disclosure forms (for those employees required to file the SF-278) and from employees who voluntarily disclosed the amount of compensation on their HHS-520s or supporting documentation. We only obtained information from the SF-278 when the employee reported the exact amount of compensation, rather than a range.

This portion of our analysis is limited by the fact that compensation amounts were self-reported by the employees. We did not independently verify that employees received the same amounts and types of compensation they disclosed on these forms.

*Fifty-seven percent of approved outside activities involved some amount of time off and 7 percent required a week or more of time off.* In order to participate in outside activities, employees often take time off from work. Those employees who reported taking time off reported that they would take between 1 and 96 hours of time off per approved outside activity. The median amount of time employees anticipated taking off per approved outside activity was 8 hours (1 day).

Employees may also use personal time, or hours outside the normal working day, to engage in outside activities. Overall time commitments for approved outside activities including both time off from work and personal time ranged from 1 to 300 hours. The median length per approved outside activity was 12 hours. The NIH Manual does not impose limits on the number of hours that employees spend on outside activities, “except when time spent on outside activities interferes with the performance of an employee’s official duties.”<sup>9</sup> The employee’s supervisor is typically responsible for making this assessment.

Employees may perform multiple outside activities simultaneously, which can increase their overall time commitments to outside activities. Between 2001 and 2003, senior-level employees who participated in multiple approved outside activities documented spending anywhere between 2 and 964 hours on their outside activities. To do so, they reported taking a median of 34 hours (about 4 days) of time off. Four senior-level employees took 1 month or more of time off to engage in outside activities.

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<sup>9</sup> NIH Manual 2300-735-4–Outside Work and Related Activities with Outside Organizations, release date February 17, 1998, p. 8.

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## HHS & NIH INITIATIVES RELATED TO OUTSIDE ACTIVITIES

HHS and NIH have the following efforts to strengthen the NIH review and approval process for outside activities planned or under way.

### **Interim Final Rule**

HHS issued an interim final rule in February 2005 that provides new restrictions on the types of outside activities in which NIH employees can participate, and also imposes new responsibilities on employees who participate in outside activities.<sup>10</sup> The following are some of the provisions of the interim final rule, relating to outside activities:

- Employees must provide additional detailed information in their outside activities requests. The revised HHS-520 form, released in April 2005, captures significantly more information than the previous version.
- Employees must file annual reports on their outside activities.
- Outside activities may only be approved for 1-year periods.
- Employees are restricted from participating in certain activities with several types of outside entities, including biotechnology and pharmaceutical companies and research institutions supported by NIH funds.

### **Enhanced Oversight**

- In November 2003, NIH established the NIH Ethics Advisory Committee (NEAC) to provide recommendations with regard to approval to the NIH DEC for all outside activity requests submitted by appointed or acting NIH Office of the Director senior staff and institute directors. The NEAC also advises the NIH DEC on all outside activity requests submitted by institute deputy directors, scientific directors, clinical directors, and extramural directors, all of whom report directly to institute directors. For all other employees, the NEAC advises the NIH DEC on any outside activity request involving a biotechnology or pharmaceutical company, compensation in excess of \$10,000, and/or compensation involving stocks, stock options, or other equity positions.
- In February 2004, NIH transferred final approving authority for senior officials from their institutes' DEC's to the NIH DEC.

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<sup>10</sup> 70 Fed. Reg. 5,543, Feb. 3, 2005.

- In February 2004, at the request of NIH, OGE determined that 93 additional NIH employees were eligible to file the public financial form (SF-278) because the responsibilities and influence of their positions were equivalent to those of other public filers. OGE issued a second equal classification determination in September 2004, adding another 547 employees to the roll of public filers.
- In August 2004, NIH added the ethics function to the performance plans for all DEC's and supervisors.

#### **Internal Reviews**

- In December of 2003, NEAC began a review of all continuing consulting activities with pharmaceutical and biotechnology companies that were initiated between January 1999 and December 2003. This review is ongoing.
- In January 2004, the Director of NIH convened a blue ribbon panel to examine NIH's process for reviewing outside activities. The panel issued its recommendations in June 2004. (See Appendix E for a list of those recommendations.)

#### **Enhanced Information Management**

- NIH is in the process of expanding the capabilities of its Ethics Management Information System (EMIS) to allow for cross-checks between proposed outside activities and official duties, research partnerships, or other potential conflicts of interest. This system will also provide detailed reporting information and will track the status of pending ethics actions. In addition, the system will allow for automated submission and approval of certain forms. Institutes are encouraged, but not required, to enter information on employees' outside activities in EMIS. The enhanced EMIS will also become a tool for random audits of employees' ethics activities.

