DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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The Honorable John D. Dingell
Ranking Member, Committee on
Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Dingell:

On March 10, 2005, the Chairman and Ranking Member of the Committee requested an update on NIH's internal review of Agency employees involved in consulting activities with nongovernmental organizations and a full explanation of the factors leading to my conclusion that there was a need for stricter ethics rules at NIH.

As I testified before the Committee, I believe collaborations and other scientific interactions between NIH personnel and nongovernmental researchers–for that matter, exchanges between all scientists–are a prerequisite for the advancement of biomedical research and the expeditious translation of discoveries to treatments. In the modern world of scientific inquiry, with fields of discovery converging amid increasing requirements for multidisciplinary research, such interactions are more important than ever before.

Yet, the need for scientific exchange does not supersede the legal and moral responsibility of NIH employees to engage with their private-sector colleagues in a manner that does not result in real or apparent financial conflicts of interest. Besides the direct harm such conflicts could pose for patients, or the inequities they could create among firms and their investors, they could undermine the public trust in biomedical research and NIH. At their worst, these conflicts, whether potential or actual, could reduce the Nation's commitment to research priorities and slow the substantial progress we have made to reduce suffering and death from disease and injury.

As the Director of NIH, I am responsible for seeking a balance between the need for collaboration and our ability to maintain public trust in the performance of our mission. After I first began to learn of the problems associated with the NIH ethics program in mid 2003, I came to believe that the loosening of ethics rules governing NIH employees in 1995, coupled with increasing complexity of the industry, had created unfortunate vulnerabilities about such issues as consulting with industry or the receipt of honoraria for lectures.

I also recognized deficiencies in the NIH ethics program. In particular, I was concerned that applications for outside activities, such as consulting with industry, had not been subjected to independent peer review by scientists who would understand the implications of providing scientific services to private companies and determine whether overlap existed between official and outside activities. Therefore, in November 2003, I announced the formation of the NIH Ethics Advisory Committee (NEAC) to review such applications.

Over time my opinion evolved on the need for restrictions on employees consulting with organizations where the potential for conflicts of interest exist, in particular the pharmaceutical and biotechnology industries that could be affected by decisions made by NIH scientists and managers. This evolution occurred as I examined information provided during hearings of the Oversight and Investigations Subcommittee, cases reviewed internally by NIH, and the deliberations of the Blue Ribbon Panel I appointed to review NIH ethics policies and procedures.

As I considered the evidence, I sought answers to the following critical questions:

1) Are the regulations governing the ethical conduct of NIH employees sufficient in terms of preventing even the appearance of conflicts of interest while ensuring public trust in NIH's ability to remain free of bias as the Agency pursues and supports biomedical research?

2) Have NIH employees violated existing regulations or conducted themselves in a manner–even in cases where the conduct is allowable–that would result in a diminishment of public trust in the Agency?

3) Is the NIH ethics program adequately processing and overseeing the outside activities and financial holdings of NIH employees?

In the case of question 1, I have concluded that the rules in existence since 1995 are not, in fact, sufficient to prevent possible conflicts of interest or even the appearance of conflicts of interest or maintain the public's trust in NIH as an unbiased supporter of biomedical research. Consulting with outside companies, promoting products, accepting equity ownership in conjunction with ongoing consulting arrangements, and consulting with organizations involved in research similar to inquiries being conducted by NIH scientists themselves were all among the activities or investments permissible under the previous rules if an employee recused himself or herself appropriately and adhered to other requirements. In addition, we have seen that additional internal oversight and review by scientists of specific consultations is needed for these activities.

In regard to question 2, we discovered cases of employees who consulted with research entities without seeking required approval, consulted in areas that appeared to conflict with their official duties, or consulted in situations where the main benefit was the ability of the employer to invoke the name of NIH as an affiliation.

As for question 3, we found that the decentralized ethics processing system at NIH lacked adequate peer review, applied policies and regulations inconsistently across the NIH, and lacked the authority or ability to sufficiently question the information being provided by NIH employees. As an illustration of our response, I asked NEAC, a committee made up of NIH scientists, to independently review the cases that had already been approved under the old rules for employees who wished to continue the activities.

