



July 26, 2004

Edgar M Swindell
Designated Agency Ethics Official
Department of Health and Human Services
700-E Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr Swindell

The Office of Government Ethics (OGE) recently completed a review of the ethics program at the National Institutes of Health (NIH), focusing specifically on the Clinical Center (CC), the National Cancer Institute (NCI), the National Institute of Allergy and Infectious Diseases (NIAID), and the Office of the Director (OD). This review was conducted pursuant to section 402 of the Ethics in Government Act of 1978, as amended. Our objective was to determine the program's compliance with applicable ethics laws and regulations, rather than investigate any particular case of employee misconduct. We also evaluated NIH's systems and procedures for ensuring that ethics violations do not occur. The review was conducted from January through May 2004.

In addition, while our review was ongoing, outside consulting and the receipt of awards by NIH employees was the subject of inquiry of both Houses of Congress. A blue ribbon panel commissioned by the NIH Director issued a report with recommendations to address Congress' concerns, and the NIH Director made proposals for improvement in the NIH ethics program in testimony before Congress. Accordingly, this report addresses some of the matters discussed in the Department of Health and Human Services (HHS) and NIH statements made to Congress. Finally, because outside activities by NIH employees have been the subject of our reviews for more than 15 years, this report summarizes the history of NIH policies and practices relating to outside activities and our reviews of the issues that have been raised over that period, as well as the findings and recommendations of our current review.

Currently you are developing proposals to remedy the issues raised by the Congress and similar issues identified during our review. These proposals are in draft and as such are not discussed in this report.

SCOPE OF REVIEW

Based on the results of our pre-review, which included discussions with you and NIH ethics officials, we focused primarily on the overall structure and administration of NIH's ethics program,

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the public and confidential financial disclosure systems, and the policies and procedures for approving the participation in outside activities and the acceptance of awards by NIH employees

HIGHLIGHTS

Our examination revealed that the ethics program needs to be improved. One major concern we have is that the structure of the ethics program at NIH seems to allow for minimal involvement and oversight on your part. Program management duties are bifurcated between you and the NIH Deputy Director. This apparent disconnect between you and the employees who administer the day-to-day operations of the program appears to have contributed to some of the problems identified in our review and in recent testimony before Congress. While we commend the steps that you and the NIH Director have taken recently to improve the program, further action is needed.

During our examination, we identified areas in need of improvement in the program elements we reviewed. In particular, requests for approval of outside activities often were untimely, and for some outside activities, no requests for approval were ever made. We also have systemic concerns with regard to the approval of the acceptance of awards by NIH employees. Also, while many aspects of the financial disclosure systems were sound, we identified some deficiencies in the consistent collection of confidential reports and the timely certification of public reports.

Finally, steps need to be taken to ensure that NIH ethics officials are correctly applying the relevant provisions of the Standards of Ethical Conduct in outside activity and award determinations.

PRIOR OGE REVIEWS

OGE has conducted four reviews of NIH's ethics program since 1987. Although we examined a number of different program elements during these reviews, the majority of our findings focused on NIH's policies and procedures relating to the outside activities of its employees.

OGE conducted its first review of NIH's ethics program in 1987. The findings of this review focused almost exclusively on NIH's policies and procedures for approving outside activities. The findings included our determination that there had occasionally been a "blurring" of the distinction between what should be properly authorized as official business and outside activities. We reported that this had led to possible violations of the NIH Manual Chapter 2300-735-4, "Outside Work and Activities," issued in 1985 (the Manual), the HHS standards of conduct regulation,¹ and 18 U.S.C. § 208(a). We also reported that the apparent blurring of this distinction was contrary to certain OGE

¹Prior to the Standards of Ethical Conduct, 5 C.F.R. part 2635, becoming effective in 1993, agencies issued standards of conduct regulations under the old executive branch model standards of conduct at 5 C.F.R. part 735. Much of part 735 and the agency regulations thereunder were superseded by part 2635. Currently, 5 C.F.R. § 2635.105 provides for the concurrence by, and joint issuance with, OGE of supplemental agency regulations.

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guidance on the acceptance of compensation for speeches, lectures, and articles related to an employee's official Government duties ²

OGE conducted its second review at NIH in 1991. As with the 1987 review, the most serious problems we identified were with NIH's system for approving outside activities. These problems appeared to be due to both an HHS policy that was inconsistent with OGE regulations and an ineffective NIH review process involving Deputy Ethics Counselors relying on poor guidance in the Manual. We concluded that NIH's permissive attitude toward outside activities and its fear that further restricting outside activities might hinder recruitment and retention of scientific personnel also played a major role in the problems and issues we identified. We recommended that your predecessor assist NIH in establishing an NIH ethics office to be directed by an HHS ethics official.

In our 1995 report, our findings again focused largely on NIH's outside activity approval system, particularly the Manual revised as of August 30, 1993 (the August 1993 Manual). During this review we identified several NIH restrictions and limitations that were broader in scope than provided for by the Standards of Ethical Conduct and one restriction that was narrower in scope. Further explanation of the findings of our 1995 review is addressed below in the "OUTSIDE ACTIVITIES" section.

Our most recent review of NIH's ethics program took place in 2000. Our most significant finding again dealt with outside activities. At one of the institutes included in our review, we found that the requisite approvals were not on file for all outside activities reported on employee financial disclosure reports. At the time of our review, the institute's Deputy Ethics Counselor had only recently taken over the day-to-day management of the institute's ethics program and, therefore, could not definitively determine if all appropriate approvals had been granted.

