Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# OUTSIDE ACTIVITIES OF FDA EMPLOYEES


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# EXECUTIVE SUMMARY

## OBJECTIVES

1. To describe the nature of outside activities for which Food and Drug Administration (FDA) employees received approval between 2000 and 2003.
2. To determine the extent to which FDA senior-level employees provided required information on their outside activity request forms and financial disclosure statements between 2000 and 2003.
3. To assess FDA's process for reviewing outside activity requests between 2000 and 2003.

## 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. Employees may be financially compensated for these activities. Outside activities must be approved in accordance with regulations issued by the Office of Government Ethics and supplemental rules issued by HHS.

The media and Congress have recently paid increased attention to the oversight of outside activities within HHS. A December 2003 investigative report in The Los Angeles Times raised concerns regarding the ethics program at the National Institutes of Health (NIH). In a hearing conducted by the U.S. House of Representatives Committee on Energy and Commerce that focused on the NIH, an FDA employee was called to testify regarding his approved participation in an outside activity with a significantly regulated organization. Certain FDA employees are prohibited from working with significantly regulated organizations, which are entities whose products are regulated by FDA.

In June 2004, FDA completed an internal review of all ongoing outside activities to determine whether they complied with applicable laws and regulations. To further ensure the integrity of the FDA review process for outside activities, the Committee on Energy and Commerce requested that the Office of Inspector General conduct an independent review of FDA's oversight of outside activities.

The Ethics and Integrity Staff within FDA's Office of the Commissioner, Office of Management, implements and oversees the ethics program at FDA, which includes providing oversight of outside activities and the filing of financial disclosure statements that collect details on employees' assets, income, liabilities, and outside activities. FDA, through the Ethics and Integrity Staff, takes a decentralized approach to the review and approval of outside activities, delegating the review and approval authority to the eight offices and centers within FDA, hereafter referred to as centers.

When an employee seeks to participate in an outside activity, he or she submits an outside activity request (the HHS-520 form) to his or her supervisor. The supervisor makes a recommendation regarding whether the activity should be approved and then forwards the form to staff reviewers who provide additional review before forwarding it to the final approving official, who determines whether the activity will be approved.

We reviewed FDA's database of all outside activity requests employees submitted between 2000 and 2003. We also conducted a retrospective review of all outside activity requests and supporting documentation that senior-level employees submitted to FDA between January 1, 2000, and December 31, 2003. We defined senior-level employees to be those who, as of January 2004, were required to file Standard Form 278 public disclosure financial forms. We only reviewed requests that were received by FDA; we did not assess whether employees conducted any additional outside activities that were not reported in requests to FDA.

We also interviewed the staff in each center identified by FDA as the most knowledgeable about the outside activity review process between 2000 and 2003. Finally, we reviewed written procedures related to outside activities from the eight centers.

## NATURE OF OUTSIDE ACTIVITIES

**Eleven percent of all FDA employees received approval for a total of 2,592 outside activities between calendar years 2000 and 2003.** Of the 13,973 employees at FDA as of the end of fiscal year 2003, 1,571 employees received approval to participate in outside activities between 2000 and 2003. Most employees participated in only one activity. Eighty percent of the activities were conducted by employees who file confidential financial disclosure forms. The most common types

of outside activities involved teaching, lecturing, speechwriting, and presenting.

**Twenty-six percent of FDA senior-level employees received approval for a total of 55 outside activities between calendar years 2000 and 2003.** Of the 90 senior-level employees at FDA as of January 2004, 23 received approval to participate in outside activities between 2000 and 2003. Most senior-level employees participated in one or two outside activities, and most of the activities were not compensated. The most common types of outside activities for senior-level employees involved serving on boards or writing and editing. Forty percent of senior-level employees' approved activities were performed during time off from work.

## VULNERABILITIES

**Limited information inhibits FDA's ability to effectively review outside activity requests.**

- Complete information allows FDA reviewers to effectively assess the appropriateness of proposed outside activities and to identify potential conflicts of interest. Of the 55 approved outside activities for senior-level employees, all but 3 were missing at least 1 piece of information required on the HHS-520 form.
- Although nearly all of the forms had deficiencies, most of these omissions, considered independently, appeared to be minor. However, the extent and frequency of these deficiencies in the forms we reviewed raise systemic concerns about how FDA collects and reviews information regarding employees' outside activities.
- Even when required information was provided, it was often limited. The information contained in the senior-level employees' outside activity requests reviewed often contained vague or minimal information, or lacked position descriptions or documentation regarding the details of the outside activities.
- Outside activities of senior-level employees were not disclosed as required on annual financial disclosure forms 46 percent of the time.
- Limited information made it difficult for our reviewers to identify potential conflicts of interest and to determine the appropriateness of several activities of senior-level employees.

**Inadequacies in the review process limit FDA's ability to effectively review outside activity requests.**

- FDA policies and procedures do not fully address many key aspects of the process.
- Twenty-three of the fifty-five outside activity requests we reviewed for senior-level employees were approved after the start date. Seven activities were approved for longer than the 5-year maximum period allowed at the time of our review. In three instances, forms with multiple activities were approved.
- We did not find written recusals for any of the senior-level employees' outside activities. However, we were not able to determine whether written recusals were required. No center routinely notified supervisors of approved outside activity requests.
- Staff in the eight centers do not receive specialized training regarding the review of outside activity requests. At five of the eight centers, the function of review of outside activities was a collateral duty for staff responsible for determining the completeness of information on the request forms.

## RECOMMENDATIONS

We identified numerous problems regarding inadequate documentation and insufficient processes and procedures that may hinder the ability of reviewers to assess the appropriateness of the outside activities. Considered together, these vulnerabilities indicate the importance of continued vigilance to ensure the integrity of the review process. We recognize that both HHS and FDA have several initiatives planned or underway. The effectiveness of FDA's new system for reviewing outside activities will continue to be dependent on the quality of information submitted and the adequacy of the review process. We make the following recommendations to FDA on ways to improve and ensure the integrity of its review process for outside activities:

**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 all employees fill out their outside activity requests completely.
- Cross-check financial disclosure forms with those employees' outside activities for the previous year.

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

- Develop complete policies and procedures on outside activities for all centers and employees.
- Ensure that outside activity requests are approved before their scheduled start dates.
- Ensure that activities are approved for periods not exceeding the maximum amount of time allowed by HHS or FDA.
- Ensure that each outside activity receives its own separate review.
- 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 supervisors are notified of all approvals and disapprovals.
- Enhance training related to outside activities.
- Consider centralizing some or all aspects of the review process for outside activities.

## SUMMARY OF AGENCY COMMENTS

In its comments, FDA notes a variety of HHS and agency initiatives that address the recommendations we made, including the revised HHS-520 and new written policies and procedures.

One area with which FDA clearly takes issue is our discussion of recusals. FDA points out that the HHS-520 form itself provides information on recusal obligations to employees, and that by recommending approval of an outside activity, a supervisor acknowledges that an employee will recuse himself or herself whenever appropriate. FDA also suggests that our recommendation regarding recusals implies that when a written recusal is made, an

activity that otherwise would not be approved because of a conflict of interest becomes approvable.

## OFFICE OF INSPECTOR GENERAL RESPONSE

While this review was underway, both HHS and FDA announced or implemented initiatives aimed at strengthening the review process for outside activities. We recognize that the revised supplemental regulations and FDA's forthcoming policies and procedures address some of the recommendations we make in this report. We encourage HHS and FDA to continue their efforts to improve the outside activities review process.

In response to FDA's concerns about recusals, we reiterate that written recusals, when necessary, are protective of employees who are participating in outside activities. The process of an employee writing a separate recusal statement and the supervisor reviewing that statement provides an opportunity for important, deliberate discussion and planning that may not arise in the absence of a written statement. Under no circumstances should FDA approve outside activities that pose conflicts of interest, and in fact, we found no evidence that it has.

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# INTRODUCTION

## OBJECTIVES

1. To describe the nature of outside activities for which Food and Drug Administration (FDA) employees received approval between 2000 and 2003.
2. To determine the extent to which FDA senior-level employees provided required information on their outside activity request forms and financial disclosure statements between 2000 and 2003.
3. To assess FDA's process for reviewing outside activity requests between 2000 and 2003.

## 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 and 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 employees of FDA with opportunities to work with industry, academia, hospitals, and nonprofit organizations to help enhance knowledge and foster scientific discoveries. Some outside activities can allow FDA employees to build and maintain their professional expertise. Outside activities can also provide opportunities for FDA employees to maintain licensures or certifications.

Certain 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 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 has certain defined associations or interests that would "cause a reasonable person . . . to question his impartiality in the matter."

### Recent Concerns Regarding Outside Activities Within HHS

The media and Congress have recently paid increased attention to the oversight of outside activities within HHS. A December 2003 investigative report in The Los Angeles Times raised concerns regarding the ethics program at the National Institutes of Health (NIH).[1] The Los Angeles Times article alleged that the approval of consulting arrangements for several senior-level scientists at NIH had created serious conflicts of interest that may have biased agency decisions. These allegations resulted in a number of internal and external inquiries, including several congressional hearings, into potential conflicts of interest arising from outside activities at NIH.

In a hearing conducted by the U.S. House of Representatives Committee on Energy and Commerce that focused on NIH, an FDA employee was called to testify regarding his approved participation in an outside activity with a significantly regulated organization. Certain FDA employees are prohibited from working with significantly regulated organizations, which are organizations whose products are regulated by FDA (see pages 4–5 for more information). FDA indicated, in a prepared statement submitted to the committee, that at the time of approval the organization was not significantly regulated, but that the organization's status had changed during the course of the activity. After learning of this case, FDA conducted an internal review of all ongoing outside activities to determine whether they complied with applicable laws and regulations. To further ensure the integrity of the FDA review process for outside activities, the Committee on Energy and Commerce requested that the Office of Inspector General (OIG) conduct an independent review of FDA's oversight of outside activities.

### Requirements for Outside Activities at FDA

*Office of Government Ethics*. OGE was established by the Ethics in Government Act of 1978, 5 U.S.C. App. OGE oversees 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.[2] OGE regulations require employees to comply with 18 U.S.C. § 209, which bars employees from accepting outside compensation for work conducted in an official capacity.[3] 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.[4] Further, employees are required to endeavor to avoid actions that would create any appearance of violating the standards of ethical conduct.[5]

Although OGE promulgates the rules that provide a general framework for ethical conduct, it delegates to individual departments the authority to permit particular kinds of outside activities and/or to require prior approval for outside activities. However, OGE does conduct routine audits of agencies' ethics programs to ensure compliance with applicable regulations. OGE conducted such a review of FDA's ethics program in 2004.

OGE also oversees Government financial disclosure requirements. Certain executive branch employees, including some FDA employees, must disclose their compensated outside activities on annual financial disclosure forms. Financial disclosure may be public or confidential, depending on an employee's pay schedule and grade.

Employees 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 annually file the public financial disclosure form, the Standard Form (SF)-278.[6] An agency may also propose that OGE require filing of the SF-278 for additional positions, through a process known as equal classification. An agency would propose equal classification if it could demonstrate that the responsibilities and influence of certain positions were equivalent to those of employees in other agencies or components who, by virtue of their salary structures, were required to file the SF-278. When equal classification is granted, employees in those positions must file the SF-278.

