ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

June 3, 2004

Ms. Marilyn L. Glynn
Acting Director
U.S. Office of Government Ethics
1201 New York Avenue, N.W., Suite 500
Washington, D.C. 20005-3917

Dear Ms. Glynn:

On May 18, 2004, you testified before the Subcommittee on Oversight and Investigations in a hearing entitled "NIH Ethics Concerns: Consulting Arrangements and Outside Awards." We now ask for your help on several additional questions (attached).

Because we wish to include the questions and responses in the printed record of this hearing, please respond no later than Friday, June 18, 2004. Please fax and e-mail the response. The faxed response should be directed to Billy Harvard, Committee on Energy and Commerce, Majority staff, at 202-226-2447, and Voncille Hines, Committee on Energy and Commerce, Minority staff, at 202-225-5288. The e-mail copy of the response should be directed to (Billy.Harvard@mail.house.gov) and Voncille Hines (Voncille.Hines@mail.house.gov). Due to the uncertainties of postal deliveries on Capitol Hill, we ask that your response not be sent through the postal service.

If you have any questions, please have your staff contact David Nelson, Minority Investigator/Economist, Committee on Energy and Commerce, at 202-226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

Attachment

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

Questions for Ms. Marilyn L. Glynn, Acting Director
U.S. Office of Government Ethics
from the Honorable John D. Dingell
regarding the May 18, 2004, hearing entitled
"NIH Ethics Concerns: Consulting Arrangements and Outside Awards"

1. After reading Mr. Swindell's testimony, one would be left to believe that the Department of Health and Human Services (HHS) has no authority or role in determining appropriate ethics practices or regulations for the National Institutes of Health (NIH). I was wondering if you agreed with his representation about the role that the Office of General Ethics (OGE) plays, and if you agreed with his representation about the lack of role that he asserts the Office of the General Counsel (OGC) plays?

2. Mr. Swindell squarely rests all blame regarding financial disclosure matters on the OGE's shoulders, noting that the "OGE has historically viewed the [financial disclosure] form as serving a conflicts of interest purpose rather than a disclosure purpose." He goes on to state that, "OGE did not historically believe that amounts of compensation were normally relevant to conflict analyses." Is it accurate to state that HHS has no role in making determinations about the significance or purpose of forms used in its agency and that this is the OGE's sole responsibility?

3. Mr. Swindell notes that, "the OGE did not believe that the authorities in the Ethics in Government Act could support the collection of compensation amounts for completed and closed outside activities." Is it the sole responsibility of OGE to determine whether or not compensation amounts for completed and closed outside activities should be collected, and is it true that HHS had no role in making these sorts of judgments and no accountability for what decisions ultimately come out of OGE?

4. When discussing the issue of bona fide awards and barring agencies from receiving awards from entities that have matters pending under that individual's official responsibilities, Mr. Swindell notes that these decisions are, "ultimately a matter for OGE deliberation, that OGE has not formally opined on it, and that OGE may well choose a different approach than that of the Department," and that HHS is, "required to implement the OGE interpretation." So does this mean that HHS has no role in determining whether or not NIH employees should be allowed to accept bona fide awards from certain agencies, and that HHS's sole responsibility is to enforce whatever decisions OGE reaches?

5. Would OGE support a request from HHS to ban NIH employees from receiving outside activity income from drug and biotech firms?

6. In your testimony you stated that, "Some outside consulting relationships may involve a subject matter that is so closely related to an employee's official work that the overlap would give rise to an appearance that the employee took advantage of his official position to obtain the outside consulting opportunity or that the employee is providing insights obtained on the job only to those willing to pay."

The attached Slide 10 demonstrates how Kenneth Korach, Chief at the Laboratory of Reproductive and Developmental Toxicology, at NIH's National Institute of Environmental Health Sciences, received $78,180 to consult on biochemical and pharmacological actions of estrogens for Schering AG, another biotechnology firm. Doesn't consulting on the actions of estrogens seem to involve a subject matter very closely linked to his official duties at the Laboratory of Reproductive and Developmental Toxicology?

7. In your testimony, you cite an important NIH standard which states that, "employees may not use their public office for their own private gain."