PROGRAM ADMINISTRATION

As the HHS Designated Agency Ethics Official (DAEO), you are responsible for coordinating and managing the ethics program departmentwide. The Deputy Associate General Counsel for Ethics Advice and Financial Disclosure (a newly created position) serves as the Alternate DAEO.

Each NIH institute and center (IC), including OD, has a Deputy Ethics Counselor (DEC) in charge of the IC's ethics program and one or more Ethics Coordinators who assist in the program's day-to-day administration. All of NIH's 27 ICs have DEC's who are deputy directors or executive officers, except for a few cases where the IC director serves as the DEC.

²Much of this guidance, contained in OGE Informal Advisory Memorandum 85 x 18, was later incorporated in 5 C F R § 2635 807

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The NIH Deputy Director recently was appointed DEC for NIH as a whole, as well as for OD, a position long held by the previous Deputy Director. The NIH DEC is assisted in the day-to-day administration of the NIH and OD ethics program by a three-person NIH Ethics Office. In addition, however, an attorney from your office (the HHS Office of General Counsel/Ethics Division (OGC/ED)) serves as the on-site NIH Ethics Counsel. She is the only NIH ethics official that reports to you. She is responsible for, among other things, reviewing and certifying the financial disclosure reports filed by DECs who are IC directors (non-director DEC reports are filed with the NIH Ethics Office) and providing advice and counseling. Under a recent organizational redesign of OGC/ED, another attorney and a secretary have been assigned to serve with the NIH Ethics Counsel. Eventually, either the NIH Ethics Counsel or the new attorney will be named NIH Senior Ethics Counsel.

ETHICS PROGRAM MANAGEMENT

Under 5 C F R §§ 2638 201 and 2638 203, the DAEO is required to coordinate and manage the agency's ethics program. You have delegated this authority to the NIH DEC and the DECs assigned to the ICs, and thus do not have direct involvement in the NIH program. This program structure appears to have prevented you from carrying out your coordination and management duties, and may have resulted in some of the deficiencies identified during this review and during Congressional hearings. Ceding authority to NIH officials to direct the NIH ethics program might be a viable arrangement if NIH had a history of adequately addressing the types of problems confronting NIH at this time. Unfortunately, the opposite is true. Both prior OGE reviews and recent testimony before Congress indicate that NIH has had a permissive culture on matters relating to outside compensation for more than a decade. We believe that strong leadership on your part is essential to ensuring that the deficiencies in this area do not continue.

Moreover, we believe there is confusion at NIH as to who is responsible for the ethics program. This result stems, in part, from your having an OGC/ED satellite ethics office at NIH as well as a separate NIH ethics office. During our Exit Conference, we discussed the possibility of merging these two staffs into one NIH ethics office, with possibly additional staff being added, to ensure that the program is carried out effectively. We suggested that this office should be headed by a strong ethics professional who would serve as the HHS Deputy DAEO for NIH and who would report directly to you. In order to ensure that the DAEO's office is more engaged in the management and reform of the NIH ethics program, we thought it appropriate to recommend that the head of this central NIH ethics office be a member of your own staff, rather than an official primarily answerable to NIH.

At the time of the Exit Conference, both you and the NIH DEC opposed this recommendation. Among the arguments against this proposal, the NIH DEC believes the appointment of an OGC/ED official to oversee the program would be an unnecessary step in ensuring your direct involvement. He acknowledged that for purposes of carrying out his ethics duties, which include the oversight of the NIH program as a whole, he is fully accountable to you.

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He added that as the Deputy Director for NIH, he is better positioned to institute the needed changes in the program and ensure their consistent implementation. He stated that many of the problems identified in the NIH ethics program are the result of, in some part, the permissive culture that has existed at NIH and that as a senior-level NIH employee, he would be better able to reshape this culture. Finally, both you and the NIH DEC agreed that instituting a new ethics program structure at this point would be premature, as you have implemented, or are currently developing, various new policies and procedures to correct the deficiencies identified during the recent Congressional hearings and in the course of our review.

In response to these arguments, we have decided to forego making a formal recommendation for the reorganization of the NIH ethics program at this time. However, we are recommending that certain steps be taken to ensure your direct coordination and management of the program.

First, you should meet periodically with NIH management so that you will be fully cognizant of current and emerging ethics issues at NIH and be able to react to them accordingly. These meetings should ensure that you are aware when policies and procedures at NIH are not effective, and enable you to make changes as needed. Second, you should meet with NIH ethics officials and NIH management to determine what policies need to be developed to deal with the issue of outside consulting by NIH employees and develop an NIH-specific section of the HHS supplemental regulation for submission to our Office for concurrence and joint issuance (addressed below in the "OUTSIDE ACTIVITIES" section). Finally, to formalize the responsibilities of the IC DECs, their position descriptions should contain a description of their ethics duties. The NIH DEC should rate each DEC annually on the ethics portion of his or her work.

While we are not formally recommending a reorganization of the program at this time, we will periodically review the success of your changes in policies and procedures, beginning with our initial six-month follow-up review. Based on our assessment of the success of these changes, we will decide whether a reorganization is necessary.

OUTSIDE ACTIVITIES

Under HHS' supplemental standards of conduct regulation, and as implemented in the Manual revised as of February 17, 1998 (the current Manual), NIH employees are required to receive written approval prior to engaging in certain outside employment and activities. Because of recent serious concerns about NIH policies on outside activities, this report contains the following detailed summary of (1) our 1995 report on NIH's outside activity approval procedures, (2) the current HHS supplemental standards of conduct regulation, (3) our current review of the outside activity procedures, (4) the recent changes to these procedures, and (5) our observations on the current case-by-case review of requests for approval, and the need for supplemental rules.