The SF-278 form captures all outside sources of assets worth at least $1,000, as well as outside income and liabilities, along with the financial value for each item. Also, the SF-278 captures all 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 FDA, are required to annually file the confidential financial disclosure form, the OGE-450. Recently, FDA expanded the number of employees who are required to annually file the OGE-450.[7] This form captures certain assets worth at least $1,000; income, liabilities, and outside activities for which compensation exceeds $200; and certain compensated and uncompensated positions. However, the OGE-450 form does not require employees to disclose the precise financial values of these items.

In fiscal year 2003, 54 percent of FDA employees were required to file one of these financial disclosure forms. Employees who do not meet the criteria for either the SF-278 or the OGE-450 do not file any annual financial disclosure forms.

*Department of Health and Human Services*. Agencies may impose, with OGE concurrence, additional limitations on outside activities. In 1996, HHS promulgated the HHS Supplemental Standards of Ethical Conduct for employees.[8] The HHS supplemental regulations prohibit HHS employees from engaging in any compensated employment related to HHS-funded activities; they also prohibit employees from 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 require employees to request and receive written approval for certain outside activities prior to engaging in those outside activities. The types of activities that trigger the prior approval requirement include, but are not limited to: (1) providing consultative or professional services; (2) teaching, speaking, writing, or editing that relates to official duties or results from contact with certain prohibited sources; and (3) serving on certain boards or advisory bodies.[9]

The HHS supplemental regulations provide additional restrictions on relationships between FDA employees and significantly regulated organizations.[10] The regulations define significantly regulated organizations as "organization[s] for which the sales of products regulated by the Food and Drug Administration (FDA) constitute ten percent or more of annual gross sales in the organization's previous fiscal year; where an organization does not have a record of sales of FDA-regulated products, it will be deemed to be significantly regulated

if its operations are solely in fields regulated by FDA."[11] With limited exceptions, FDA employees and their spouses and children are prohibited from having financial interests in significantly regulated organizations. In addition, FDA employees who are required to file annual financial disclosure forms are also generally prohibited from participating in outside activities with significantly regulated organizations. Finally, all FDA employees are required to obtain prior approval before engaging in any outside employment or self-employed business activity.[12]

In February 2005, HHS issued, with OGE concurrence, an interim final rule that revised portions of the HHS supplemental regulations.[13] Previously, the HHS supplemental regulations stipulated that outside activities shall be approved unless they violated a statutory or regulatory requirement. Under the interim final rule, however, the standard for approval is higher. Previously, the regulations stated 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 . . . ."[14] However, the interim final rule established a higher standard for approval: "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 . . . ."[15] Our review was conducted prior to the interim final rule; therefore, our findings are based on the previous version of the supplemental regulations.

### Outside Activity Approval Process at FDA

The Ethics and Integrity Staff within FDA's Office of the Commissioner, Office of Management, implements and oversees the ethics program at FDA, which includes providing oversight of outside activities and the filing of financial disclosure statements. During the period of our review, FDA's Deputy Ethics Counselor delegated the authority to approve outside activity request forms to the Ethics and Integrity Staff. The Ethics and Integrity Staff took a decentralized approach to the review of outside activities, delegating the review authority to the eight offices and centers within FDA, hereafter referred to as centers.[16]

*Outside activity requests*. Generally, the review process for outside activity requests begins when an employee completes and submits a Request for Approval of Outside Activity form, the HHS-520. All full-time and part-time HHS employees who wish to engage in certain outside activities must complete this document. The HHS-520 collects

information on an employee's position, the nature of the proposed outside activity, the period of time over which the outside activity will be performed, and the method of compensation; it thereby helps reviewers determine whether a proposed outside activity may pose a real or apparent conflict of interest. As of January 2004, the amount of compensation must also be provided, pursuant to a HHS-wide directive from the Designated Agency Ethics Official.[17] This official has authority delegated from the Secretary of HHS to oversee the HHS ethics program. Further, in April 2005, HHS released a new version of the HHS-520, which requires employees to provide additional information regarding their requests for outside activities. Our review covered requests submitted prior to these changes.

The review process for outside activities has also changed since the period of our review, calendar years (CY) 2000 through 2003. In this report, we capture the review process that was in place during the period of our review. Although this process varied across the eight centers, generally an employee submitted the HHS-520 form to his or her supervisor, who performed an initial review and recommended whether the request should be approved. Staff reviewers in the centers, typically program or management analysts, then saw and reviewed the request before forwarding it to the final approving official, who made the final determination regarding approval.[18] The final approving official was typically the center director but, during the period of our review, final approving officials often delegated the final approving authority to members of their staffs, often the staff reviewers in the centers. However, as of June 2004, FDA required center directors to provide the final review of all requests, and no longer permitted them to delegate this authority.[19] Throughout this report, we use the general term reviewers to refer to all of the individuals who have roles in the outside activity review process, which includes supervisors, staff reviewers, and final approving officials.

As stated previously, regulations generally prevent FDA employees who are required to file annual financial disclosure reports from engaging in outside activities that involve significantly regulated organizations. The list of these organizations, referred to as the yellow book, is updated annually by the Ethics and Integrity Staff.

After requests have been approved or disapproved, centers forward HHS-520 forms to FDA's Ethics and Integrity Staff, who maintain a database of all outside activity requests.

## METHODOLOGY

Our review is based on four data sources: (1) FDA's database of outside activities, (2) a file review of outside activity requests and related documentation, (3) interviews, and (4) a procedure review. (For a complete description of our methodology, see Appendix A.)

We analyzed FDA's database of all outside activity requests submitted between CYs 2000 and 2003 to make summary statements about the number and nature of outside activities at FDA as a whole.

We chose the timeframe between CYs 2000 and 2003 because it allowed us to examine trends by year. We did not include CY 2004 because complete data were not available and some outside activities policies and procedures changed during CY 2004.

For our file review, we conducted a retrospective review of all outside activity requests that senior-level employees submitted for approval between CYs 2000 and 2003. We defined senior-level employees to be those who were required to file SF-278 public disclosure forms as of January 2004. FDA provided us with a list of 90 employees who met that criterion. This group of senior-level employees included, but was not limited to, center and office directors and deputy directors.

Our file review included three methodologies: (1) a descriptive review, (2) a completeness review, and (3) a compliance review. 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 CYs 2000 and 2003 that were not reported to FDA 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 OIG 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 FDA and did not follow up with employees or reviewers for further details on the outside activities.

We also interviewed the employees in each center who were identified by FDA as being those most knowledgeable about the review process in

the centers between CYs 2000 and 2003. These employees are typically program and management analysts in the centers (we refer to them throughout this report as staff reviewers). We used a structured questionnaire to conduct the interviews. Questions addressed topics such as centers' procedures for reviewing outside activity requests and challenges staff reviewers face in reviewing outside activity requests.

Finally, we requested operating procedures related to outside activities from all centers. We assessed and compared these documents.

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

## NATURE OF OUTSIDE ACTIVITIES

In this section we provide a summary of the number and types of outside activities in which FDA employees participated between CYs 2000 and 2003. We start with a summary of all employees, then address senior-level employees. For more information on the nature of FDA employees' outside activities, see Appendix B.

### Eleven percent of all FDA employees received approval for a total of 2,592 outside activities between CYs 2000 and 2003

**FDA approved all but 14 outside activity requests**

- Of the 13,973 employees at FDA as of the end of fiscal year 2003, 1,576 employees requested approval for 2,606 outside activities between CYs 2000 and 2003. FDA approved 2,592 outside activity requests for 1,571 employees. It is not surprising that most activities were approved; departmental supplemental regulations at the time the requests were submitted stipulated that outside activity requests are to be approved unless they violated statute or regulation.[20]

**Most employees received approval for one outside activity, but a few received approval for more than five**

- Of the 1,571 employees who received approval for outside activities between CYs 2000 and 2003, 68 percent received approval for just 1 activity, and another 20 percent received approval for 2 activities.
- Three percent of employees participated in more than five activities between CYs 2000 and 2003. The maximum was 38 approved outside activities for 1 employee.

**Employees who filed the confidential financial disclosure statement accounted for 80 percent of the approved outside activities**

- Employees who did not file financial disclosure statements accounted for 18 percent of the approved outside activities, and employees who filed public financial disclosure statements accounted for the remaining 2 percent.

**Employees at the two largest centers accounted for 60 percent of the approved outside activities**

- Employees at the Center for Drug Evaluation and Research received approval for 812 outside activities, and employees at the

Office of Regulatory Affairs received approval for 750 approved outside activities, between CYs 2000 and 2003.

**The most common types of approved outside activities involved teaching, lecturing, speechwriting, and presenting**

- FDA characterized 19 percent of approved outside activities as involving teaching, lecturing, speechwriting, and presenting. Seventeen percent involved activities characterized by FDA as "miscellaneous" activities, including self-employment. Fourteen percent involved providing consultative or professional services.[21]

## Twenty-six percent of FDA senior-level employees received approval for a total of 55 outside activities between CYs 2000 and 2003

**FDA approved all 55 outside activity requests made by senior-level employees**

- Of the 90 senior-level employees at FDA as of January 2004, 23 submitted 55 outside activity requests. FDA approved all of them.

**Most of the 23 senior-level employees with approved outside activities received approval for 1 or 2 outside activities**

- Of the 23 senior-level employees who received approval for outside activities, 14 received approval for only 1 or 2 outside activities between CYs 2000 and 2003. The maximum was five approved outside activities for one employee.

**Senior-level employees at three centers accounted for 64 percent of the approved outside activities for senior-level employees**

- Senior-level employees at the Center for Food Safety and Applied Nutrition received approval for 15 outside activities; senior-level employees at the Center for Drug Evaluation and Research and the Center for Veterinary Medicine each received approval for 10 outside activities.

**The most common types of approved outside activities for senior-level employees involved serving on a board or writing and editing**

- Thirty-six percent of the approved outside activities for senior-level employees involved serving on a board. Another 20 percent involved writing and editing.

**The most common venues for senior-level employees' outside activities were journals and other publications, professional societies, and universities**

- Journals and other publications, professional societies, and universities each accounted for 20 percent of the approved outside activities for senior-level employees.
- None of the activities involved the biotechnology or pharmaceutical industries or any significantly regulated organizations.

**Fifty-eight percent of approved outside activities for senior-level employees involved no compensation**

- For the 20 activities that did involve compensation, the most common form was reimbursement for travel and expenses.

**Forty percent of approved outside activities for senior-level employees involved time off, and 29 percent of these activities involved a week or more of time off**

- Senior-level employees indicated that they would take time off to perform 22 outside activities. For those 22 activities, employees indicated that they would take between 1 and 36 business days off. The median amount of time off was 7 business days per activity.

## Limited information inhibits FDA's ability to effectively review outside activity requests

**Of the 55 approved outside activities for senior-level employees, all but 3 were missing at least 1 piece of information required on the HHS-520 form**

Although nearly all of the forms had deficiencies, most of these omissions, considered independently, appeared to be minor. However, the extent and frequency of these deficiencies raise systemic concerns about how FDA collects and reviews information regarding employee outside activities. The areas highlighted in this section represent some of the more serious omissions or errors. Appendix C contains a complete listing of deficiencies on the outside activity requests.

When the information provided on outside activity request forms is incomplete, it becomes more difficult for supervisors, staff reviewers, and final approving officials to identify and address potential concerns. The information contained on the HHS-520 is, at FDA, the only information that employees are required to provide when they request approval for outside activities. Complete information allows FDA reviewers to consider potential conflicts of interest and make informed recommendations with regard to approval.