   Does it surprise you to learn that in attempting to recruit potential scientists for NIH, some NIH officials and employees have sought to woo new employees by advertising outside consulting possibilities as a way for NIH employees to supplement their government salaries? Would you consider this a case of employees using their public office, and public titles, for their own private gain?

8. Have any of OGE's audit activities, complete or non-complete, suggested that HHS has any kind of standard for reviewing the indirect effects of consulting relationships on NIH employees and their personal interests? For example, what about the potential that NIH employees, engaging in such consulting relationships, might be able to unfairly benefit companies who pay them, or damage the interests of competitors who don't?

9. Is there a model anywhere in the Federal Government for effective oversight of an employee's behavior in his or her private consulting work, after the outside activity has been approved? Would it be an appropriate use of government resources to require regular reports from the employee and his private sector employer as to the specific services/advice provided?

10. In your testimony you stated that the OGE standards permit agencies to promulgate blanket prohibitions on certain outside activities and that HHS has, in fact, promulgated certain supplemental prohibitions on outside activities.

    Would the OGE have any objection if NIH were to ban the acceptance of outside activities involving pharmaceutical or biotechnology firms?

11. You note that a 1995 OGE review of the NIH ethics program discovered that NIH had a series of restrictions on outside consulting that were not promulgated in accordance with the procedures prescribed in the Executive Order and that the OGE directed that NIH either remove these restrictions or propose them for inclusion in the HHS supplemental regulation. You then said that, "At that time, NIH chose to remove the restrictions and did not propose any additional outside activity restrictions in the HHS supplemental regulation."

What were the special circumstances that led to the OGE order, and who at HHS made the decision not to submit restrictions on outside activities?

12. It is our understanding that virtually all public disclosure requirements were removed in 1995 (94% of NIH employees became exempt), and that the agency even stopped collecting information on the consulting agreements for their internal private records. To what extent were those decisions mandated by OGE?

13. It appears that NIH, in conjunction with HHS, has consistently ignored and even fostered real or apparent conflicts of interest relating to NIH employees. Would similar conflicts of interest be condoned or ignored in other governmental agencies?

    For instance, does the Department of Energy allow its employees to negotiate outside consulting arrangements with oil and gas companies such as Halliburton or Exxon?

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    Does the Department of Education encourage its technical employees to consult with, or accept awards and stocks from, school districts or the National Education Association?

14. If HHS came to you and asked for supplemental standards for ethics governing NIH employees, similar to those governing Food and Drug Administration (FDA) employees in 5 C.F.R. 5501, would your office have any objection to such a request?

15. As you are aware, 5 C.F.R. 5501 contains supplemental restrictions on FDA employees. Could you explain the additional restrictions on outside activities and financial interest applicable to FDA employees' dealings with firms regulated or likely to be regulated by that agency (e.g., start up biopharmaceutical firms)?

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STATEMENT OF

EDGAR M. SWINDELL
ASSOCIATE GENERAL COUNSEL FOR ETHICS
OFFICE OF THE GENERAL COUNSEL
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

NIH ETHICS CONCERNS:
CONSULTING ARRANGEMENTS AND OUTSIDE AWARDS

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
UNITED STATES HOUSE OF REPRESENTATIVES

MAY 18, 2004

MR. CHAIRMAN , MR. DEUTSCH, AND MEMBERS OF THE SUBCOMMITTEE:

Thank you for inviting me to speak with you today to discuss the ethics issues relating to the National Institutes of Health (NIH).

The goal of ensuring public confidence in the integrity of NIH is one that the Department very much shares with the Committee – and a goal which we can best accomplish together. The Committee's oversight in this area has been edifying and helpful in identifying areas of concern. As NIH moves forward, with the help of the Department, to address those concerns, the Department values the Committee's informed views and welcomes the Committee's suggestions regarding steps that can be taken to ensure that the tremendous trust that the Congress and the public place in NIH is as unquestioned as the vast contributions NIH has made towards advancing the nation's health and the promise it holds to continue doing so. To this end, we believe the recommendations of the Blue Ribbon Panel provide an important perspective and serve as a helpful starting point.