1995 OGE Report

In June 1995, we issued a report on NIH's ethics program which focused largely on NIH's policies and procedures for approving outside activities. In this report, we explained that HHS'

preserved standards of conduct regulation required that employees obtain administrative approval prior to engaging in certain types of outside activities of a professional or consultative nature ³

The report further explained that NIH had documented its internal guidance on the policies and procedures governing outside activities in the August 1993 Manual. During the 1995 review we identified several restrictions and limitations in the Manual that were broader in scope than provided for by the Standards of Ethical Conduct, and one restriction that was narrower than the Standards.

At the time, NIH officials conceded that some of the guidance provided in the August 1993 Manual was broader in scope than the Standards of Ethical Conduct. However, they added that the Manual had been revised to address some of the concerns identified during OGE's 1991 review of NIH's ethics program.

In the 1995 report, we recommended that if NIH wished to continue these prohibitions and limitations, HHS should consider including them in the agency's proposed supplemental regulation. In response to this recommendation, the then-NIH Director issued a directive to all IC directors and senior staff in November 1995 rescinding the outside activity policies that were more restrictive than the Standards of Ethical Conduct. The August 1993 Manual was revised to reflect these changes in policy, resulting in the current Manual ⁴. According to the memorandum, based on a discussion among the IC directors, the more restrictive policies were removed rather than proposed for inclusion in a supplemental regulation for OGE concurrence and joint issuance. Therefore, the subsequently-issued HHS supplemental standards of conduct (detailed below) do not contain any of the aforementioned broader restrictions and limitations.

Current HHS Supplemental Standards Of Conduct Regulation

On July 30, 1996, HHS, with OGE concurrence, issued a supplemental standards of conduct regulation at 5 C F R part 5501. As previously noted, this regulation does not contain the narrower or any of the broader restrictions or limitations that were in the August 1993 Manual. However, this regulation requires that employees obtain approval prior to engaging in certain outside activities, whether or not compensated.

³At the time of the 1995 review, HHS had submitted its proposed supplemental regulation, including a prior approval requirement, to OGE for concurrence, in accordance with 5 C F R § 2635 105. This supplemental regulation was to supercede the requirements contained in HHS' preserved standards of conduct under the old executive branch model standards.

⁴Our review of the current Manual revealed that all of the required revisions to the previous version have in fact been made.

First, employees are required to obtain prior approval to engage in consultative or professional services, including service as an expert witness⁵

Second, employees are required to obtain prior approval to engage in outside teaching, speaking, writing, or editing that relates to the employee's official duties within the meaning of 5 C F R § 2635 807(a)(2)(i)(B) through (E) or would be undertaken as a result of an invitation to engage in the activity that was extended to the employee by a person who is a prohibited source within the meaning of 5 C F R § 2635 203(d), as modified by section 5501 102

Third, employees are required to obtain approval prior to providing advice, counsel, or consultation to a non-Federal entity as an officer, director, or board member, or as a member of a group, such as a planning commission, advisory council, editorial board, or scientific or technical advisory board or panel. However, prior approval is not required if the service is provided without compensation (other than reimbursement of expenses to a political, religious, social, fraternal, or recreational organization) and the position held does not require the provision of professional services within the meaning of 5 C F R § 5501 106(b)(3)

Fourth, the standard for approval is that the outside activity is not expected to involve conduct prohibited by law or regulation, including 5 C F R parts 2635 and 5501. In this connection, section 2635 802 prohibits an employee from engaging in outside employment or any other outside activity that conflicts with the employee's official duties if it (1) is prohibited by law or by agency supplemental regulation or (2) under sections 2635 402 and 2635 502, would require the employee's disqualification from matters so central or critical to the performance of his or her official duties that the employee's ability to perform the duties of the position would be materially impaired.

Much of the criticism leveled at NIH relates directly to its implementation of these provisions. In particular, the Standards of Ethical Conduct also caution that an outside activity may be prohibited under other provisions in the Standards. See 5 C F R § 2635 802(b). Notably, section 2635 801(c) emphasizes that these "include the principle that an employee shall endeavor to avoid actions creating an appearance of violating any of the ethical standards in this part and the prohibition against use of official position for an employee's private gain or for the private gain of any person with whom he has employment or business relations or is otherwise affiliated in a nongovernmental capacity." As discussed in more detail below, it is not clear to us what standards NIH was applying in its outside activity approval process.

⁵Consultative services are defined in the regulation as the provision of personal services by an employee, including the rendering of advice or consultation, which requires advanced knowledge in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, a hospital, or other similar facility. Professional services are defined as the provision of personal services by an employee, including the rendering of advice or consultation, which involves the skill of a profession as defined in 5 C F R § 2636 305(b)(1).

Current Outside Activity Prior
Approval Procedures

In the current Manual, NIH has documented procedures to implement the outside activity prior approval requirements contained in the HHS supplemental regulation. In accordance with the current Manual, requests for approval of outside activities are initiated by the employee completing an HHS-520 form, Request for Approval of Outside Activity, and appropriate supplemental attachments. The HHS-520 requires the reporting of basic information regarding the nature of the outside activity, the name of the employer, the estimated time to be devoted to the activity, and any relationship between the employee's official duties and the proposed activity.⁶ To further facilitate the review of proposed outside activities, the supplemental attachments require an explanation of how the proposed outside activity is different from the scientific activities performed as part of the employee's official duties, specific consulting and outside professional practice information, and the employee's position description.