Several items on the HHS-520 solicit information that is used to provide assurance that potential conflicts of interest, prohibited by regulations, are not present in proposed activities. Forms were often missing responses to these items. Seven requests were missing statements about whether compensation would be derived from HHS grants or contracts. Five requests were missing statements about whether would-be associates would be seeking grants from Federal agencies. One request was missing a statement that the outside activity did not conflict with official duties.

Though all centers use the same HHS-520 form, internal processing policies and procedures vary from center to center. Three of eight centers explicitly state in their procedures that forms submitted for approval should always be complete, and as we have noted, complete information is crucial for making informed decisions on outside activity requests. FDA staff reviewers at six of eight centers described forms not being filled out completely or adequately as a moderate or minor challenge.[22]

We also found a number of examples of supervisors failing to provide required information on the forms. Four requests were missing the

supervisors' signatures. Seven requests were missing supervisors' recommendations regarding approval. The supervisor is responsible for verifying that proposed outside activities do not overlap with employees' official duties. The result of this substantive review is a recommendation to the final approving official on whether requests should be approved.

Nine requests were missing the signature of the final approving official, and 14 were missing the final approving official's decision regarding approval. All five centers that have written procedures on outside activities detail the appropriate signature and approval processes for outside activity requests in those procedures.

Nine requests were missing the second page of the HHS-520. This page contains space for reviewers to comment on the requests. This page also generally contains a signed statement that the employee received 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 summarize the responsibilities of employees who are engaged in outside activities.

When request forms are incomplete, the staff reviewers must follow up to obtain complete information on proposed outside activities. At two of the eight centers, the FDA staff reviewers we interviewed indicated that they always or often follow up with employees for additional information during the review process; staff reviewers at another two centers indicated that they sometimes follow up with employees for more information.

**Even when required information was provided, it was often limited**

In our review of senior-level employees' outside activity requests, we often encountered information that was vague or otherwise limited. Based on the limited nature of information provided on the HHS-520 forms, it was often not possible for our reviewers to determine what tasks were involved in the proposed outside activities or how those tasks related to employees' official duties; therefore, it was difficult to determine whether the activities were appropriately approved for these senior-level employees. At least 1 of our reviewers needed more information on employees' job duties for 53 of the cases reviewed, and at least 1 reviewer needed more information on the nature of employees' proposed outside activities for 50 of the cases reviewed. For all requests, at least one reviewer needed more information on the

difference between employees' official duties and the proposed outside activities. For 49 of the cases reviewed, at least 1 reviewer wanted additional information on the outside organizations with which the employees would be working.

Beyond the HHS-520 form, FDA does not require additional documentation that could be useful for the supervisors, staff reviewers, and final approving officials. Only eight of the senior-level employees' requests had additional information attached. Of these eight, four requests included letters of invitation, three included correspondence related to the outside engagements, and one included additional information on the outside organization. No position descriptions or job billets were attached to any requests. Information contained in these types of attached documents can provide important context to FDA reviewers.

To address concerns about inadequately detailed requests, the HHS Designated Agency Ethics Official recently reminded officials throughout HHS of the importance of performing due diligence when reviewing ethics forms. In a memo, this official stated that: "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 . . . ."[23]

**Outside activities of senior-level employees were not disclosed as required on annual financial disclosure forms 46 percent of the time**

Regulations require employees who file annual financial disclosure reports to disclose any outside activities in each year they are engaged in the outside activities.[24]

However, supervisors, staff reviewers, and final approving officials in the centers do not oversee the employees' annual financial disclosure statements and therefore cannot reconcile outside activity requests with financial disclosure forms. Recently, FDA announced that it will be reconciling employees' outside activity requests and financial disclosure statements annually.[25]

**Limited information made it difficult for our reviewers to determine the appropriateness of several activities of senior-level employees**

Determining whether an outside activity comported with pertinent ethics regulations required a judgment based on limited information. To increase the consistency of this judgment, two OIG reviewers independently reviewed each outside activity request to assess its

appropriateness. A third and final reviewer resolved cases in which the two initial reviewers disagreed.

Our review included all available documentation associated with these activities for senior-level employees, as provided by FDA. However, it is important to point out that these documents do not necessarily include all facts known to or considered by the FDA reviewers at the time of their reviews. FDA staff reviewers indicated that they sometimes conduct additional research to get information about proposed activities. Reviewers may also have additional information and knowledge regarding particular center employees' official duties.

In no instance was the documentation we reviewed adequate for us to make a definitive determination regarding whether an activity was appropriate. As demonstrated in this section, the information contained in the documentation for outside activity requests was often minimal, which made it difficult to determine whether activities were appropriate. Therefore, based upon the information contained on the forms alone, we could not state with 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, or (3) cannot determine.

For cases in 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 would only have identified activities as "appears not to be allowable" if the documentation suggested any violations 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 available raised concerns that the activity may have violated the regulations.

None of the outside activity requests we reviewed involved significantly regulated organizations. Ultimately, our reviewers determined that 44 activities appeared to be allowable and none appeared not to be allowable; however, our reviewers could not determine the appropriateness of the remaining 11 activities because the information provided was so incomplete or the forms were filled out incorrectly. Inadequate documentation for outside activities can, intentionally or unintentionally, obscure potential violations. If reviewers conduct additional research on requests, they may uncover and resolve those

potential problems before violations occur, but this may not happen in every case. We forwarded the 11 activities for which we could not make determinations on appropriateness to FDA for further review. FDA determined through additional review that all of these 11 activities were allowable.

## Inadequacies in the review process limit FDA's ability to effectively review outside activity requests

In this section, we describe several inadequacies in the review process for outside activities. In many cases, neither FDA policies nor center procedures address these issues.

### Approvals after the start date

FDA approved 23 of the 55 outside activity requests we reviewed for senior-level employees after the start dates listed on those requests. HHS regulations mandate that outside activities must be approved in advance.[26]

In our review, many approvals after the start dates were due to late submissions. For 12 of the 23 late approvals, employees submitted the outside activity requests after the activities had already begun. Late requests were filed anywhere between 4 and 279 calendar days after those activities were supposed to begin, with a median of 65 calendar days after the start dates provided on the HHS-520 forms. Additionally, late approvals may occur if any of the reviewers need to follow up with employees for additional information on their requests.[27]

Between 2000 and 2003, none of the eight centers provided deadlines for the submission of outside activity requests in their written procedures. However, one center recently changed its procedures to specify that requests should be submitted at least 3 weeks in advance of the start dates to allow sufficient time for review.

### Approvals exceeding the maximum time period allowed by FDA

Between CYs 2000 and 2003, FDA allowed employees to request approval for activities for periods up to 5 years.[28] We found seven instances of activities of senior-level employees being approved for periods exceeding 5 years. Not only does this violate FDA policy, but it also makes it difficult to ensure that activities continue to be appropriate as employees may change official job duties over time. Recently, both HHS and FDA have limited the timeframe for approvals of outside activities to 1-year periods.[29]

### Approvals of multiple activities on one request form

In three instances, outside activity requests of senior-level employees were approved despite the fact that multiple outside entities were listed on the forms. In one case, an employee requested permission to review articles for multiple publications. In another case, an employee requested permission to work with multiple clinical and research centers. In a third case, an employee requested permission to work with five separate organizations, including a foreign government entity. Neither FDA policies nor center procedures address the issue of multiple activities on a single request. It is important that a unique HHS-520 form be submitted for each distinct outside activity, because this form is designed to provide details on only one particular activity. Activities with different entities may pose different types of concerns, and so requests to engage in separate outside activities should be submitted and reviewed independently.

### Inadequate use of written recusals

We did not find written recusals present for any of the senior-level employees' outside activities that we reviewed. However, we were not able to determine whether written recusals were required. Staff reviewers we interviewed indicated that they had limited experience with recusals, and it is uncertain to what extent recusals are addressed at the time activities are approved. Also, FDA's expectations with regard to written recusals are unclear; neither FDA policies nor center procedures mention the use of written or unwritten recusals.

Pursuant to the prohibition in the Federal conflict of interest statute, 18 U.S.C. 208, and OGE regulations, all employees who participate in outside activities are obligated either 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, or to request a waiver or authorization.[30] To make employees aware of this obligation, all employees participating in outside activities are supposed to receive two forms, the "Notice to Applicants for Prior Approval of Outside Activities" and "Excerpts from the Standards of Ethical Conduct," which mention the requirement that employees recuse themselves, but do not include further details. OGE guidance suggests that written recusals can help to prevent conflicts of interest from arising.[31]

### Inadequate notification of supervisors

Staff reviewers at none of the eight centers reported that they routinely notify employees' supervisors of final decisions on outside activity requests, although staff reviewers at some centers did indicate that employees' administrative staffs may be notified of final decisions. Therefore, even though supervisors review and sign off on outside activity requests before sending them for final approval, they are frequently not made aware of final decisions. When supervisors are unaware of ongoing outside activities, they may not be able to monitor employees' assignments to avoid conflicts of interest. Neither FDA policies nor center procedures address notification of supervisors.

### Inadequate followup on ongoing outside activities

Staff reviewers at only two centers reported that they follow up on ongoing outside activities, and they reported that they only follow up to determine whether activities are continuing or whether they will be renewed at the end of their approval periods. Staff reviewers at none of the centers reported that they follow up to determine whether the nature or time commitment of approved activities are in line with the specifications of the requests, whether employees' official job duties have changed, or whether ethics rules are being observed.

Neither FDA policies nor center procedures address the frequency or amount of followup for ongoing outside activities; however, in 2004, FDA announced that it will only approve activities for 1-year periods.[32] In addition, the interim final rule limits approvals to 1-year periods, and further calls for employees who participate in outside activities to submit reports on their outside activities annually.[33] This shortened period of approval will result in followup for all outside activities at least once per year.

### Inadequate training

Staff reviewers at only one of the eight centers reported providing training on outside activities to its employees during the past several years. There is currently no requirement for annual ethics training for all employees at FDA, although new FDA employees receive ethics training, and annual ethics training is required for employees who file financial disclosure reports.[34] Still, staff reviewers at only one center identified inadequate training of employees as a moderate challenge, staff reviewers at four centers identified it as a minor challenge, and staff reviewers at the remaining three centers indicated that it was not a challenge.

Neither FDA nor any of the centers have provided training specifically geared toward supervisors, and none of the staff reviewers we interviewed indicated that this posed a major or moderate challenge, although staff reviewers at four centers identified inadequate supervisor training as a minor challenge. Yet, it is crucial to have well-trained supervisors who understand their roles in the outside activity review process and vet outside activity requests adequately.

Finally, neither FDA nor any of the centers have provided training specifically geared toward reviewers. It is important that these reviewers are trained to effectively review outside activity requests. FDA staff reviewers we spoke with at one center indicated that insufficient training of reviewers posed a moderate challenge, and staff reviewers at two other centers indicated that this was a minor challenge. It is crucial that reviewers are trained regarding how to properly screen requests for potential conflicts of interest.