As Associate General Counsel for Ethics, my principal role is to advise the Secretary and the General Counsel on government ethics, restrictions on political activity by federal government employees, and related issues. Concurrently, under an appointment directly from the Secretary, I serve as the Designated Agency Ethics Official (DAEO) for the Department. The DAEO is the point of contact with the Director of the Office of Government Ethics (OGE). That office sets ethics policy for the entire executive branch under an Executive Order issued by the first President Bush replacing a system of individual agency regulation of employee conduct.

I understand that concerns have been raised by the Committee about the role of the Office of General Counsel, within the Department, in responding to the Committee's oversight, with particular attention to information requested by the Committee regarding payments, expenses, and stock options paid to NIH employees for consulting arrangements since January 1, 1999. NIH proposed asking employees for information regarding compensation for outside activities. Accordingly, the Department, working through OGC, has worked extensively with NIH and the Committee's staff, as well as other federal agencies, to identify and resolve legal issues relevant to obtaining this information.

When the Committee first asked NIH to obtain amounts of compensation for outside activities, these amounts were unavailable for those individuals who file the confidential OGE 450 financial disclosure form or who do not file any financial disclosure form. This is because OGE has historically viewed the form as serving a conflicts of interest purpose rather than a disclosure purpose. And the conflicts

analysis for reviewing potential outside activities has historically focused, government-wide, on the type and source of compensation rather than the amount. For the same reason, the HHS 520 form, used for review of potential outside activities, did not, until my January 27, 2004 memorandum, request the amount of compensation. Historically, OGE has advised that it did not view the dollar amount as normally relevant to the outside activity conflicts analysis.

HHS strove to help NIH find a way to collect the information and was successful in doing so. This information is critically important and so we have taken steps, consistent with the Privacy Act, to obtain this data in the future for all outside activity requests.

HHS advised NIH about the Privacy Act, and its requirement that collection and maintenance of identifiable information be for purposes authorized by statutes, regulations, or Executive Order, and that such authority must be cited in the Privacy Act statement accompanying the request for information. Although the interest of Congress alone would not be a sufficient legal basis to collect and maintain the information, an agency interest pursuant to statutes, regulations, or Executive Order, would be an appropriate basis. At first, we hoped that the Ethics in Government Act, administered by OGE, could serve such a basis. The difficulty was that OGE did not historically believe that amounts of compensation were normally relevant to conflicts analyses.

OGC worked with OGE to devise an interpretation of the authorities provided in the Ethics in Government Act that would support the collection of compensation amount information for ongoing activities as well as activities being reviewed for compliance with the relevant rules. At that time, OGE did not believe that the authorities in the Ethics in Government Act could support the collection of compensation amount for completed and closed outside activities.

On January 27, 2004, I issued a directive informing Deputy Ethics Counselors [DECs] that in the context of any agency evaluation of any previously approved, ongoing outside activity for continued compliance with existing law and in order to request prior approval for any new outside activity, employees would be required to provide both retrospective (if applicable) and prospective compensation information. Such amounts were to be noted on the HHS 520. This allowed NIH to collect compensation amounts for all ongoing outside activities.

HHS explained to Committee staff the potential difficulties in collecting information pertaining to completed and closed outside activities. Referencing these discussions in its February 25, 2004 letter to the Department, the Committee said "the Department is attempting in good faith to assist the Committee."

In addition, HHS continued to work to develop an interpretation of the Ethics in Government Act that would support the collection of information for completed outside activities. In so doing, we discussed the legitimate and important need for NIH to collect the information NIH and OGC felt was important for the agency to collect. As a result, OGE agreed that, in this case, the Ethics in Government Act and its implementing regulations providing the DAEO with authority to evaluate the agency's supplemental standards to determine their continued adequacy and effectiveness in relation to current agency responsibilities, supported the collection of information regarding completed and closed activities with pharmaceutical and biotechnology companies. OGC further applied the same reasoning to all for-profit entities.

As a result of these efforts, Dr. Zerhouni was able to write to the Committee on March 12, 2004, that "We consider this collection [of information] authorized by the Ethics in Government Act of 1978 and Executive orders mentioned above." It is my understanding that NIH decided to manage litigation risk from NIH employees who might not wish to comply with a required collection of information by first attempting to collect the information on a voluntary basis.