As an additional oversight effort, the current Manual also requires employees to submit an annual update for each continuing (versus one-time) activity that was performed during the previous 12 months.⁷

Current Review

To evaluate HHS'/NIH's policies and procedures for ensuring outside activities are approved in accordance with the HHS supplemental regulation and the current Manual, we examined a sample of 155 outside activities reported on the public and confidential financial disclosure reports we reviewed from filers at the 4 ICs. During our examination, we assessed whether sufficient information was contained in the outside activity requests to allow the reviewing and approving officials to determine if any conflicts of interest existed between the employee's official duties and the proposed outside activity. However, while we examined the activities with an eye toward ensuring that all required information was provided in the requests, we were generally not in a position to identify potential conflict-of-interest situations because a lack of scientific expertise prevented us from determining how the employees' official duties may have related to their outside consulting activities. Finally, we assessed the timeliness of the requests and approvals, i.e., whether the requests were submitted and approvals were granted prior to the activity taking place.

⁶Based on your January 27, 2004 directive, employees are now also required to provide compensation information on the HHS-520.

⁷Although the use of the HHS-521 (the form previously used to collect the annual update information) is no longer required, the information collected thereon is required, i.e., whether the outside activity is still continuing and the number of hours the employee was engaged in the activity.

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Our examination revealed that a significant number of reported outside activities were not approved in a timely manner and many appeared not to have been approved at all. Of the 155 activities we examined, 81 were approved prior to the employee engaging in the activity. However, 39 were approved after the activity start date. Moreover, we did not find any approvals for 35 of the outside activities we examined.

We examined 73 outside activities at NCI. Of these, 53 (73 percent) were approved prior to the activity taking place, while 16 (22 percent) were approved after the start date. Four (five percent) of the outside activities sampled from this institute did not have approvals on file.

Of the 49 outside activities we examined from OD employees, 19 (39 percent) were approved prior to the activity taking place, and 11 (22 percent) were approved after the start date. Nineteen (39 percent) of the activities did not have approvals on file.

At CC, we found that 6 (40 percent) of the 15 outside activities we examined were approved prior to the activity taking place, while 9 (60 percent) were approved late. We did not find any approvals for an additional 11 activities which were listed as outside activities on the sample of financial disclosure reports we examined. We were informed by CC ethics officials that all 11 activities were actually official duty activities and thus did not require approval as an outside activity. If these were in fact official duty activities, they should not have been reported on the financial disclosure reports.

Of the 18 outside activities we examined at NIAID, 3 (17 percent) were approved prior to the activity taking place, 3 (17 percent) were approved after the activity start date. More notably, 12 (66 percent) of the outside activities reported at NIAID had no approvals on file.

In regard to the annual update on the HHS-521, or by other method, of continuing activities, none of the four institutes appear to be collecting this information on a consistent basis. In many cases, the required annual supplemental information was collected only once, sporadically over several years, or sometimes not at all. While the reporting of this information is still required by the current Manual, the NIH OD Ethics Officer stated that it was her understanding that the annual updates were no longer required unless there was a substantive change in the activity, thus essentially rendering it a new activity requiring a completely new approval. We recommend that this issue be clarified and either (1) improve the procedures for collecting the required annual information regarding continuing outside activities or (2) eliminate the requirement from the Manual.

While obviously we are concerned about the lack of timely and consistent initial approval and subsequent annual reporting, NIH has taken the initiative to improve this situation. The NIH Director has mandated that all employees engaged in ongoing outside activities requiring approval under the HHS supplemental regulation obtain re-approval if they intend to continue engaging in the activity.

During our examination, we particularly tried to identify the number of outside activities that involved employees consulting for, or serving on the advisory boards of, biotech or pharmaceutical companies. Of the public filers from the four ICs, six did consulting work for a biotech or pharmaceutical company and two were board members. A total of 17 confidential filers were involved in consulting work for these types of companies and 3 served on boards. The majority of the confidential filers (10) who were or who continue to be involved in consulting work with a biotech or pharmaceutical company were from NCI.

Notwithstanding the timeliness issue, the requests we examined for which approvals were on file appeared to generally contain the information required by the HHS supplemental regulation and the current Manual. Nevertheless, we believe our overall findings provide evidence of the difficulties inherent in a case-by-case approval method and lend additional weight to our recommendation to implement specific supplemental restrictions on certain outside activities, as discussed below. And while we cannot say that any particular request that we examined was approved in violation of the Standards of Ethical Conduct, other consulting arrangements examined by the House Energy and Commerce Oversight and Investigations Subcommittee seem to demonstrate that NIH officials may not have applied all relevant provisions of the Standards when reviewing requests for approval. As mentioned above, outside activities that technically are not prohibited under 5 C F R § 2635.802 may still be prohibited under other provisions of the Standards of Ethical Conduct, such as the appearance of the use of public office for private gain. It is not clear to us how NIH officials analyzed the requests they received, and whether they applied all relevant provisions of the Standards.

Recent Changes To Approval Procedures

During the course of our review, NIH amended its procedures for approving outside employment and activities by NIH employees. These changes were implemented primarily through the formation of the NIH Ethics Advisory Committee (NEAC).