### Varying levels of staffing

At five of the eight centers, the review of outside activities was a collateral duty for staff reviewers. This includes the two centers with the most outside activity requests between CYs 2000 and 2003. The other centers had at least one full-time person dedicated to outside activities and, in some cases, other ethics matters. In centers where outside activity review is a collateral duty, it may be difficult for staff reviewers to develop expertise in the review of requests. Perhaps this is one reason that staff reviewers did not recognize as challenges many of the inadequacies we have identified. Staff reviewers at one center identified inadequate staffing as a moderate challenge, and staff reviewers at three centers indicated that it was a minor challenge. Staff reviewers at the remaining four centers indicated that inadequate staffing was not a challenge.

## RECOMMENDATIONS

Although we did not identify any outside activities that appeared to violate applicable statutes or regulations, we did identify numerous problems regarding inadequate documentation and insufficient processes and procedures that may hinder the ability of reviewers to assess the appropriateness of the outside activities. Considered together, these vulnerabilities indicate the importance of continued vigilance in ensuring the integrity of FDA's review process and in preventing employees from participating in inappropriate outside activities in the future.

We recognize that both HHS and FDA have several initiatives planned or underway that aim to improve the review process for outside activities. (See Appendix D for a list of these initiatives.) Most notably, in February 2005, HHS issued an interim final rule to revise the supplemental regulations; this interim final rule addresses some of the vulnerabilities identified in this report. Over the past year, FDA also issued to employees new guidance documents on outside activities processes. We encourage HHS and FDA to continue their efforts to improve the outside activities review process.

The effectiveness of FDA's new system for reviewing outside activities will continue to depend on the quality of information submitted and the adequacy of the review process. Below, we make recommendations to FDA on ways to improve information and ensure the integrity of its review process for outside activities.

**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*. Having sufficient information on the nature of an activity is crucial to determining whether the activity should be approved. Equally important is having sufficient information on the nature of an employee's current job duties. Together, this information allows reviewers to identify any overlap between a proposed outside activity and an employee's official duties. HHS has revised the HHS-520 form to capture additional information on outside activities. However, FDA must ensure that employees provide adequate, substantive information.

We recommend that FDA require employees to submit the following with all outside activity requests:

- Statements, written by employees, that describe precisely and accurately in substantive ways the work that will be performed for outside entities.

- Detailed descriptions of employees' current job-related activities, in addition to copies of their position descriptions. The interim final rule requires employees to submit additional information about their official duties and any relationships between their official duties and their outside activities.[35]
- Written letters of invitation and agendas, whenever they are available. These items can provide important information on what is involved in proposed outside activities.
- All consulting contracts and other agreements, whenever they are available. These agreements can provide important information on the nature of proposed activities.

*Ensure that all employees fill out their outside activity requests completely.* We found that not only were required forms incomplete, but also that answers were sometimes too vague to be meaningful. It is important for reviewers to have complete information because it allows them to consider potential conflicts of interest and make informed recommendations as to whether requests should be approved. To assist employees in filling out these forms properly, FDA could develop standardized checklists that would provide employees with guidance to ensure that all proper documentation is submitted and complete. In no instance should FDA approve an outside activity when documentation is incomplete.

*Cross-check financial disclosure forms with employees' outside activities for the previous year.* We found that outside activities were not always properly disclosed on the applicable financial statements as required by OGE regulations.[36] Ensuring disclosure on these forms promotes transparency in employees' outside affiliations and earnings. It also serves as another check on whether employees are free of conflicts of interest. FDA has already indicated that it will begin performing this annual cross-check; we encourage FDA to develop a policy that explicitly requires this annual review, which will help ensure that employees are accurately reporting required information.

**Address the Inadequacies in the Review Process for Outside Activities**

*Develop complete policies and procedures on outside activities for all centers and employees.* The FDA Ethics and Integrity Staff maintains a Web site with information on outside activities, including the supplemental regulations, recent advisories, and directions for completing the HHS-520 form. However, these policies and procedures do not address many key aspects of the process that we found to be problematic. Despite the

problems we found, staff reviewers at only one of eight centers indicated that a lack of clear policies posed a major challenge.

Although FDA provides some guidance for outside activities on its ethics Web site, it lacks agency-wide policies and procedures. Furthermore, not all centers maintain their own written procedures. To ensure that employees are aware of the ethics rules for outside activities and to ensure consistency, it is important that FDA develop standard agency-wide policies and procedures that address how to submit requests, as well as how to review requests. These policies and procedures should encompass the recommendations we offer in this report. FDA is currently developing policies and procedures for reviewing outside activities and intends to distribute them to staff upon completion.

*Ensure that outside activity requests are approved before their scheduled start dates*. HHS regulations require that all approvals occur prior to start dates.[37] However, we found that many outside activity requests are still being approved after the start date. FDA should reemphasize the expectation that centers comply with these regulations and should ensure that centers are in compliance.

Further, it is important for centers to collect information when employees come forward after the fact to disclose activities, as this provides a record of employees' noncompliance and the nature of the activities conducted. However, this does not mean that activities should be approved when they are disclosed after the start date. In fact, if centers discover that ongoing or completed outside activities are not allowable, appropriate disciplinary action should be taken (e.g., counseling, written or oral reprimands, requiring the employee to return any compensation, prohibiting participation in future outside activities, and, in the most extreme circumstances, removing the employee). Even for cases in which outside activities are allowable, FDA should consider taking appropriate disciplinary action, especially if employees demonstrate patterns of submitting late requests.

To help ensure that there is adequate time for a careful, thorough review of each request, FDA should establish an appropriate timeframe for employees to submit their requests. This should allow time for reviewers to conduct their reviews and follow up with the employees, if necessary, for clarification. We recognize that such a deadline may not always be feasible, but we encourage FDA to use the deadline whenever possible.

*Ensure that activities are approved for periods not exceeding the maximum amount of time allowed by HHS or FDA*. We found seven activities that FDA approved for more than 5 years, in violation of its policy at the time of approving outside activities for a maximum of 5 years. Recently, FDA changed its policy so that outside activities can only be approved for 1-year periods.[38] FDA must ensure that its employees and reviewers comply with this policy.

*Ensure that each outside activity receives it own separate review*. We found three instances in which employees requested approval for multiple outside activities on the same forms, and one additional instance in which an employee said only that he would review articles for journals, but did not provide the names of the journals or publishers. FDA must ensure that each outside activity request receives its own complete and independent review. Each request should be submitted individually, with its own supporting documentation. This will help ensure that reviewers are able to thoroughly review each individual proposed activity for potential conflicts of interest.

*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*. Pursuant to the prohibition of 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 actual or apparent conflicts of interest unless they request and receive a waiver or authorization.[39] OGE guidance suggests that written recusals can help to prevent conflicts of interest from arising.[40]

All employees participating in outside activities are supposed to receive two forms, the "Notice to Applicants for Prior Approval of Outside Activities" and "Excerpts from the Standards of Ethical Conduct," which mention the requirement that employees recuse themselves, but do not include further details. These materials are included in the revised HHS-520 form. Recusals protect employees who are participating in outside activities by allowing for the establishment of screening and gatekeeping practices that help to ensure that employees do not encounter conflicts between their official duties and outside activities.[41]

Having a recusal in writing is important because it provides a way to inform supervisors and subordinates of a disqualification and its scope. It also serves as a point of accountability. Supervisors and other key personnel who are informed of recusals can serve as important checks

on employees to ensure that they are meeting their recusal obligations. We recognize that simply by recommending approval of an outside activity a supervisor is acknowledging that an employee is obligated to recuse himself or herself whenever necessary. However, the process of an employee writing a separate recusal statement and the supervisor reviewing that statement provides an opportunity for important, deliberate discussion and planning that may not arise in the absence of a written statement.

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

*Ensure that supervisors are notified of all approvals and disapprovals*. We found that supervisors were not systematically notified of final decisions on outside activity requests. In addition to being aware of any recusals, 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 remains free of conflicts even after activities are approved as job duties and assignments change over time.

*Enhance training related to outside activities*. Existing OGE regulations require annual ethics training for only those employees who file financial disclosure forms.[42] The regulations do not require annual ethics training for all employees. We recommend that FDA require all employees, regardless of whether they file financial disclosure forms, to participate in annual ethics training that addresses outside activities. The fact that so many of the HHS-520 forms we reviewed contained deficiencies signaled to us that employees may need additional training on how to adequately complete these forms.

In addition to training all employees, FDA should also require all supervisors to receive regular training on how to review requests for outside activities. Supervisors play a critical role in the review process, and therefore they should know how to conduct these reviews effectively. Further, all staff reviewers and final approving officials should receive training on how to review requests.

*Consider centralizing some or all aspects of the review process for outside activities*. FDA already has a centralized ethics office, the Ethics and Integrity Staff, that reviews all financial disclosure forms. This office

currently maintains copies of all outside activity requests. Further, it has begun to perform an additional check of outside activity requests submitted by FDA employees after final determinations have been made within requesting employees' respective centers. Staff reviewers indicated that they frequently contact the Ethics and Integrity Staff with questions on proposed outside activities.

FDA may have much to gain in terms of consistency and complete documentation by centralizing all or some facets of the outside activities review process, including:

- Centralized training for all employees, supervisors, staff reviewers, and final approving officials;
- Centralized routine internal audits of the outside activity review process conducted by the centers; and
- Centralized decisionmaking regarding outside activity requests.

We recognize that centers vary in size and mission and that taking steps toward centralization may be challenging. Further, the presence of reviewers in the centers may serve as a reminder of the important role of ethics in the day-to-day business of FDA. Entirely removing the current role of reviewers from the centers may have the effect of losing specialized knowledge regarding (1) the activities common to individual centers, and (2) the evolving duties and activities of center employees who are engaged in outside activities.

Yet, consolidating the oversight of these functions into one area with full-time experts may have significant benefits. First and foremost, it would allow FDA to further develop the knowledge and experience of its cadre of full-time ethics officials, whose expertise in the review of outside activities would continue to evolve. Currently, the review of outside activities is a collateral duty for some staff.

Centralization could help ensure the independence of the decisionmaking process, since the Ethics and Integrity Staff is more removed than current reviewers from the employees in the centers. Reviewers would not be making decisions regarding their immediate colleagues. Further, a central ethics staff would be in a better position than individual center staff to ensure that financial disclosure forms and outside activity requests correspond, as the review of financial forms is already a centralized duty of the Ethics and Integrity Staff.

Finally, centralization would provide FDA with the ability to conduct analysis to identify potentially problematic trends within and across centers over time.

## SUMMARY OF AGENCY COMMENTS

In its comments, FDA notes a variety of HHS and agency initiatives that address the recommendations we made. For example, FDA describes how the recently revised HHS-520 form will capture additional information on all proposed outside activities. Further, FDA is creating written policies and procedures regarding outside activities and has enhanced aspects of its outside activities training. FDA also identifies some of the potential benefits of outside activities.

One area with which FDA takes issue is our discussion of recusals. FDA points out that the HHS-520 form itself provides information on recusal obligations to employees, and that by recommending approval of an outside activity, a supervisor acknowledges that an employee will recuse himself or herself whenever appropriate. FDA also suggests that our recommendation regarding recusals implies that when a written recusal is made, an activity that otherwise would not be approved because of a conflict of interest becomes approvable.

For FDA's complete comments, see Agency Comments, page 54.

## OFFICE OF INSPECTOR GENERAL RESPONSE

While this review was underway, both HHS and FDA announced or implemented initiatives aimed at strengthening the review process for outside activities. We recognize that the revised supplemental regulations and FDA's forthcoming policies and procedures address some of the recommendations we make in this report. We encourage HHS and FDA to continue their efforts to improve the outside activities review process.