However, because of inadequate response, I believe that Dr. Zerhouni is now going to instruct all NIH employees who had consulting arrangements since January 1, 1999 that are now closed to report the compensation amounts received pursuant to the consulting as a requirement and condition of their employment.

Background. HHS has a workforce of more than 60,000 individuals, of which approximately 1,000 file public financial disclosure reports and 25,000 file confidential financial disclosure reports and receive annual ethics training. These 60,000 employees safeguard the nation's health and provide essential human services through myriad programs, policies, and initiatives that affect countless stakeholders and a large part of the American economy. Whether in allocating grant funds, awarding contracts, entering into public-private partnerships, approving lifesaving drugs, protecting patient privacy, or reducing health care costs, our employees must address the concerns of the many while avoiding the appearance or fact of undue influence by the few. To assist those who bear that responsibility, the Ethics Division advises on how to ensure these duties are carried out impartially and unimpeachably. This is largely accomplished through legal advice to agency decision-makers and ethics officials, guidance to employees, education of the workforce, development of guidance documents, and, when necessary, liaison with OGE.

In HHS, as in most large Cabinet Departments, the DAEO oversees and coordinates a decentralized Departmental ethics program. As DAEO, I appoint Deputy Ethics Counselors (DECs) chosen by each operating division, such as the Food

and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and NIH. Each of these DECs, along with agency heads and management in each component, are responsible for running ethics programs tailored to the needs of extensive, geographically dispersed workforces composed of many professionally trained employees with varied responsibilities that range from insuring the health care needs of the elderly and disadvantaged to ensuring the safety and efficacy of drugs and medical devices.

The DECs are senior management officials within each component, and they have staff who assist them in carrying out the ethics functions, either as collateral duties or as members of an ethics program office. NIH in particular has such an office under its DEC. As managers closest to day to day operations, they are equipped and responsible for identifying and evaluating the relevant ethics issues in their component. Additionally, the DECs and their staff possess the scientific and technical expertise necessary to identify and resolve ethics issues in situations involving science, medicine, and other complex fields. Within their respective operating divisions, the DECs are responsible for establishing a system for reviewing public and confidential financial disclosure forms, considering outside activity requests, providing ethics advice to individual employees, initiating ethics education and training programs, and ensuring that violations of the conflicts statutes or the conduct standards are reported to investigatory authorities and where appropriate, seeing that disciplinary action is taken. Individual employees are, of course, ultimately responsible for their own actions.

In addition, the Ethics Division has responsibilities similar to those of a DEC but for the Office of the Secretary and with respect to political appointees. Staff lawyers within the Ethics Division provide legal advice to the DECs to assist them in their role in making ethics decisions. Furthermore, we conduct training such as an all day DEC workshop each year to keep DECs current on ethics law, and approximately thirty ethics officials from across the Department attend the annual OGE conference and its various break-out sessions or classes conducted on a wide variety of ethics topics. OGE's periodic program reviews or audits provide us with a sense of how well the Department's components meet their ethics responsibilities. In these reviews, OGE has recognized that the Ethics Division provides sound guidance and instruction and that a clear "road map" is in place.

Ethics Initiative. Based upon a process begun by the General Counsel in December, the Ethics Division has undertaken a series of efforts to intensify our ability to scrutinize and oversee the Department's ethics activities. We are dedicating additional resources to enhance the Ethics Division. As part of this initiative, the Department will institute systematic oversight of the ethics programs within the various operating divisions of the Department through regularized compliance auditing and program review, as well as dramatically strengthen our ability to provide guidance to these programs and their officials. The initiative will increase component

accountability for ethics program implementation, augment financial disclosure review and training development, and enhance the **capabilities of the Ethics Division** and the authority of the DAEO. Our staffing will more than double from 11 to 25. To my knowledge, this will make us the largest single legal office devoted exclusively to government ethics, outside of OGE. **We will create two units within the Ethics Division: the Advice and Financial Disclosure Branch and the Education and Program Review Branch. These branches will be staffed by a mix of attorneys, paralegals, computer/training developers, legal resource analysts, auditors, and support staff.**

The **steps we are undertaking will enhance the Department's operations and work on behalf of the public. Specifically, this initiative will strengthen the Department's identification and prevention of employee actions that would or would appear to be motivated by private, pecuniary, or associational interests, rather than an impartial assessment of the public interest.**