NEAC is co-chaired by the NIH DEC and the Deputy Director for Intramural Research, and consists of 10 other rotating members appointed by the co-chairs and 2 ex officio members (the NIH OD Ethics Officer and a representative of the OGC/ED). The 10 rotating members consist of IC directors and deputy directors, scientific directors, clinical directors, certain extramural directors, OD senior staff, and others. Under the new approval procedures, NEAC reviews

- (1) Without regard to compensation or dollar amounts, all outside activity and cash award requests from IC directors and deputy directors, scientific directors, clinical directors, certain extramural directors, and OD senior staff, and,
- (2) All requests from other NIH staff to accept or participate in
 - "lecture awards" where compensation equals or exceeds \$2,500,

- outside activities with biotechnology or pharmaceutical companies,
- outside activities where total anticipated compensation exceeds \$10,000 or is expressed as a future income stream, and
- activities for which compensation proposed is stock, stock options, or other equity position

All requests from OD senior staff and IC directors go through the appropriate IC DEC, then to NEAC for recommended approval/disapproval, and finally, if recommended for approval, to the NIH DEC for final approval

All requests from deputy directors, scientific directors, clinical directors, and certain extramural directors go to the appropriate IC DEC for recommended approval/disapproval, then to the appropriate IC director for supervisory review and recommendation, back to the appropriate IC DEC for review and routing, then to NEAC for review and recommendation, and finally to the NIH DEC for final approval

Covered requests from other NIH staff are submitted to their initial supervisor for review and recommendation, forwarded to the appropriate IC DEC for review, submitted to NEAC for review and recommendation, and then submitted to the NIH DEC for final approval

While we recognize the formation of NEAC as a positive step in enhancing NIH's outside activity approval process, we recommend that after review and recommendation by NEAC, the NIH Senior Ethics Counsel make the final approval decision. This would address some of the concerns expressed above under "ETHICS PROGRAM MANAGEMENT." In addition, as discussed in more detail below, NEAC must apply appropriate standards and criteria to each request it receives. Your office should develop a set of guidelines to help NEAC determine when an activity is permissible under the Standards of Ethical Conduct.

Supplemental Rules For Outside Activities

OGE strongly recommends that HHS and NIH develop and propose new supplemental standards of conduct specifically to address the kinds of consulting activities that have raised concerns and that pose the unfortunate potential for widespread public questioning of the integrity of NIH employees. After HHS and NIH decided in 1995 to forego any supplemental restrictions specific to the outside activities of NIH employees, presumably, it was anticipated that case-by-case application of the Standards of Ethical Conduct in 5 C F R part 2635 would be adequate to prevent any actual or apparent ethical problems. Subsequent experience has shown, however, that the case-by-case approach has not been adequate to protect the reputation of the agency and its employees.

Apart from questions about what criteria NIH has used to evaluate outside activities for compliance with the Standards of Ethical Conduct, our review also indicates that NIH's case-by-case regime has suffered from systemic problems of untimely and even nonexistent approvals. Although we do have some suggestions below for ways in which NIH can improve its case-by-case review of proposed consulting activities, we believe that recent history suggests it would be risky for NIH to place too much reliance on such reviews in lieu of specific supplemental restrictions on the types of consulting activities that have occasioned the most public concern.

This report does not contain a specific prescription for the particulars of a supplemental regulation, but rather a set of more general considerations that OGE believes are important for HHS and NIH to take into account in fashioning any supplemental restrictions. A program review report is not the appropriate vehicle for the specifics of a proposed supplemental regulation, so much depends on the actual language of any proposed provision, and OGE must work closely with you to ensure that the language agreed to is adequate and not likely to yield unintended consequences. However, the following observations should be taken into account in drafting a proposed supplemental regulation.⁸

1. Some of the preliminary proposals that have been aired publicly, including the proposals of the Blue Ribbon Panel and the tentative proposals announced in the NIH Director's Congressional testimony of June 22, place fewer restrictions on intramural researchers than on employees involved in NIH's extramural programs. Other than certain "senior level" employees (see more below), intramural researchers generally would not be subject to the same across-the-board restrictions as extramural officials with respect to consulting activities with pharmaceutical and biotechnology companies. As we understand it, the rationale for permitting more latitude on the part of intramural researchers is to keep NIH's intramural program attractive to researchers who might otherwise work in settings, such as academia, where they are generally free to pursue their intellectual interests through collaborations with industry. In addition, HHS and NIH believe that the compensated exchange of scientific information with industry is an important incentive that will promote cutting-edge research.

OGE certainly recognizes that the development of any set of restrictions on the outside activities of NIH employees involves balancing and accommodating competing concerns, including concerns about recruitment and retention and the creation of a work environment that adequately permits scientists to pursue their research interests. Nevertheless, we believe that NIH should seriously consider whether the distinctions between extramural and intramural officials are sufficient to justify a more lenient approach with respect to the outside activities of the latter.

⁸Additionally, we would draw your attention to the enclosed letter to Representative Dingell—especially paragraphs 2, 5, 9, 10 and 14—which highlights certain questions that HHS and NIH may want to consider in connection with possible supplemental rule proposals. Letter to Marilyn L. Glynn, Acting Director, OGE, to Representative John D. Dingell, Ranking Member, Committee on Energy and Commerce, June 17, 2004.

Many of the very consulting activities that have become the subject of public controversy have involved intramural researchers. In fact, from OGE's perspective, probably the most compelling argument that can be made for any absolute prohibition on consulting with drug companies is that some NIH officials actually are involved in making clinical decisions affecting the health and safety of patients and other intramural research subjects, and those subjects need to be confident that decisions about their care are free from any potential influence from extraneous business connections. Even those intramural officials who do not perform research on human subjects still may be in a position to study the products of particular drug companies, and it is possible that such research could affect, or create the appearance of affecting, the interests of those companies or their competitors. Overall, it appears to us that intramural researchers are more likely to have official duties that directly involve drug companies--for example, cooperative research and development agreements or other arrangements to use a particular company's products--than do extramural officials. It seems somewhat counterintuitive to place the more restrictive limits on extramural officials, who generally are not as directly involved with drug companies and whose duties more typically involve funding arrangements with universities. This is not to say that potential conflicts of interest cannot arise among extramural officials--after all, much extramural research involves the products of drug companies--but only to suggest that HHS and NIH consider whether the potential for conflicts among intramural researchers may be at least as great, if not greater.