In response to FDA's comments about recusals, we reiterate that written recusals, when necessary, are protective of employees who participate in outside activities. As OGE has observed, "Documentation, whether or not required, provides greater protection both for the individual employee and the agency with regard to the scope and terms of the commitment to recuse."[43] The process of an employee writing a recusal statement and the supervisor reviewing that statement provides an opportunity for important, deliberate discussion

and planning that may not arise in the absence of a written statement. That written recusal statement may be made somewhere on the HHS-520 form itself, or in a separate e-mail or memorandum.

Further, we reiterate that written recusals allow for the establishment of screening and gatekeeping practices that help to ensure that employees do not encounter conflicts between their official duties and outside activities. As OGE has stated, ". . . a screening arrangement creates a viable process for preventing covered matters from coming before an employee. This, in turn, could prevent a violation of an employee's recusal obligations."[44] We do not mean to imply that otherwise-problematic activities are approvable where recusals are present; rather, recusals inform supervisors and coworkers of *potential* conflicts that could arise during the course of an outside activity. Under no circumstances should FDA approve outside activities that pose conflicts of interest, and in fact, we found no evidence that it has.

# ENDNOTES

[1] Wilman, D. December 7, 2003. Stealth Merger: Drug Companies and Government Medical Research. The Los Angeles Times: A1, A32-33.

[2] 5 CFR Part 2635.

[3] 5 CFR § 2635.801(d)(5).

[4] 5 CFR § 2635.802(b).

[5] 5 CFR § 2635.801(c).

[6] 5 CFR § 2634.202.

[7] Food and Drug Administration memorandum to all FDA employees, June 4, 2004.

[8] 5 CFR § 5501.

[9] 5 CFR § 5501.106(d).

[10] 5 CFR § 5501.106(c)(3). This section of the supplemental regulations remained essentially unchanged under the interim final rule. 70 Fed. Reg. 5543, 5559 (Feb. 3, 2005).

[11] 5 CFR § 5501.101.

[12] 5 CFR § 5501.106(d)(2).

[13] 70 Fed. Reg. 5543 (Feb. 3, 2005). The final rule was issued in 70 Fed. Reg 51559 (Aug. 31, 2005).

[14] 5 CFR § 5501.106(d)(4).

[15] 70 Fed. Reg. 5543,5559 (Feb. 3, 2005).

[16] The FDA Deputy Ethics Counselor is now the final approving official for all outside activity requests.

[17] Department of Health and Human Services memorandum to Deputy Ethics Counselors and Ethics Contacts, January 27, 2004.

[18] Further, staff reviewers indicated that additional individuals may review requests or comment before the final decision is made.

[19] Food and Drug Administration memorandum to all FDA employees, June 4, 2004.

[20] 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 interim final rule of February 2005, 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].

[21] We aggregated two of FDA's classifications of outside activities: Professional and Consultative Services (295), and Consulting (65).

[22] Staff reviewers at two centers described it as not being a challenge at all.

[23] Department of Health and Human Services memorandum to Deputy Ethics Counselors and Ethics Contacts, August 13, 2004, p. 1.

[24] 5 CFR § 2634.307 for public filers; 5 CFR § 2634.907(a)(6) for confidential filers.

[25] Food and Drug Administration memorandum to all FDA employees, June 4, 2004.

[26] 5 CFR § 5501.106(d)(1). This expectation remains the same in the February 2005 interim final rule. 70 Fed. Reg. 5543, 5559 (Feb. 3, 2005).

[27] For initial outside activity requests that were submitted prior to the start dates listed on those requests, the median amount of time between employees' signatures and final approving officials' signatures was

12.5 calendar days. Of the 16 initial outside activity requests for which we could perform this calculation, 8 were submitted less than 12.5 calendar days in advance.

[28] Food and Drug Administration memorandum to all FDA employees, October 4, 2004.

[29] Food and Drug Administration memorandum to all FDA employees, October 4, 2004. Also, the February 2005 interim final rule calls for approvals not to exceed 1 year.

[30] 5 CFR § 2635, Subpart D (for conflicting financial interests) and 5 CFR § 2635, Subpart E (for appearance of loss of impartiality).

[31] U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials ("Recusal Obligation and Screening Arrangements"), April 26, 1999. OGE referenced and elaborated on this 1999 memorandum in a subsequent memorandum to Designated Agency Ethics Officials, General Counsels, and Inspectors General ("Effective Screening Arrangements for Recusal Obligations"), June 1, 2004.

[32] Food and Drug Administration memorandum to all FDA employees, October 28, 2004.

[33] 70 Fed. Reg. 5543, 5559 (Feb. 3, 2005).

[34] 5 CFR § 2638.704(a) for public filers; 5 CFR § 2638.705(a)(3) for confidential filers.

[35] Additionally, 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 . . . ." 70 Fed. Reg. 5543, 5559 (Feb. 3, 2005).

[36] 5 CFR § 2634.307 for public reports; 5 CFR § 2634.907(a)(6) for confidential reports.

[37] 5 CFR § 5501.106(d)(1). The requirement for prior approval remains the same in the February 2005 interim final rule.

[38] Food and Drug Administration memorandum to all FDA employees, October 4, 2004. Also, the February 2005 interim final rule calls for approvals not to exceed 1 year.

[39] 5 CFR § 2635, Subpart D (for conflicting financial interests) and 5 CFR § 2635, Subpart E (for appearance of loss of impartiality).

[40] U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials ("Recusal Obligation and Screening Arrangements"), April 26, 1999. OGE referenced and elaborated on this 1999 memorandum in a subsequent memorandum to Designated Agency Ethics Officials, General Counsels, and Inspectors General ("Effective Screening Arrangements for Recusal Obligations"), June 1, 2004.

[41] Ibid.

[42] 5 CFR § 2638.704(a) for public filers; 5 CFR § 2638.705(a)(3) for confidential filers.

[43] U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials, April 26, 1999, p. 2.

[44] U.S. Office of Government Ethics memorandum to Designated Agency Ethics Officials, General Counsels, and Inspectors General, June 1, 2004, p. 2.

# METHODOLOGY

### FDA Database

FDA provided us with a copy of a database maintained by the Ethics and Integrity Staff that contained information on all outside activity requests submitted by all FDA employees between CYs 2000 and 2003. We used this database to make summary statements about the number and nature of outside activities at FDA as a whole.

Throughout this report, we analyze data from the timeframe between CYs 2000 and 2003. We chose this period because it allowed us to examine trends by year. Further, complete data for CY 2004 were not available, and some outside activities policies and procedures changed during CY 2004.

### File Reviews

We conducted a retrospective review of all outside activity requests that senior-level employees submitted to FDA between CYs 2000 and 2003. We defined senior-level employees to be those who were required to file SF-278 public disclosure forms as of January 1, 2004. FDA provided us with a list of 90 employees who met that criterion. This group included, but was not limited to, center and office directors and deputy directors.

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 may be most likely to pose the greatest risk for FDA in terms of potential conflicts of interest. However, restricting our review to employees in this group presents some limitations. For example, 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-520 forms) and supporting documentation for all outside activities requested by these senior-level employees within the timeframe of our review. Supporting documentation that we received included, as appropriate:

- Public Financial Disclosure (SF-278) Reports,
- Confidential Financial Disclosure (OGE-450) Reports,
- Correspondence,
- Reviewer notes, and
- Letters of invitation.

We considered a request to be within the timeframe of our review if the date the employee signed the request fell between January 1, 2000, and December 31, 2003. We received 55 outside activity requests from FDA that met this criterion. We did not assess whether employees conducted any additional outside activities between 2000 and 2003 that were not reported in outside activity requests, which represents a potential limitation of our review. However, the responsibility for submitting request forms rests with employees.

Our review included initial requests, revised requests, and renewal requests. An initial request is made 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 provided on an initial request. A renewed request is submitted if an activity continues beyond the end date originally stated in the initial request. Our population of approved outside activities included initial requests, renewals, revised requests, and outside activity requests that did not specify the request type. Because we intended to analyze all outside activity requests submitted in the timeframe of our study, we included all types of requests regardless of whether the supervisor or final approving official provided complete information.

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 Microsoft Access® 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. 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. When an employee provided an estimated range for the time commitment, we used the midpoint in our analysis.

*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, the supervisor, and the final approving official signed off on the outside activity request. We also recorded, whenever applicable, whether or not the employee had listed the outside activity on his or her

financial disclosure form (SF-278 or OGE-450) for that year.[1] We documented the number of missing signatures, and also noted other missing items of information on the HHS-520 form.

*Compliance review.* We reviewed all approved outside activity requests that senior-level employees submitted between January 1, 2000, and December 31, 2003, to determine whether the activities complied with the pertinent requirements for avoiding conflicts 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
- FDA policy.

We compared the organizations listed on outside activity request forms to the FDA yellow book listings of significantly regulated organizations for each year in the period of our review to determine whether proposed activities involved organizations listed as significantly regulated at the time the requests were made. (An exception to the prohibition on outside activities with significantly regulated organizations applies where "the employment is limited to clerical or similar services (such as cashier or janitorial services) in retail stores, such as supermarkets, drug stores, or department stores.")[2]

Aside from employment with significantly regulated entities, it is important to note that the criteria used for our compliance review do not explicitly prohibit certain types of outside activities (e.g., consulting arrangements). Therefore, determining whether an outside activity

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[1] We used this information to calculate the frequency with which outside activity requests were recorded as required by regulation. For each year between CYs 2000 and 2003, we determined whether an activity was ongoing by checking the start and end dates provided on the HHS-520 form. If an activity was ongoing during a particular year, we cross-checked the employee's appropriate financial disclosure (if available) to determine whether that activity was listed anywhere on the form. We then divided the number of times that activities were disclosed in the years during which they were ongoing (56 times) by the number of times activities should have been disclosed (104 times). Overall, activities were only disclosed as required 54 percent of the time.

[2] 5 CFR § 5501.106.

adhered to the regulations necessarily involved a judgment call on our part. To increase consistency, two OIG reviewers used a standardized protocol to independently review each outside activity request and any available supporting documentation. A final OIG reviewer was consulted to resolve cases in which the two initial reviewers disagreed. For the cases in which the two initial reviewers agreed, no third reviewer was used.

Our review included all available FDA documentation regarding these activities. However, it is important to point out that these documents do not necessarily include all facts known to or considered by FDA reviewers at the time of their reviews. The staff reviewers we interviewed 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 our reviewers to make a definitive determination regarding whether an activity was appropriate. As demonstrated in the "Vulnerabilities" section of this report, the information contained in the documentation for outside activity requests was often inadequate; inadequate information limits reviewers' ability to make decisions on appropriateness. 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.

For the cases in which the documentation contained enough information and did not appear to violate any regulations, our reviewers identified the activity as "appears to be allowable," even if more information would be necessary to definitively determine that the activity was in fact allowable. Our reviewers would only have identified an activity as "appears not to be allowable" if the documentation indicated 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 11 activities, but did determine that none of the activities violated statute or regulations. However, it is quite possible that 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 reviewers

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 reviewers at FDA or research outside organizations with which employees requested permission to work. As a result, an important limitation of this methodology is that we cannot comment on whether FDA reviewers considered additional facts during their reviews of these outside activity requests.