Historical Context. To provide further background to the Committee in connection with its review of these issues, following is an understanding of how we came to where we are on the issues of financial disclosure, outside consulting arrangements, and awards at NIH.

a. *Financial Disclosure.* The degree to which the public may have access to the personal financial information of employees at NIH is governed by federal law and OGE regulations. The Ethics in Government Act and implementing regulations in 5 C.F.R. part 2634 provide for two types of financial reporting: (1) public disclosure of detailed information about assets, income, liabilities, and outside affiliations on a report form called the SF 278; and (2) a less intrusive, confidential version known as the OGE 450. On the SF 278, filers must disclose income amounts and asset values within broad categories, by checking, for example, a block indicating a figure between $1,001 and $15,000, and so on. The OGE 450 does not ask for any disclosure of amounts, only the identity of holdings and income sources, in other words, the information necessary at a minimum to assess conflicts.

By statute, the public SF 278 filing requirement is reserved exclusively for highly paid, senior employees, such as Senate confirmed Presidential appointees, non-career and career members of the Senior Executive Service, Schedule C political appointees in the General Schedule, uniformed service officers in the Public Health Service Commissioned Corps at pay grade O-7 or above, Administrative Law Judges, and employees in other pay systems if the lowest rate of basic pay for that pay plan exceeds $104,927 per year. The confidential OGE 450 basically is filed by career employees in the General Schedule, generally at grade levels 12 or above, and by special Government employees who do not serve beyond 60 days. Under current law, increased public disclosure can occur only through a process of demonstrating to OGE that the duties of a particular position – that would not ordinarily be required to file publicly under the existing rules – is nevertheless equivalent to the positions that do file. This process is required because many of the alternative pay systems at NIH do not have minimum rates of basic pay that exceed the threshold.

In 1997, the Ethics Division wrote to the Director of OGE asking for an interpretation of the law to require employees hired under the authority of Title 42, Section 237, establishing the Senior Biomedical Research Service (SBRS), to file SF 278s if the actual annual salary received by the employee was equal to or above 120% of the rate of basic pay for GS-15, Step 1. The letter urged that these employees be required to file public financial disclosure forms and argued that not doing so would be "inconsistent with what would seem to be the prevailing rule in the post-employment context [and] appears contrary to the purpose of the public financial disclosure requirement. Conceivably an ... employee with a salary equivalent to an Assistant Secretary would not be required to file a Public Financial Disclosure Report. ... [A]ll SBRS employees with such salary above 120% of the GS-15, step 1, level should be automatically required to file a Public Financial Disclosure Report."

On February 11, 1998, the Director of the OGE declined that request and responded that for purposes of the public financial disclosure requirement, the term "rate of basic pay" was defined as "the lowest level of pay authorized for a position's pay grade." Director Potts opined that the definition of "rate of basic pay" for SBRS employees is the lowest step or entry level pay authorized for a particular pay grade or range. Thus, since the entry level minimum pay authorized for SBRS positions is set by statute as the minimum rate payable for GS-15, and since that will always be less than the Ethics in Government Act SF 278 threshold of 120% of GS-15, Step 1, the SBRS employees would not be required by the Ethics in Government Act to file public financial disclosure reports. Like the SBRS employees hired under the authority of Section 237, the employees hired under the authority of section 209(f) (who do not have any fixed rate of basic pay) have a "rate of basic pay" that is less than the statutory SF 278 threshold.

Although, for the reasons stated above, "Title 42" employees are not statutorily defined as SF 278 public financial disclosure report filers, it is our understanding that all of the NIH Institute and Center Directors who were appointed under section 209(f) continued to file public financial disclosure form SF 278s even during the time they were not required to do so. To ensure that this continues to be the case, as well as to increase transparency with respect to the next level of senior employees identified by NIH, we have been successful in securing an OGE equivalency determination for 93 positions that requires, as of February 6, 2004, the Directors, Deputy Directors, Scientific Directors, and Clinical Directors within each NIH Institute and Center to file publicly available SF 278s. This determination was in response to our letter of January 12, 2004. Following our request that NIH identify other positions with equivalent authority and responsibilities that meet the statutory test, we recently forwarded to OGE a list of another 506 positions for this special classification.

b. *Outside Consulting and Financial Interests.* HHS employees currently are required by an agency supplemental regulation to seek prior approval only for professional or consultative activities, teaching, speaking, or writing, and board service. They submit an HHS Form 520 that solicits detailed information about the proposed activity, and each operating division may specify various levels of review, which may start with the supervisor and end with the DEC.