#### **Increased Training for Supervisors and Employees**

- In February 2004, NIH issued a memorandum to supervisors explaining how to properly review outside activities.
- In 2004, NIH conducted face-to-face ethics training effort for all of its 18,000 employees.

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## RECOMMENDATIONS FROM THE OFFICE OF GOVERNMENT ETHICS

OGE issued a program review of NIH's ethics system in July 2004. The resulting recommendations, which were directed to the Designated Agency Ethics Office for HHS (who oversees the NIH ethics program), are quoted below.<sup>11</sup> The Designated Agency Ethics Official for HHS responded to OGE's recommendations in October 2004.<sup>12</sup>

1. Take certain steps to ensure that you directly coordinate and manage the program. First, you should meet periodically with NIH management so that you will be fully cognizant of current and emerging ethics issues at NIH and be able to react to them accordingly. These meetings should ensure that you are aware when policies and procedures at NIH are not effective, and enable you to make changes as needed. Second, you should meet with NIH ethics officials and NIH management to determine what policies need to be developed to deal with the issue of outside consulting by NIH employees and develop an NIH-specific section of the HHS supplemental regulation for submission to our Office for concurrence and joint issuance. Finally, to formalize the responsibilities of the institute DECs, their position descriptions should contain a description of their ethics duties. The NIH DEC should rate each DEC annually on the ethics portion of his or her work.
2. Ensure that NIH continues efforts to re-examine ongoing outside activities.
3. Ensure that outside activities are approved in accordance with the requirements of the NIH Manual and the HHS supplemental standards of conduct regulation, including the activities that we identified for which no requests were submitted.

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<sup>11</sup> U.S. Office of Government Ethics memorandum to the Director of NIH, July 26, 2004, pp. 19-20.

<sup>12</sup> Department of Health & Human Services memorandum to the Acting Director of OGE, October 22, 2004.

4. Ensure that the requirements to collect annual updated information on ongoing outside activities is clarified, and then either: (1) improve the procedures for collecting the required annual information or (2) eliminate the requirement from the current Manual.
5. Ensure that after review and recommendation by NEAC, the NIH Senior Ethics Counsel has final approval/disapproval over outside activity requests.
6. Develop and propose new supplemental standards of conduct specifically to address the kinds of consulting activities that have raised recent concerns.
7. Help NIH develop guidelines to use in determining whether an individual outside activity request should be approved. The guidelines should make clear that NIH must apply all relevant provisions of the HHS Standards of Ethical Conduct to each request it is considering.
8. Develop internal procedures and criteria for NIH award reviewers in connection with future award requests so that the recent OGE guidance will be implemented consistently across all the ICs [institutes and centers].
9. Ensure that CC [Clinical Center] and OD [Office of the Director] public financial disclosure reports are certified in a timely manner.
10. Ensure that OD [Office of the Director] annual confidential reports are collected in a timely manner.

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## RECOMMENDATIONS FROM THE NIH BLUE RIBBON PANEL

NIH convened a Blue Ribbon Panel of independent experts in ethics, academic research, and industry to assess the state of NIH's ethics system and policies. This Panel put forth 18 recommendations to NIH, which are quoted below.<sup>13</sup>

1. NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and application review, should not engage in consulting activities with pharmaceutical or biotechnology companies or in paid consulting for academia. The Panel considers speaking for compensation at an industry site as equivalent to consulting for industry. The Panel does not include in this prohibition time spent in clinical practice by health care practitioners, if approved as an outside activity free of conflicts.
2. The Panel reaffirms current Federal law, which states that intramural scientists conducting research with human subjects—for example, investigators and research team members involved in patient selection, the informed consent process, and clinical management of a trial—should not be allowed to have any financial interest in or relationship with any company whose interests could be affected by their research or clinical trial, except in special circumstances, and with an appropriate waiver or authorization.

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<sup>13</sup> Blue Ribbon Panel Report on Conflict of Interest Policies, Report of the National Institutes of Health, June 22, 2004, pp. 2-5.