2 Some of the proposals that have been discussed publicly place more restrictive limits on the consulting activities of "senior" employees. OGE, of course, agrees that concerns about the appearance of using public office for private gain are more likely to arise in the case of higher level employees. Much will depend, however, on how HHS and NIH define "senior level." We recommend that the class of senior level officials not be drawn too narrowly. It would be unfortunate if a cornerstone of any new supplemental rule is a set of restrictions that does not even cover many of the NIH positions whose occupants have been the subject of recent controversy.⁹

3 We also note that a number of proposals that have been discussed publicly involve expanded public availability of certain kinds of information about the activities and financial interests of NIH employees. Some of the questions that might be raised by such proposals were already addressed in my April 19, 2004 letter to the Co-Chairs of the Blue Ribbon Panel (enclosed). Without reiterating all the points made in that letter, we do want to emphasize again our view that expanded disclosure is not a substitute for appropriate substantive standards of ethical conduct. Activities creating the appearance that an employee is using public office for private gain are not cleansed of all taint simply because they are open and notorious.

⁹In this connection, we observe that your most recent "equal classification" request concerning public filers at NIH identifies over 500 positions (in addition to those NIH positions already covered by financial disclosure requirements) involving "particularly high levels of responsibility." Letter of HHS DAEO to OGE Acting Director, May 7, 2004.

4 We have similar concerns about proposals involving limits on the amount of time NIH employees may spend and the amount of income they may receive in connection with outside activities. Whatever the merits of such proposed restrictions, we do not believe that time and compensation ceilings alone, or in combination with inadequate substantive restrictions, are an appropriate solution. Indeed, we are concerned that such proposals, if not accompanied by other adequate and effective restrictions, could give the appearance that some level of misuse of office is tolerable.

5 Finally, to whatever extent that NIH continues to rely on a case-by-case review of certain types of consulting activities--i.e., those activities that would not be covered by any new supplemental prohibition but would be assessed in light of the Standards of Ethical Conduct--OGE recommends that NIH develop specific criteria for reviewers to apply in deciding whether to approve a consulting activity. These criteria would not themselves be part of a supplemental regulation, but should be part of an internal guidance document, such as an NIH outside activities manual. The purpose would be two-fold: (1) to regularize the decision-making of a large and diverse number of approving officials, and (2) to translate the generic standards found in the OGE rules, such as the proscription against using public office for private gain, into practical operating guidance tailored to the specific circumstances of NIH as a biomedical science agency. OGE has already articulated a number of general factors that agencies should use in determining whether a consulting activity would create the appearance that any employee is using his public office for private gain. See DAEOgram DO-04-011, May 27, 2004, and attachment. NIH now will need to operationalize this guidance. Among other things, NIH should identify common situations, such as specific types of official duties and consulting activities, and indicate what circumstances are most likely to raise concerns. OGE is mindful that the scientific enterprise is complex and that it is not always easy to mark the lines between an employee's official scientific work and his outside research, but this is all the more reason that the agency itself should provide its reviewers with guidance that is as explicit as possible.

ACCEPTANCE OF AWARDS

In addition to evaluating NIH's procedures for ensuring that outside activities are approved in accordance with the HHS supplemental regulation, we also evaluated NIH's procedures for approving the acceptance by employees of bona fide awards given for meritorious public service or achievement in accordance with 5 C F R § 2635 204(d)(1). In doing so, we paid particular attention to awards requiring the provision of a lecture or presentation to determine whether they were bona fide awards or, instead, compensation for teaching and speaking governed by the outside activities restrictions at section 2635 807.

5 C F R § 2635 204(d)(1) states that an employee may accept a bona fide award (other than cash or an investment interest) with an aggregate market value of \$200 or less from a person who does not have interests that may be substantially affected by the performance or nonperformance of the employee's official duties or from an association or other organization the majority of whose

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members do not have such interests. Otherwise, bona fide awards having an aggregate market value in excess of \$200 and awards of cash or an investment interest may be accepted only upon a written determination by an ethics official that the award is made as part of an established program of recognition under which (1) awards have been made on a regular basis, and (2) selection of award recipients is made pursuant to written standards. The current Manual states that awards are not to be treated as outside activities, awards may be accepted either on official duty time or personal time, and employees must apply for approval to accept awards from their DEC, regardless of value or type, on the HHS form, Approval of an Award from an Outside Organization.

Current Review Of Awards

To evaluate NIH's procedures for ensuring that awards are approved in accordance with 5 C F R § 2635 204(d)(1), we examined 50 awards accepted by employees from the 4 ICs from 2003 through the time of our review. OGE's review of this subject was prompted, in part, by concerns expressed by the House Energy and Commerce Oversight and Investigations Subcommittee. These concerns involved essentially two questions: (1) was the awards rule being used to approve payments that were really speaker's fees, and (2) were certain awards being received from impermissible sources? OGE's own examination of NIH awards during the review period confirmed that some of the approved awards do, in fact, raise these same questions. The information about specific awards was not sufficient for OGE to determine whether any payments actually were accepted in violation of the rules, and, in any event, OGE's central purpose is to evaluate and make recommendations concerning NIH systems, rather than individual conduct. However, as discussed below, NIH needs to revise its system for reviewing awards, consistent with guidance recently issued by OGE in response to questions raised by the Subcommittee about the criteria used by NIH and HHS to review proposed awards.