The HHS Form 520, which was designed in 1982 and has since remained virtually unchanged. It does not require the applicant to specify the amount of compensation to be received in connection with the outside activity. Until recently, it was not understood that this information would be relevant to the outside activity approval process because the requisite legal analysis focuses on the identity of the payor and the nature of the outside activity. This information is critically important and so I have taken steps, as DAEO, consistent with the Privacy Act, to obtain this data in the future for all outside activity requests.

Approval requires an assessment of whether the proposed outside activity violates any statute or regulation, including the OGE Standards of Ethical Conduct for Employees of the Executive Branch or the HHS supplemental ethics regulation. Included in the OGE Standards is the requirement that the proposed activity cannot create an actual or apparent conflict that would result in recusals that would materially impair an employee's ability to do his job.

In evaluating conflicts, the reviewer must address two provisions that form the core of Federal ethics law. A criminal statute, 18 U.S.C. § 208, deals with an "actual conflict" due to the employee's own or imputed financial interest in the resolution of a government matter. A regulatory provision in the OGE Standards, 5 C.F.R. § 2635.502, principally addresses disqualifications called for when an "appearance of a conflict" arises from a "covered relationship."

Under section 208 of the criminal code, to avoid a conflict of interest that results, for example, from stock ownership or outside employment, a federal employee must not participate personally and substantially in a particular matter that, to his knowledge, directly and predictably affects his own financial interest or that of his outside employer. To prevent an "appearance of a conflict" that results from serving in a role short of employment, for example, as an advisor, consultant, or other type of independent contractor compensated with fees and expenses, a different rule applies[6 CFR 2635.502].

Both sections are disqualification provisions in that they do not prohibit the acquisition of an asset or relationship, rather they bar actual "participation" in a potentially conflicting matter, either personally or through the direct and active supervision of the participation of a subordinate. However, neither section is triggered by mere knowledge of, or official responsibility for, a particular matter. In short, under 5 C.F.R. § 5501.106(d)(4), prior approval to engage in an outside activity "shall be granted," provided there are no other statutory or regulatory impediments.

In addition, a number of statutes and regulations do preclude certain outside activities. For example, if an employee sought approval to be a lobbyist, the anti-representation statutes, 18 U.S.C. §§ 203 and 205, would be implicated. If the activity were clearly one that should be done as an official duty, then approval would be denied, under 18 U.S.C. § 209, as an improper salary

supplementation. Another regulation prohibits the use of public office for private gain 5 CFR 2635.702.

Another regulation, 5 C.F.R. § 2635.807, precludes compensation, subject to certain exceptions, if an employee wants to teach a course, deliver a speech, or write a book that relates to his official duties. (Consulting, technically, is not covered by this section, but the analysis does provide guidance in evaluating many outside activities.) For career employees, compensation is precluded if, among other things, the teaching, speaking, or writing deals in *significant* part with any current assignment (or one completed within the last year) or any ongoing policy, program, or operation of the agency. However, the provision contains an important explanatory note. A career employee may receive compensation for "teaching, speaking, or writing on a subject within the employee's discipline or inherent area of expertise based on his educational background or experience even though the [activity] deals generally with a subject within the agency's areas of responsibility."

Finally, there are also special ethical restrictions that focus on the receipt of earned income by political appointees. Under Executive Order 12,731, issued by the first President Bush and modifying Executive Order 12,674, certain Presidential appointees may not receive "any earned income for any outside employment or activity performed during" their Presidential appointment. Similarly, the Ethics in Government Act limits the annual amount of outside earned income, including honoraria, that high-level political appointees such as non-career members of the Senior Executive Service may receive. This year, that limit is $23,715.

As noted earlier, outside activities must also comply with applicable provisions governing the avoidance of actions creating an appearance of violating the ethical standards, including the prohibition against use of official position for an employee's private gain or for the private gain of any person with whom the employee has employment or business relations or is otherwise affiliated in a non-governmental capacity.