We recorded, as part of our assessment, whether specific pieces of additional information would have been helpful in making determinations. This information included greater detail on the following items: the nature of the outside activity, the nature of the employee's job duties, the difference between the outside activity and the employee's job duties, and the outside organization.

**Interviews With FDA Staff Reviewers**

We interviewed the employees in each of the eight centers whom FDA designated as responsible for and/or most knowledgeable about the review process for outside activities between CYs 2000 and 2003. We refer to these employees as staff reviewers. We used a structured questionnaire to conduct these interviews. The questionnaire addressed centers' procedures for reviewing outside activity requests; the training that centers provide to employees, supervisors, staff reviewers, and final approving officials on outside activities; staff reviewers' approaches to identifying ethics violations regarding outside activities; challenges staff reviewers face in the outside activities review process; and staff reviewers' recommendations for improving processes for outside activities. We conducted all interviews by telephone. We also spoke with FDA Ethics and Integrity Staff to learn of initiatives FDA has planned or underway to improve its system for addressing outside activities. FDA Ethics and Integrity Staff served as a resource for clarifying our questions on FDA ethics policy throughout our review.

### Procedure Review

We requested operating procedures related to outside activities from all eight centers. FDA allows, but does not require, its centers to develop written operating procedures for implementing FDA policies on outside activities. Staff reviewers at five centers indicated that their centers have written procedures and provided those procedures to us. These included standard operating procedures, Web site printouts, and memoranda. We counted the number of centers that maintained these documents and compared the documents to one another.

## NATURE OF OUTSIDE ACTIVITIES

**Eleven percent of all FDA employees received approval to participate in a total of 2,592 outside activities between CYs 2000 and 2003.**

*FDA approved all but 14 outside activity requests*. Of the 13,973 employees at FDA, 1,576 employees submitted 2,606 outside activity requests between CYs 2000 and 2003. FDA approved 2,592 requests for 1,571 employees and disapproved 14 requests. (See Table 1 below.) It is not surprising that the overwhelming majority of requests were approved. For the period covered by this review, HHS supplemental regulations called for outside activity requests to be approved unless they clearly violated statute.[3] The interim final rule calls for a higher standard of approval: activities are only to be approved "upon a determination that [activities are not] expected to involve conduct prohibited by statute or Federal regulation . . . ." Further, FDA employees may confer with supervisors, staff reviewers, or Ethics and Integrity Staff before formally submitting requests to ensure that their proposals are approvable.

The number of requests for outside activities increased between CYs 2001 and 2002. One possible explanation for this increase may be the overall growth of the FDA workforce between CYs 2001 and 2002.

**Table 1. Number of FDA Employees and Outside Activity Requests by Year, CY 2000–2003**

| Calendar Year | Number of Employees * | Number of Outside Activity Requests | Number of Approved Outside Activity Requests |
|---|---|---|---|
| 2000 | 13,047 | 515 | 515 |
| 2001 | 13,104 | 515 | 512 |
| 2002 | 14,038 | 784 | 779 |
| 2003 | 13,973 | 792 | 786 |
| **Totals** | **-** | **2,606** | **2,592** |

* Reported as the number of employees at the end of the fiscal year.
Source: Office of Inspector General analysis of FDA data, 2005.

[3] 5 CFR § 5501.106.

*Most employees received approval for one outside activity, but a few received approval for more than five*. Of the 1,571 employees who received approval to participate in outside activities between CYs 2000 and 2003, 68 percent received approval for only 1 activity, and another 20 percent received approval for 2 outside activities. Three percent of employees received approval for more than 5 activities over the 4-year period. The maximum was 38 approved outside activities for 1 employee between CYs 2000 and 2003. (See Table 2 below.)

**Table 2. Number of Approved Outside Activities for FDA Employees, CY 2000–2003**

| Number of Approved Activities | Number of Employees Participating | Percent of Employees Participating |
|---|---|---|
| 1 | 1,066 | 68 |
| 2 | 311 | 20 |
| 3 | 92 | 6 |
| 4 | 49 | 3 |
| 5 | 16 | 1 |
| 6 | 17 | 1 |
| 7 or more | 20 | 1 |
| **Totals** | **1,571** | **100** |

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

*Employees who file the confidential financial disclosure form accounted for 80 percent of the approved outside activities*. Employees who are required to annually file the confidential financial disclosure form (OGE-450) accounted for 80 percent of approved outside activities between CYs 2000 and 2003. Employees who do not file any financial disclosure accounted for 18 percent of approved outside activities, and employees who file the public financial disclosure form accounted for only 2 percent of approved outside activities, between CYs 2000 and 2003. (See Table 3 below.)

**Table 3. Number of Approved Outside Activities for FDA Employees by Filer Status, CY 2000–2003**

| Filer Status | Number of Approved Outside Activities | Percent of Approved Outside Activities | Number of Employees * | Percent of Employees |
|---|---|---|---|---|
| Confidential Filer | 2,084 | 80 | 7,374 | 53 |
| Nonfiler | 457 | 18 | 6,463 | 46 |
| Public Filer | 51 | 2 | 136 | 1 |
| **Totals** | **2,592** | **100** | **13,973** | **100** |

* Reported as the number of employees at the end of fiscal year 2003.
Source: Office of Inspector General analysis of FDA data, 2005.

Certain FDA employees must disclose their compensated outside activities on an annual financial disclosure form, which may be public or confidential, depending on an employee's pay. By statute, some employees who meet income or appointment requirements must file the public financial disclosure form, the SF-278. FDA requires additional employees in positions of significant decisionmaking authority to annually file the confidential financial disclosure form, the OGE-450. This form requires employees to list certain compensated and uncompensated positions. Most employees, however, are not required to file any sort of financial disclosure.

*Employees at the two largest centers accounted for 60 percent of the approved outside activities.* Employees at the Center for Drug Evaluation and Research received approval for 812 outside activities, and employees at the Office of Regulatory Affairs received approval for 750 approved outside activities, between CYs 2000 and 2003. The percentage of employees participating in outside activities, by center, ranged from 7 percent at the Office of the Commissioner to 14 percent at the Center for Veterinary Medicine. (See Table 4 below.)

**Table 4. Approved Outside Activities for FDA Employees, by Center, CY 2000–2003**

| Center | Number of Approved Outside Activity Requests | Percent of Approved Outside Activity Requests | Number of Participating Center Employees | Percent of Participating Center Employees ** |
|---|---|---|---|---|
| Center for Drug Evaluation and Research | 812 | 31 | 423 | 13 |
| Office of Regulatory Affairs | 750 | 29 | 536 | 13 |
| Center for Food Safety and Applied Nutrition | 259 | 10 | 131 | 10 |
| Center for Biologics Evaluation and Research | 244 | 9 | 116 | 10 |
| Center for Devices and Radiological Health | 205 | 8 | 142 | 9 |
| Office of the Commissioner | 142 | 5 | 113 | 7 |
| Center for Veterinary Medicine | 130 | 5 | 78 | 14 |
| National Center for Toxicological Research | 50 | 2 | 32 | 9 |
| **Totals** | **2,592** | * | **1,571** | - |

* Column does not sum to 100 due to rounding.
** Reported as the number of employees at the end of fiscal year 2003.
Source: Office of Inspector General analysis of FDA data, 2005.

*The most common types of approved outside activities involved teaching, lecturing, speechwriting, and presenting*. Nineteen percent of the approved outside activities involved teaching, lecturing, speechwriting, and presenting. Seventeen percent involved what FDA designated as "miscellaneous" activities, and another 14 percent involved consulting or providing professional or consultative services. (See Table 5 below.)

**Table 5. Nature of Approved Outside Activities for FDA Employees, CY 2000–2003**

| Type of Outside Activity[1] | Number of Approved Outside Activities | Percent of Approved Outside Activities |
|---|---|---|
| Teaching, Lecturing, Speechwriting, and Presenting | 490 | 19 |
| Miscellaneous[2] | 436 | 17 |
| Consulting, Professional, and Consultative Services[3] | 360 | 14 |
| Trade, Industrial, and Service Occupations | 294 | 11 |
| Writing, Editing, and Serving on Editorial Boards[4] | 227 | 9 |
| Clinical Professional Practice | 221 | 9 |
| Holding Office in a Professional Organization or Society | 218 | 8 |
| Sales and Clerical Positions | 189 | 7 |
| Serving on a Board or Committee | 65 | 3 |
| Private Professional Practice and Other Professional Activities[5] | 55 | 2 |
| Self-Employed Positions | 37 | 1 |
| **Totals** | **2,592** | **100** |

[1] We report the types of activities by the classifications FDA made in its database of outside activities.
[2] This category included, for example, a variety of self-employed positions that were categorized as miscellaneous before FDA created a separate self-employed activity category in the database.
[3] We aggregated two of FDA's classifications of outside activities: Professional and Consultative Services (295) and Consulting (65).
[4] We aggregated two of FDA's classifications of outside activities: Writing and Editing (162) and Writing/Editing/Member of Editorial Board (65).
[5] We aggregated two of FDA's classifications of outside activities: Other Professional Activity with Remuneration (35) and Private Professional Practice (20).
Source: Office of Inspector General analysis of FDA data, 2005.

**Twenty-six percent of FDA senior-level employees received approval to participate in a total of 55 outside activities between CYs 2000 and 2003.**

We defined senior-level employees as those who were required to file the SF-278 public financial disclosure form as of January 2004. This group includes, for example, center directors and deputy directors.

*FDA approved all 55 outside activity requests made by senior-level employees.* Of the 90 senior-level employees at FDA as of January 2004, 23 submitted 55 outside activity requests. FDA approved all of these requests. (See Table 6 below.) As described earlier in this Appendix, there are several possible explanations for a high approval rate.

The number of senior-level employees requesting approval, and the number of approvals, remained relatively constant from CYs 2000 to 2003.

**Table 6. Number of FDA Senior Level Employees and Approved Outside Activity Requests by Year, CY 2000–2003**

| Calendar Year | Number of Employees Requesting Approval | Number of Approved Outside Activity Requests |
|---|---|---|
| 2000 | 9 | 13 |
| 2001 | 9 | 11 |
| 2002 | 12 | 15 |
| 2003 | 11 | 16 |
| **Totals** | **-** | **55** |

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

*Most senior-level employees received approval for one or two outside activities*. Over half of the senior-level employees at FDA received approval for only one or two outside activities between CYs 2000 and 2003. The median number of outside activities approved per employee was two. The maximum was five approved outside activities for one employee between CYs 2000 and 2003. (See Table 7 below.)

**Table 7. Number of Approved Outside Activities for FDA Senior Level Employees, CY 2000–2003**

| Number of Activities | Number of Participating Employees | Percent of Participating Employees |
|---|---|---|
| 1 | 6 | 26 |
| 2 | 8 | 35 |
| 3 | 4 | 17 |
| 4 | 4 | 17 |
| 5 | 1 | 4 |
| **Totals** | **23** | ***** |

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

*Senior-level employees at three centers accounted for 64 percent of the approved outside activities.* Senior-level employees at the Center for Food Safety and Applied Nutrition received approval for 15 outside activities between CYs 2000 and 2003. At both the Center for Drug Evaluation and Research and the Center for Veterinary Medicine, senior-level employees received approval for 10 outside activities between CYs 2000 and 2003. (See Table 8 below.)