First, certain awards were described as "lectureships" or had similar designations. As you know, OGE recently issued guidance, originally as part of Congressional testimony concerning the acceptance of awards by NIH employees, in which we emphasized the importance of distinguishing between true awards for meritorious public service or achievement, and mere speaker's fees, particularly in the context of "lectureships" and "lecture awards." See DAEOgram DO-04-011, May 27, 2004, and attachment. It is not apparent, from the information available to us, whether the "lecture awards" approved by NIH would have been consistent with the OGE guidance, but there is no indication that these awards were given the kind of scrutiny that would be required under the OGE guidance.

Second, the available information raises questions about whether some of the awards may have been offered by impermissible sources, i.e., persons with interests that may be substantially affected by the duties of the employee. Some of the awards were offered by universities, which may have been grantees of the employee's office, and other awards were offered by nonprofit organizations whose mission would appear to overlap with the subject area of the employee's position. In either case, it is not clear from the documentation how NIH reviewed the proposed awards to determine whether there was any foreseeable connection between the employee's duties

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and the interests of the offeror Our recent guidance on awards provides several factors for agencies to consider in determining whether a particular award is offered by an impermissible source See id Based on the available information, it is not clear whether the approval of these awards would have been consistent with the OGE guidance

In light of the foregoing, NIH should develop internal procedures and criteria for reviewers in connection with future award requests so that the recent OGE guidance will be implemented consistently across all the ICs The NIH guidance should be reviewed by you to ensure that it is both adequate and consistent with the Department-wide approach to this subject

We are aware that the NIH Director, in his June 22 testimony before the Subcommittee, proposed to develop procedures for "pre-screening" awards programs, including involvement by a committee of "non-government individuals" Although OGE has not received sufficient details to assess the merits of this proposal, there will be limitations to any pre-screening system While it may be possible to develop a standing list of awards programs that have been judged to meet the two-pronged regulatory test of "an established program of recognition," such determinations must be made by an "agency ethics official," under section 2635 204(d)(1) As we have stated in another context, providing final interpretations and determinations under the Standards of Ethical Conduct is an "inherently governmental activity" and may not be delegated to non-employees DAEOgram DO-03-011, June 30, 2003 (Note also that individuals serving on advisory committees to make recommendations about such matters may be deemed "special Government employees," depending on the circumstances) Moreover, it will almost always be the case that the determination of whether a particular award is from a permissible source will depend on the circumstances of the individual case, including the duties of the particular individual and the nature of any matters the source may have before the agency

FINANCIAL DISCLOSURE

While many aspects of the financial disclosure systems we reviewed were sound, we identified some deficiencies in the consistent collection of confidential reports and the timely certification of public reports To evaluate the financial disclosure systems at the four ICs included in our review, we examined all of the available public reports and a sample of the confidential reports filed at the ICs in 2003 As a part of our typical review of these reports, we examined the outside activities disclosed on the reports to ensure that, if required, prior approval for these activities was granted Our findings with regard to the outside activities we examined are described above in the "OUTSIDE ACTIVITIES" section

CC

To evaluate CC's public financial disclosure system, we examined all four public reports required to be filed in 2003 Three of these reports were filed in a timely manner The one late report was filed in January 2004 The filer of this report had been serving in a public filing position in an acting capacity in 2002 and 2003 She assumed the position on a full-time basis in 2004 at

which time she filed the public report we examined. During the filer's acting status in 2002 and 2003, the CC DEC mistakenly believed the filer was not required to file a public report. We informed the CC DEC that because the filer had served in an acting capacity for more than 60 days in calendar years 2002 and 2003, she was in fact subject to the public filing requirement during that period. The CC DEC subsequently collected public reports from the filer covering the periods during which the filer was in an acting status and waived the \$200 late filing fees for those reports, as the filer was not timely notified of the filing requirements.

While all four reports were initially reviewed in a timely manner, three of them were not certified in a timely manner (approximately six to eight months after the initial review date). The CC Ethics Coordinator stated that she had not provided the reports to the DEC for certification in a timely manner. She explained that the reports had gotten "lost in the shuffle." She added that, in the future, she will provide the reports to the DEC immediately following the completion of her initial review.

We also examined a sample of 43 of the 188 confidential reports required to be filed in 2003. All of the reports were filed in a timely manner. In addition, all of the OGE Forms 450 were reviewed and certified in a timely manner. For those reports we examined which were OGE Optional Forms 450-A, and thus did not require certification, we also examined the filers' most recently filed OGE Forms 450. The only deficiency we identified on those reports was that the DEC had not certified two of them (although both had been initially reviewed by the Ethics Coordinator). The DEC has since certified both of these reports.

NIAID

At NIAID, we examined the two public reports required to be filed in 2003. Both of the reports were filed, reviewed, and certified in a timely manner.

To evaluate NIAID's confidential system, we examined a sample of 99 of the 560 reports required to be filed in 2003. As far as we could determine, only five of these reports were filed late¹⁰. In addition, all but one of the OGE Forms 450 were reviewed and certified in a timely manner. As with the CC, for those reports we examined which were OGE Optional Forms 450-A, we also examined the filers' most recently filed OGE Forms 450. Virtually all of these reports were filed, reviewed, and certified in a timely manner.

NCI

At NCI, we examined all 13 public reports required to be filed in 2003. All of the reports were filed, reviewed, and certified in a timely manner.