As can readily be seen, supervisors, ethics program officers, and the DECs, in particular, have difficult assessments to make when reviewing outside activity requests. For example, at NIH, review of the requests often necessitates an ability to analyze the relationship between technically complex official scientific duties and similarly complex outside activities, both of which might be in the same general field of expertise. Even when the activities are approved, individual employees remain personally responsible for abiding by their recusal obligations and avoiding violations of any other applicable provisions. These responsibilities are exacerbated by mergers, acquisitions, joint ventures, partnerships, and even name changes, within industry that, on any given day, may make it difficult to know whether one has a conflict to avoid.

As outlined in the Blue Ribbon Panel report, prior to 1995, NIH had stringent internal policies that barred certain outside activities, limited the amount of outside compensation, capped the number of hours that could be spent in outside work, and precluded the receipt of stock or stock options as compensation. However, during a program review conducted in 1995,

OGE notified NIH that its requirements went beyond the 1993 executive-branch wide Standards of Ethical Conduct. By Executive Order, OGE was required to ensure uniformity within the executive branch with respect to the core ethics requirements. OGE did not permit agencies unilaterally to impose ethics requirements or policies that were more restrictive than the OGE Standards, absent the submission to OGE for its approval a supplemental regulation with adequate justification. The then NIH Director did not pursue that option, and the internal policies at NIH were changed to conform to the case-by-case evaluation process prescribed in the OGE regulations.

Therefore, whether NIH employees can hold "drug or biotech" stocks or consult with companies in these industries is governed by the application of OGE regulations. Currently, conflicting stock holdings are subject to a de minimis exception that allows employees to work on specific party matters as long as the value of the affected stock does not exceed $15,000 and on a general matter if the value of any one affected holding does not exceed $25,000, subject to a $50,000 cap when cumulating all affected interests. Also, NIH employees can consult with various companies involved in scientific research, if the legal requirements are satisfied.

c. *Awards*. Another important issue is whether NIH employees should be allowed to receive *bona fide* awards from outside entities with interests affected by NIH programs and operations. Depending upon the resolution of these questions, it is conceivable that the NIH Director might be barred from receiving the Nobel Prize in Physiology or Medicine because, as we understand, the awarding entity on behalf of the Nobel Committee is the Karolinska Institute, which collaborates in research matters with NIH.

Bona fide awards for meritorious public service or achievement are conceptualized as gifts. Gifts to executive branch employees are governed by 5 U.S.C. § 7353, which bars the solicitation or acceptance of anything of value from persons or entities defined as prohibited sources, subject to such reasonable exceptions as the supervising ethics office for the executive branch, by regulation, deems appropriate. OGE implemented this statute in the Standards of Ethical Conduct for Employees of the Executive Branch at 5 C.F.R. Part 2635, Subpart B. These rules expressly permit employees to accept *bona fide* awards and cash incident thereto from most prohibited sources, e.g., contractors, grantees, regulated entities, applicants for governmental action, etc., including organizations a majority of whose members are of the enumerated type, *provided* that the award is determined by agency ethics officials to be part of an established program of recognition, as defined in regulatory criteria. Specifically, under 5 C.F.R. § 2635.204(d)(1), the reviewer must ascertain whether the award is made as part of an established program of recognition for meritorious public service or achievement:

> (1) Under which awards have been made on a regular basis or which is funded, wholly or in part, to ensure its continuation on a regular basis; and
>
> (2) Under which selection of award recipients is made pursuant to written standards.

This exception to the prohibited gifts rule is unavailable, however, if the awarding entity is a special type of prohibited source, i.e., a person or entity who "has interests that may be substantially affected by the performance or nonperformance of the [award recipient's] official duties."

As OGE notes in their testimony today, "one possible reading" of this phrase could be to bar an agency official from receiving an award from any entity that has matters pending under that individual's official responsibility, i.e., from any entity or person doing business with the recipient's office, or it could specify a "situational" approach predicated on the interpretive assumption that the use of terms such as "performance" and "duties" suggests that some actual involvement by the official must at least be reasonably foreseeable. Included with the Committee's initial inquiry on this subject was an opinion of the Congressional Research Service that suggests the former interpretation. When NIH asked for help in preparing a response to the Committee's inquiry and the Congressional Research Service analysis, I drafted a White Paper describing the existing policy and its derivation.