3. In addition to existing requirements for engaging in outside activities, and the restrictions posed in Recommendations 1 and 2, the following requirements should be in place for all employees who are involved in the administration or conduct of NIH research programs:
  - a. The total amount earned annually from compensated consulting with industry or academia should not exceed an amount equal to 50 percent of the employee's annual salary, and no one source should account for an amount exceeding 25 percent of annual salary.
  - b. Employees eligible to engage in compensated outside professional activities should not:
    - i. receive compensation in the form of stock options or other forms of equities for their services, or
    - ii. spend more than 400 hours per year on these activities (writing excepted).
  - c. An exclusion to the above limits should exist for NIH employees who are health care practitioners. For these employees, there should be a more flexible time limitation and the capitation for compensated outside medical care and patient services should be 100 percent of base pay, with the one-source limitation removed.
4. To improve NIH's ability to manage and track approved outside activities:
  - a. All requests for outside activities (Form 520) should be updated on an annual basis (with such updates indicating only those changes that have occurred);
  - b. Supervisors should be held accountable for the evaluation and approval of outside activity requests, and this supervisory function should be a component of a supervisor's performance evaluation; and
  - c. NIH should publish an annual agency-wide statistical report on the number and types of outside activities approved for its employees.

5. NIH should seek a change to OGE regulations to allow NIH scientists to receive compensation for teaching, speaking, or writing about their research providing that the information is to be shared in a public forum and that it has appeared in the published literature.
6. NIH intramural scientists should continue to be allowed to engage in compensated speaking, teaching, and writing for professional societies and for academic and research institutions as an outside activity providing that all ethics review and approval requirements are met.
7. NIH should seek a change to OGE regulations to permit employees to be identified by their title or position (and institutional affiliation) when engaged in teaching, speaking, or writing as an approved outside activity. Disclaimers should be provided that the activity is not being conducted in the employee's official capacity as an NIH employee and that the views expressed do not necessarily represent the views of NIH.
8. There should be no restrictions on royalties received on works written, edited, or published or on income received from patents licensed by any NIH employee who conducted the work as an approved outside activity.
9. The current OGE rules regarding receipt of bona fide cash awards for meritorious public service or achievement and NIH's interpretations of the rules are reasonable and should apply to all employees. There should be no limit on the amount of money received from a bona fide award. These awards are considered gifts under current law and are not considered outside activities because the employee accepts the award in his or her official capacity.
10. To increase NIH's ability to manage conflicts of interest, it should move immediately to either increase the number of employees required to annually file a confidential disclosure form (Form 450) or find some other means to achieve comparable levels of internal disclosure.

11. NIH should ask OGE to make a regulatory change or seek statutory modifications to provide NIH with greater discretion in determining whether certain Title 42 employees should file a public financial disclosure form (Form 278). This would promote the public interest by increasing transparency and would thereby enhance trust in government. In the meantime, NIH should seek additional equivalency rulings from OGE to increase the number of public filers to include the senior employees specified in Recommendation 1.
12. NIH supervisors should be provided with enhanced training on the criteria to be used for their annual review of financial disclosures so that they can become more effective in managing and avoiding employee conflicts of interest.
13. To preserve public confidence in NIH, the agency should put in place a policy that requires employees to disclose all relevant outside relationships and financial holdings in their work products, such as publications, speeches, and invention disclosures. In addition, where relevant, such disclosures should be made to potential research subjects as part of the informed consent process.
14. NIH employees should be required to submit recusals in writing to immediate supervisors when a potential conflict of interest emerges. The supervisor should then be required to inform those who should be aware of the employee's need to be recused from the official duties for which there is a conflict. As is currently the case, when an employee must be recused from official duties, those duties can be reassigned only to someone at an organizational level above the employee. As such, recused employees or their supervisors will need to inform both superiors and affected subordinates of the recusal.
15. The NIH Ethics Office should prepare a user-friendly document and website that displays the ethics rules in simple language and emphasizes examples of outside activities and financial interests that are permissible, as well as those that are not. Employees seeking approval of outside activities should, as part of their submission of Form 520 and its supplements, indicate in writing that they have reviewed these summary materials and have discussed any questions they have with their relevant ethics official and/or supervisor.

16. The NIH Ethics Advisory Committee should issue a report of its findings, in the form of anonymous case studies and generalizable principles, on a regular basis to provide the NIH community with a clear common body of knowledge by which to understand and interpret ethics rules.
17. NIH management should assure that sufficient resources are provided for the administrative and management functions of its ethics activities to guarantee that the expanded program proposed in this report can be implemented.
18. The NIH Director, working with Congress, should ensure that the agency has authority under Title 42, or some other hiring mechanism, to recruit senior scientific staff in the current highly competitive market. In addition, the NIH Director should ask HHS to review and, if appropriate, raise the current annual salary capitation of \$200,000 for the most senior Title 42 employees at NIH. The Panel is concerned that the present ceiling is limiting the agency's ability to recruit and retain the nation's best scientists as the leaders of NIH.



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

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