**Table 8. Approved Outside Activities for FDA Senior Level Employees, by Center, CY 2000–2003**

| Center | Number of Approved Outside Activity Requests for Senior-Level Employees | Percent of All Approved Outside Activity Requests for Senior-Level Employees | Number of Senior-Level Employees at Center Participating | Number of Senior-Level Employees at Center ** |
|---|---|---|---|---|
| Center for Food Safety and Applied Nutrition | 15 | 27 | 7 | 18 |
| Center for Drug Evaluation and Research | 10 | 18 | 6 | 13 |
| Center for Veterinary Medicine | 10 | 18 | 3 | 7 |
| Office of the Commissioner | 9 | 16 | 3 | 25 |
| Center for Biologics Evaluation and Research | 6 | 11 | 2 | 9 |
| Office of Regulatory Affairs | 4 | 7 | 1 | 9 |
| National Center for Toxicological Research | 1 | 2 | 1 | 1 |
| Center for Devices and Radiological Health | - | - | 0 | 8 |
| **Totals** | **55** | ** | **23** | **90** |

* Column does not sum to 100 due to rounding.
** Reported as the number of senior-level employees as of January 1, 2004.
Source: Office of Inspector General analysis of FDA data, 2005.

*The most common types of approved outside activities of senior-level employees involved serving on a board or writing and editing.*
Thirty-six percent of the approved outside activities for senior-level employees involved serving on boards. Another 20 percent of approved outside activities for senior-level employees involved writing and editing. (See Table 9 below.)

**Table 9. Nature of Approved Outside Activities for FDA Senior Level Employees, CY 2000–2003**

| Type of Outside Activity * | Number of Approved Outside Activities | Percent of Approved Outside Activities |
|---|---|---|
| Serving on a Board | 20 | 36 |
| Writing and Editing | 11 | 20 |
| Clinical Professional Practice | 4 | 7 |
| Serving on a Committee | 4 | 7 |
| Lecturing | 4 | 7 |
| Serving as a Professor | 4 | 7 |
| Legal Consulting | 3 | 5 |
| Other | 2 | 4 |
| Performing Research | 2 | 4 |
| Consulting | 1 | 2 |
| **Totals** | **55** | ** |

* We report the types of activities by the classifications our reviewers made.
** Column does not sum to 100 due to rounding.
Source: Office of Inspector General analysis of FDA data, 2005.

*The most common venues for senior-level employees' outside activities were journals and other publications, professional societies, and universities.* Journals and other publications, professional societies, and universities each accounted for 20 percent of the approved outside activities for senior-level employees. None of the activities involved the biotechnology or pharmaceutical industries or any other significantly regulated organizations. (See Table 10 below.)

**Table 10. Types of Organizations With Which FDA Senior-Level Employees Received Approval for Outside Activities, CY 2000–2003**

| Type of Outside Organization * | Number of Approved Outside Activities | Percent of Approved Outside Activities |
|---|---|---|
| Professional Societies | 11 | 20 |
| Journals and Publishers | 11 | 20 |
| Universities | 11 | 20 |
| Hospitals and Clinics | 6 | 11 |
| Personal and Social Organizations | 5 | 9 |
| Financial Institutions | 3 | 5 |
| Law Firms | 3 | 5 |
| Cannot Determine | 2 | 4 |
| Charities | 2 | 4 |
| Museums | 1 | 2 |
| **Totals** | **55** | **100** |

* We report the types of organizations by the classifications our reviewers made.
Source: Office of Inspector General analysis of FDA data, 2005.

*Fifty-eight percent of approved outside activities for senior-level employees involved no compensation.* Employees must report on their HHS-520s the type(s) of compensation they are to receive for performing outside activities. An outside activity may involve more than one type of compensation; employees may also perform outside activities without compensation. There are no limits on the types or amounts of compensation that employees may receive for outside activities.

Of the 20 activities for which employees reported that they would receive compensation, the most common form was reimbursement for travel and expenses. Of these 20 activities, we were able to obtain the actual amount of compensation for only 5. Four of these five activities involved reimbursement for travel and expenses ranging from $1,800 to almost $32,000 per activity. The other activity involved an honorarium valued between $1,000 and $15,000.[4] (See Table 11 below.)

**Table 11. Types of Compensation That FDA Senior Level Employees Received for Approved Outside Activities, CY 2000–2003**

| Type of Compensation * | Number of Approved Activities Involving This Type | Percent of Approved Activities Involving This Type ** |
|---|---|---|
| None | 32 | 58 |
| Expense and Travel Reimbursement | 12 | 22 |
| Fees | 5 | 9 |
| Royalties | 2 | 4 |
| Honoraria | 1 | 2 |
| Salaries | 1 | 2 |
| Per Diem Payments | 1 | 2 |

* Three outside activity requests did not indicate whether or what types of compensation would be received.
** Column sums to more than 100 percent because some outside activities involved more than one type of compensation.
Source: Office of Inspector General analysis of FDA data, 2005.

[4] Prior to January 2004, employees were not required to report the amount of compensation to be received for outside activities on the HHS-520 forms. Therefore, when possible, we obtained this information from annual financial disclosure forms and from employees who voluntarily disclosed the amount of compensation on their HHS-520 forms.

This portion of our analysis regarding compensation is limited by the fact that compensation amounts were self-reported by the employees. We did not independently verify the types or amounts of compensation that employees actually received.

*Forty percent of approved outside activities for senior-level employees involved time off, and 29 percent of these activities involved a week or more of time off.* To participate in outside activities, employees often have to take time off from work. For the 22 outside activities for which senior-level employees indicated that time off would be required, these employees reported that they would take off between 1 and 36 business days from work. The median amount of time employees anticipated taking off to perform outside activities was 7 business days per activity.

As noted earlier in this report, 13 senior-level employees received approval for multiple outside activities between CYs 2000 and 2003. To do so, three of these senior-level employees reported taking more than a month off from work over this 4-year period. Further, one senior-level employee reported taking more than 7 months off from work to perform outside activities between 2000 and 2003.

Employees may also use personal time, or hours outside of the normal workday, to engage in outside activities. For 46 of the 55 senior-level outside activity requests we reviewed, employees documented the amount of time that would be spent on the activities. Total time spent on activities, including both time off and time outside of the workday, ranged from 1 to 143 calendar days per activity. The median amount of time spent on outside activities, per activity, was 12.5 calendar days. There are no explicit limits on the amount of time that employees may use to perform outside activities.

## ERRORS FOUND ON OUTSIDE ACTIVITY REQUESTS FOR FDA SENIOR-LEVEL EMPLOYEES

The following tables illustrate: (1) the frequency of errors on FDA senior-level employees' outside activity request forms, and (2) the problems we uncovered in our review of FDA senior-level employees' outside activity request forms.

**Number of Errors Found on Approved Outside Activity Requests of FDA Senior Level Employees, CY 2000–2003**

| Number of Errors | Number of Request Forms With Errors | Percent of Request Forms With Errors |
|---|---|---|
| 0 | 3 | 5 |
| 1 | 0 | 0 |
| 2 | 14 | 25 |
| 3 | 12 | 22 |
| 4 | 12 | 22 |
| 5 | 8 | 15 |
| 6 | 4 | 7 |
| 7 | 2 | 4 |
| **Totals** | **55** | **100** |

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

**Errors Found on Approved Outside Activity Requests of FDA Senior Level Employees, CY 2000–2003**

| Missing Item on the HHS-520 | Number of Requests | Percent of Requests |
|---|---|---|
| Missing at least one of the following items | 52 | 95 |
| HHS-520, Item 4: Grade and salary (one or both missing) | 40 | 73 |
| HHS-520, Item 18: Action taken (any part of Item 18) | 22 | 40 |
| Item 18a: Final action | 14 | 25 |
| Item 18b: Final approving official signature | 9 | 16 |
| Item 18c: Final approving official title | 14 | 25 |
| Item 18d: Signature date | 12 | 22 |
| HHS-520, Item 16: Additional information attached? | 16 | 29 |
| HHS-520: Request type | 15 | 27 |
| HHS-520, Item 17: Action recommended by reviewing official (any part of Item 17) | 9 | 16 |
| Item 17a: Recommended action | 7 | 13 |
| Item 17b: Reviewing official signature | 4 | 7 |
| Item 17c: Reviewing official title | 7 | 13 |
| Item 17d: Signature date | 5 | 9 |
| Second page of the HHS-520 | 9 | 16 |
| HHS-520, Item 12: Will compensation be derived from an HHS grant or contract? | 7 | 13 |
| HHS-520, Item 8: Estimated time involved | 6 | 11 |
| HHS-520, Item 10: If providing consultative or professional services, are your would-be associates receiving or will they seek, a grant or contract from a federal agency? | 5 | 9 |
| HHS-520, Item 11: Method of basis of compensation | 3 | 5 |
| HHS-520, Item 5: Name, address and business of person or organization for whom outside services will be performed | 2 | 4 |
| HHS-520, Item 6: Location where services will be performed | 2 | 4 |
| HHS-520, Item 3: Title of position | 1 | 2 |
| HHS-520, Item 9: Do your official duties relate in any way to the proposed activity? | 1 | 2 |
| HHS-520, Item 1: Name | - | - |
| HHS-520, Item 2: Organizational location | - | - |
| HHS-520, Item 7: Nature of activity | - | - |
| HHS-520, Item 13: Statement that form contains true, complete, and correct information | - | - |
| HHS-520, Item 14: Signature of employee | - | - |
| HHS-520, Item 15: Signature date | - | - |

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

## HHS AND FDA INITIATIVES

To strengthen the process for reviewing outside activity requests, HHS and FDA have the following initiatives recently completed, planned, or underway.

### HHS Interim Final Rule

HHS issued an interim final rule in February 2005 that imposes new responsibilities on FDA and other HHS employees who engage in outside activities.[5] The following are some of the provisions of the interim final rule that relate 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.

### Other HHS Initiatives

- As of January 2004, HHS employees who request approval for outside activities must list the amount of compensation to be received on their request forms.
- In August 2004, the HHS Designate Agency Ethics Official sent a memorandum to officials throughout HHS to remind them of the importance of performing due diligence when reviewing ethics forms.
- In April 2005, HHS released a revised version of the HHS-520 form that captures more information than the previous version.

### FDA Internal Review

- In June 2004, the Acting FDA Commissioner ordered a review of approximately 1,800 outside activities to assess compliance with relevant ethics rules. This review found no outside activities that raised concerns, except for one problematic activity of which FDA was already aware.

[5] 70 Fed. Reg. 5,543, Feb. 3, 2005.

### FDA Enhanced Oversight

In light of the June 2004 internal review of outside activities, the Acting FDA Commissioner announced several new requirements for outside activities, including the following:

- Prior to the interim final rule, FDA limited approvals for outside activities to 1-year periods.
- FDA first required center directors to be the final approving officials for all outside activity requests, and later required the FDA Deputy Ethics Counselor to be the final approving authority for all outside activity requests. This duty cannot be delegated, as it often was in the past.
- FDA has expanded the number of employees who are required to annually file the confidential financial disclosure form, the OGE-450.
- FDA will begin conducting annual reviews of outside activities in which they will cross-check financial disclosure forms to determine compliance with filing regulations.
- FDA is working on a comprehensive Agency-Wide Staff Manual Guide on Outside Activities, which will be released to all employees upon completion.