That paper pointed out that, because the above-quoted phrase appears in OGE's regulation, the phrase's meaning is ultimately a matter for OGE deliberation, that OGE has not formally opined on it, and that OGE may well choose a different approach than that of the Department. Furthermore, the paper observed an alternative to OGE clarification: that "Federal departments and agencies were authorized to issue, jointly with OGE approval, supplemental ethics regulations to establish prior approval procedures for outside activities, to impose prohibited financial holdings requirements, and to address ethics issues unique to the programs and operations of the respective agencies."

Today, the Acting Director of OGE provides in her statement the first definitive written guidance on the subject. OGE's analysis articulated in her testimony today does not adopt a bright line. Moreover, some of the factors relied upon by HHS are factors she has articulated. We are required to implement the OGE interpretation, of course, absent a change in law, OGE regulation, or, one other important possibility. As mentioned in the White Paper provided to NIH and, in turn, to the Committee last July, agencies are "authorized to issue, jointly with OGE approval, supplemental ethics regulations to ... address ethics issues unique to the programs and operations of the respective agencies." Therefore, if NIH policymakers decided to go so far as to outright prohibit the receipt by all or certain NIH officials or employees of all or some awards from outside entities with which NIH interacts, a request for such a provision could be included in a supplemental regulation submitted for OGE approval.

In addressing the issue of awards, it is necessary to guard against monetary awards and prizes that may appear to be little more than a payment for delivering a speech. As noted earlier, federal employees cannot receive compensation for speaking that relates to their official duties within the meaning of a very detailed regulation, 5 C.F.R. § 2635.807. Moreover, a criminal statute, 18 U.S.C. § 209, bars federal employees from receiving a supplementation of salary for

performing their official duties, and another, 18 U.S.C. § 201, proscribes illegal gratuities tied to an official act. But a *bona fide* award for meritorious public service or achievement and any money that is associated with the honor are considered gifts, rather than compensation. As you can readily see, there is a continuum between the permitted activity on the one hand – accepting a prestigious award with the prize money and then delivering the speech that is routinely expected of the honoree at the award presentation – and the prohibited activity on the other – accepting money to deliver a speech in the guise of receiving an award.

Unfortunately, the ethics rules do not provide us much guidance in distinguishing between the two scenarios. Fortunately, the Acting Director of OGE in her written statement submitted today has endeavored to tackle these issues and has even sent us in the direction of tax law for help in determining whether an award is "intended primarily to provide gratuitous honorific recognition of achievement" or is instead "primarily compensatory in nature." I am grateful to Director Glynn and her staff for providing this valuable assistance.

It must be considered that even though particular conduct may be permitted under the applicable statutes and regulations, and even where employees sincerely believe there is no appearance of impropriety in the conduct, there may be instances where employees should exercise common sense and prudence to abstain from the conduct. However, ethics officials are not empowered to compel that abstention.

In conclusion, the Blue Ribbon Panel's recommendations are certainly a helpful starting point. But we remain open-minded and interested to hear from NIH regarding its evaluation of the recommendations. As the Department moves forward with respect to the recommendations and requests from NIH, we will carefully consider what steps should be taken. At the same time, HHS, and, in particular, the expanded Ethics Division [of the Office of General Counsel], will continue accelerating and implementing our plans to independently audit ethics programs in the Department's components, ensure extensive education and training, increase transparency in the form of thorough and accurate disclosure, and provide advice and ethics counsel to the nation's premier professionals in the ever-changing field of biomedical research.

We would also very much welcome hearing from the Committee about what changes it believes are required to strengthen the ethics rules, policies, and procedures at NIH. HHS will continue to cooperate with the Committee as the Committee addresses these important issues. In this manner, working together, our two branches of government can achieve our collective goal of ensuring public confidence in agency programs and operations through whatever means will best accomplish that objective. The objective is especially meaningful and important because so too is the mission of NIH to generate knowledge which will advance our ability to care for human ailments and improve the lives of all Americans.

Thank you for the opportunity to speak with you today. I would be pleased to answer any questions that you may have.