¹⁰We could not determine the filing timeliness of an additional five new entrant reports as they did not contain the dates the filers were appointed to the filing positions.

We also examined a sample of 51 of the 1,463 confidential reports required to be filed in 2003. Thirty of the reports we examined were OGE Forms 450. Twenty-seven of these reports were filed in a timely manner and 27 were reviewed and certified in a timely manner.¹¹

The remaining 21 reports we examined were OGE Optional Forms 450-A. All of these reports were filed in a timely manner and the filers' most recently filed OGE Forms 450 were generally filed in a timely manner. However, several of these OGE Forms 450 appeared to be reviewed and certified quite late, over a year from the date of filing for some reports.

OD

To evaluate the public system for the highest-level NIH employees, we examined 47 of the 53 reports required to be filed by NIH directors and OD senior staff members in 2003.¹² All but five of these reports were initially filed with the NIH Ethics Office. The remaining five reports, filed by directors who are also DECs, were filed with the NIH Ethics Counsel.

All 47 of the reports were filed in a timely manner. Additionally, all of the reports were initially reviewed in a timely manner. However, 11 of the reports filed with the NIH Ethics Office were not certified until from 4 to 7 months after being filed.

We also examined a sample of 78 of the 450 OD confidential reports required to be filed with the NIH Ethics Office in 2003 (no confidential reports are filed with the NIH Ethics Counsel). These consisted of 36 OGE Forms 450 and 42 OGE Optional Forms 450-A.

Thirty-five of the reports we examined (consisting of both OGE Forms 450 and OGE Optional Forms 450-A) were filed between March and June 2003. According to an NIH Ethics Office official, there was a lapse in collecting confidential reports during the 2002 annual filing cycle because of insufficient staffing in the NIH Ethics Office. To remedy this situation, the NIH Ethics Office required dual filing in 2003: one filing in early to mid-2003 to make up for the failure to collect reports in October 2002 and a second in October 2003 to meet the 2003 annual filing requirement.

¹¹We could not determine the filing timeliness of one new entrant report because the filer did not provide the date he was appointed to the filing position. We also could not determine the review and certification timeliness of another report because NCI had not provided the date on which it received the report.

¹²The six remaining reports (all terminations or new entrants) were still undergoing review by NIH ethics officials at the time of our examination.

Thirty-four of the remaining 43 reports (consisting of both OGE Forms 450 and OGE Optional Forms 450-A) appeared to be filed in a timely manner. We could not determine the filing timeliness of the outstanding nine reports because the NIH Ethics Office had not provided the dates on which it received the reports.

Only 4 of the 36 OGE Forms 450 we examined appeared to be reviewed and certified late. However, due to the aforementioned failure to note dates of receipt for nine reports, we could not determine the review and certification timeliness for these reports.

RECOMMENDATIONS

To improve the overall effectiveness of NIH's ethics program, we recommend you

1. Take certain steps to ensure that you directly coordinate and manage the program. First, you should meet periodically with NIH management so that you will be fully cognizant of current and emerging ethics issues at NIH and be able to react to them accordingly. These meetings should ensure that you are aware when policies and procedures at NIH are not effective, and enable you to make changes as needed. Second, you should meet with NIH ethics officials and NIH management to determine what policies need to be developed to deal with the issue of outside consulting by NIH employees and develop an NIH-specific section of the HHS supplemental regulation for submission to our Office for concurrence and joint issuance. Finally, to formalize the responsibilities of the IC DEC's, their position descriptions should contain a description of their ethics duties. The NIH DEC should rate each DEC annually on the ethics portion of his or her work.
2. Ensure that NIH continues efforts to re-examine ongoing outside activities.
3. Ensure that outside activities are approved in accordance with the requirements of the NIH Manual and the HHS supplemental standards of conduct regulation, including the activities that we identified for which no requests were submitted.
4. Ensure that the requirement to collect annual updated information on ongoing outside activities is clarified, and then either (1) improve the procedures for collecting the required annual information or (2) eliminate the requirement from the current Manual.
5. Ensure that after review and recommendation by NEAC, the NIH Senior Ethics Counsel has final approval/disapproval over outside activity requests.

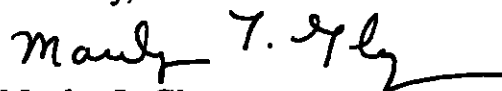
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- 6 Develop and propose new supplemental standards of conduct specifically to address the kinds of consulting activities that have raised recent concerns
- 7 Help NIH develop guidelines to use in determining whether an individual outside activity request should be approved The guidelines should make clear that NIH must apply all relevant provisions of the Standards of Ethical Conduct to each request it is considering
- 8 Develop internal procedures and criteria for NIH award reviewers in connection with future award requests so that the recent OGE guidance will be implemented consistently across all the ICs
- 9 Ensure that CC and OD public financial disclosure reports are certified in a timely manner
- 10 Ensure that OD annual confidential reports are collected in a timely manner

In closing, I would like to thank you for your efforts on behalf of the ethics program Please advise me within 60 days of the specific actions your agency has taken or plans to take on our recommendations A follow-up review will be scheduled within six months from the date of this report In view of the corrective action authority vested with the Director of OGE under subsection 402(b)(9) of the Ethics Act, as implemented in subpart D of 5 C F R part 2638, it is important that you take timely actions to implement our recommendations A copy of this letter is being forwarded to the NIH Director and the HHS Inspector General via transmittal letter Please contact me at 202-482-9292, if we may be of further assistance

Sincerely,



Marilyn L Glynn

Acting Director

Enclosures

Report Number 04- 013