### FDA Enhanced Information Management

- Prior to the release of the revised HHS-520 form in April 2005, FDA employees were required to use the HHS-520-1 outside activities request form, which was unique to FDA and, in part, completed electronically.

# APPENDIX ~ E

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: DEC 1 2005

TO: Inspector General

FROM: Acting Commissioner of Food and Drugs

SUBJECT: FDA's Comments on OIG Draft Report: "Outside Activities of FDA Employees, "(OEI-01-04-00400)

The Food and Drug Administration (FDA) has completed its review of the draft inspection report, "Outside Activities of FDA Employees". Thank you for the opportunity to comment on this draft report. We appreciate your insights and the thoroughness with which the study was conducted. The Office of Inspector General (OIG) report concluded that vulnerabilities exist which limit FDA's ability to effectively review outside activities. The vulnerabilities include: 1) Information submitted about outside activities that were in some cases incomplete or inadequate; and 2) The review process demonstrated problem areas such as approvals occurring after the start date of the activity, multiple activities listed on a single activity request, and inadequate follow-up.

This memorandum identifies the recommendations raised by the OIG and what the FDA has done or is in the process of doing regarding each of the recommendations:

**Recommendation 1: Improve the quality and extent of information for outside activities.**

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

**FDA's Response:** Section II of the newly developed "Request for Approval of Outside Activity" (HHS-520), effective April 2005, requires the employee to provide detailed information on the proposed outside activity and specifically requests a description of the activity. In addition, Section III requires the employee to describe his/her official duties or to attach a copy of their PD. Other relevant questions include the relationship of the employee's official duties to the outside activity and the effect of official duties on the outside employer. If an employee fails to provide adequate information to describe the duties to be performed, the supervisor or approving official will request additional information, such as, written invitation, copies of contracts and agreements.

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B. *Ensure that all employees fill out their outside activity requests completely.*

**FDA's Response:** The new HHS 520 form provides a section for Agency Ethics Official Review. The ethics official certifies that he/she reviewed the employee's responses and the supervisor's determination. This process ascertains that the employee answers the questions completely. FDA is currently developing instructions for the completion of form HHS 520 which will include a checklist for employees to assist in ensuring that the HHS 520 is complete prior to submitting through the approval process.

C. *Crosscheck financial disclosure forms with those employees' outside activities for the previous year.*

**FDA's Response:** The agency's current financial disclosure review process includes crosschecking forms with our outside activity tracking system to ensure that employees that report outside employment and outside activities for which prior approval is required have received such approval and the approval is current. Instructions for the completion of HHS 520 forms and internal policies for reviewing the 520 forms are currently being developed and will include the crosschecking measure.

**Recommendation 2: Address the inadequacies in the review process for outside activities.**

A. *Develop complete policies and procedures on outside activities for all centers and employees.*

**FDA's Response:** The agency is currently developing written procedures for the completion and review of outside activity forms. These procedures will be distributed agency-wide and will be posted on the Ethics web page. Information currently on the web page has been updated and expanded to provide greater details regarding the purpose of the outside activity review process and the current regulations pertaining to outside employment and outside activities

B. *Ensure that outside activity requests are approved before their scheduled start dates.*

**FDA's Response:** Employees are advised during the ethics portion of the orientation program and in periodic ethics advisories that activities requiring prior approval shall not begin prior to the receipt of such approval. In addition, once the Agency's Deputy Ethics Counselor (DEC) approves an outside activity, the HHS-520 form is returned to the Ethics and Integrity Staff and a copy of the form is provided to the employee through their supervisor. The transmittal letter clearly reminds both the employee and the supervisor that the activity may not begin prior to the signature date of the DEC.

C. *Ensure that activities are approved for periods not exceeding the maximum amount of time allowed by FDA.*

**FDA's Response:** The new HHS 520 form specifically states that approval is effective for a period not to exceed one year from the date the activity was approved. The agency's internal review will ensure the time period specified does not exceed a one-year period.

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D. *Ensure that each outside activity receives its own separate review.*

**FDA's Response:** The internal review procedures including the all-hands instructions will specify that each activity for which an employee is requesting approval be reported on a separate HHS 520 form.

E. *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 employee's official duties.*

**FDA's Response:** The HHS 520 form contains a disqualification statement in Part IV – Supervisor's Review. By checking the "Recommend Approval," box, the supervisor is acknowledging that the employee will be disqualified from performing official duties that involve or affect the organization for which he has an outside activity. Further, Part VIII of the HHS 520 form provides a notice of the employee's continuing legal obligation to disqualify from official assignments affecting the outside employer or the entity to which they are providing personal services. After the form is approved, the supervisor, as well as the employee, receives a copy.

F. *Ensure that supervisors are notified of all approvals and disapprovals.*

**FDA's Response:** The FDA Deputy Ethics Counselor approves or disapproves the HHS 520 request and returns the form to the Ethics and Integrity Staff (EIS). The EIS files the original form and sends a copy of the form to the employee through the supervisor.

G. *Enhance training related to outside activities.*

**FDA's Response:** The HHS Ethics Education and Program Review Staff, Office of General Counsel/Ethics Division, is developing ethics training for all HHS Supervisors. A module on reviewing HHS 520 and 521 forms will be included in the review. Upon completion, the training module will be provided to all HHS Deputy Ethics Counselors for use in their training programs. In addition, the FDA new employee orientation training has been revised to include a more comprehensive review of the outside activity program. An all-hands notice has been sent to FDA employees regarding the new outside activity process and the EIS Web page has been updated to reflect the current rules/regulations. Finally, the 2005 HHS Annual Ethics Training focuses on outside activities.

H. *Consider centralizing some or all aspects of the review process for outside activities that relate to official duties.*

**FDA's Response:** The newly developed HHS 520 includes a multi-layered review process incorporating center officials as well as headquarters officials. Once an employee certifying that all statements are true to the best of their knowledge completes an outside activity request, the request is then forwarded to their supervisor for review and recommendation of approval or disapproval. The request is then elevated to the designated reviewing official (Centers – the Director or Deputy Center Director; OC – the Office Director; ORA – the Associate

Commissioner for Regulatory Affairs); for concurrence or non-concurrence. The Ethics and Integrity Staff then reviews the request and recommends approval or disapproval. Finally, the Agency's Deputy Ethics Counselor provides a determination that the request be either approved or disapproved. This multi-level review process allows weigh-in by officials at the center level who understand the duties and responsibilities of the affected center as well as ethics officials that provide a review based on the applicable conflict of interest provisions and can suggest proper remedy if a conflict is identified. FDA agrees that the old system was too decentralized in that supervisors or a designated center official was conducting the approvals of outside activity requests. The current system is now more centralized in that all HHS 520 requests receive an ethics review prior to the employee receiving approval from the agencies DEC.

During the summer of 2004, FDA acted proactively to strengthen the outside activity process in several ways:

1. Developing an automated system for employees to request approval using the EASE system;
2. Changing the filing designation from the GS 14 to the GS 13 level, and the Commission Corps (CC) 05 to the CC 04 level for non-administrative positions, resulting in approximately 1000 additional confidential filers agency-wide;
3. Developing Standard Operating Procedures for the outside activity process; and
4. Elevating the outside activity approving officials to the highest level i.e., Center Director for their respective center; the Associate Commissioner for Regulatory Affairs for outside activities in ORA; and the Acting Commissioner of Food and Drugs for outside activities in OC. (This has now been superceded by the newly established HHS-520 and the final approval determination rests with the agency's DEC)

In addition to the previous comments, we appreciate your consideration of the following comments:

- The report discusses recusals (and their absence) in the summary and on page17. This seems to suggest that an activity that would otherwise be a conflict of interest could be approved if a written recusal is prepared. This is not FDA's policy. If an activity poses a conflict of interest, it generally is not approved.

- Some of the statistics mentioned on pages 9-10 are confusing. It is not surprising, for example, that the Center for Drug Evaluation and Research and the Office of Regulatory Affairs have the largest number of outside activities approved, as they are the largest units considered by the report. It would be helpful if the report acknowledged this fact or otherwise put these statistics in some sort of context. Also, Table 4, Appendix B, has a column "Percent of All Approved Outside Activities". Perhaps that Table should be expanded to show the number of approvals as a percentage of employees in a unit.

- It may be useful to note that many of the approved activities are those that keep an employee connected to his/her scientific discipline, to maintain professional license, or are leadership positions in important technical organizations. These activities are consistent with maintaining the value of the employee to FDA because they are essential to maintain employees' expertise and standing in the professional community. A

statement of this kind would provide some context for the statistic about how much time off is requested or taken for outside activities.

- The report states (p. 12) that most omissions were minor and then asserts that the omissions make review of the outside activity requests difficult. A review of Appendix C illustrates that most of the omissions were not about the activity or the employee's position, but rather occurred in the approval area such as the omission of a supervisor's title. While the Agency does not condone incomplete forms, it is important to recognize that many of the omissions were not of a nature to create conflict of interest situations.

- The report notes (p. 13-14) that the OIG reviewers needed more information about an employee's specific job duties than was available on the HHS-520. While it is true that the HHS 520 form used at the time of the review did not include specific details about an employee's job, this has been resolved with the new HHS-520 form. Part III of the HHS-520 now requires information relating to the employee's official duties including the nature of the official duties; the relationship of the official duties to the outside activity; the effect on the outside employer; and assignments involving the outside employer.

- The same comment applies to the absence of supplemental information about the outside activity. Although OIG reviewers might need it to make a determination, it is not clear that FDA reviewers, who are often knowledgeable about organizations requesting speeches or manuscripts, would require the same level of information. Regardless, the new HHS-520 form provides for detailed and specific information relating to and about the outside activity in question.

- Page 18 addresses "Inadequate training". The report states "…Currently, there is no requirement for annual ethics training for all employees at FDA; rather, annual ethics training is only required for employees who file financial disclosure reports…" While it is true that currently no policy exists for all employees to receive annual training, all employees are subject to New Employee Orientation ethics training and receive ethics training in form of ethics advisories and updates. Further, all employee have access to the Ethics web page that posts the latest ethics advisories and current information regarding the ethics rules.

- The additional requirements and processes recommended by the OIG are well noted. To date, many new policies and processes have been implemented to make the outside activity process less burdensome while continuing to safeguard the agency from a negative public perception. The agency remains open to recommendations for improving our process, without making the reporting burden so great that employees will avoid activities altogether.

The FDA comments originally provided continue to be accurate despite the fact that on February 3, 2005, and again on August 31, 2005, the Department issued revised Supplemental Standards of Ethical Conduct and Financial Disclosure Requirement regulations. The February 2005 interim final rule focused primarily on changes that affected employees of the National Institutes of Health. However, as a result of significant concerns and objections to the February interim rule, the Department carefully considered and made significant revisions to the final rule. Of

most importance to FDA, is the fact that the Department removed the requirement that FDA employees obtain prior approval for all outside activities. Activities, which never posed a conflict of interest, such as coaching a sport team, teaching a crafts class, or performing in a play, have been eliminated from requiring prior approval.

By tailoring the prior approval requirement, FDA is now able to focus more closely on those activities that are most likely to pose a conflict or raise an appearance concern. Furthermore, by developing written procedures and policies, we will ensure consistency in the process to ensure compliance with the Departments Supplemental Standards of Conduct regulations.

If you have any questions or need additional information, please contact Jenny Slaughter 301.827.5518.

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# ACKNOWLEDGMENTS

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