The long and varied review of the Agency's ethics program has been one of my top management priorities because the NIH leadership understands that, regardless of the number of scientific opportunities and advances, a requirement for the success of NIH is the unwavering trust of the patients and public whom we serve. Our process of review was detailed and deliberative. Individual cases had to be vetted carefully due to the complexity of the arrangements as well as the requirement that all employees be afforded due process, including adherence to privacy and personnel rules.

In mid-2004, I concluded that the body of evidence revealed a vulnerable ethics management system at NIH, characterized by insufficient oversight and inconsistent application of rules. The rules themselves, I decided, simply did not provide adequate protection against potential conflicts of interest and allowed activities that the Congress, the scientific community, and the general public found inappropriate. These included cases of individuals performing consulting services that, in my view, conflicted with their official duties or were used to promote the use of certain products.

Most importantly, I determined that these cases, while not representative of the significant majority of NIH employees who abide by the rules, were the symptoms of systemic weaknesses in the regulations and processes used to manage the NIH ethics program. Having reached these conclusions, I believed that the only prudent response was to completely halt consulting between NIH employees and the pharmaceutical and biotechnology industries through changes in the rules and to overhaul the ethics program at NIH.

In response to my request, the Department and the Office of Government Ethics worked with me to make changes and agreed that the regulatory changes should be interim final regulations, to be followed by an evaluation of comments and consideration of changes to ensure that the regulations will adequately and effectively address the problems identified.

Answers to your specific questions about the NIH internal review of individual cases involving allegations of ethics breaches or inappropriate conduct are contained in the attachment. We have expended considerable time and resources to review all of these activities completely, fairly, and accurately. While the review is still ongoing I am pleased to respond to your specific questions about the status, methodology, and results of our review to date. Because the entire review is not complete, I request that all the information provided in the enclosure be treated as confidential.

I want to reiterate my appreciation of the Committee's work in this area. Many of the issues of concern were identified by the Committee's inquiry and subsequent hearings. You have my pledge that I will continue to work with the Committee on this matter as we move forward by correcting deficiencies and ensuring public trust.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

cc:
The Honorable Ed Whitfield
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

The Honorable Bart Stupak
Ranking Member, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Responses to Committee Questions
July 7, 2005

1-2. Number of NIH Scientists under Review and Basis for Each Review

A total of 103 individuals are under review.

The House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, identified a total of 81 individuals who allegedly had unapproved outside consulting activities.

In addition to those individuals, we are reviewing the outside activities of seven individuals reported in the December 2003 and December 2004 *Los Angeles Times* articles, and the activities of 2 individuals cited by the Subcommittee in its hearings in May and June 2004.

Finally, we are also reviewing the pharmaceutical and biotechnology consulting activities that were reported by 29 NIH employees in response to my June 28, 2004, request that all NIH employees report outside activities that had not been previously approved or reported on financial disclosure reports.

It is important to note that there is an overlap among these three categories (e.g. some individuals identified by the Subcommittee were also included among the employees who reported activities in response to the June 28,2004 request).

3. Nature of the Source Documentation or Information Involved

We understand that the list provided by the Subcommittee was prepared from a comparison of data provided by NIH and data provided by pharmaceutical and biotechnology companies in response to the Subcommittee's request for information.

At the request of NIH, the Subcommittee provided responses and supporting documentation it had received from the pharmaceutical and biotechnology companies to assist NIH in reviewing the specific activities cited by the Subcommittee. Also, NIH contacted the pharmaceutical and biotechnology companies directly and obtained additional information and documentation related to the activities the companies had identified as being performed by NIH employees.

NIH also obtained source documents and information from the NIH Ethics Office (NEO) files, information individual employees had retained related to their outside consulting and official duty activities, and information from the files of Deputy Ethics Counselors (DECs) in the NIH Institutes and Centers.

4. Number of Interviews Conducted

Seventy-six of the 81 individuals identified by the Subcommittee were interviewed in person or contacted by phone, mail, or e-mail. The five individuals not interviewed or contacted included those no longer at NIH that we were unable to locate or those we determined it was not necessary to contact because available documents allowed us to resolve the allegation(s) involving them.

All other individuals being reviewed have been interviewed.

5. Methodology of the Review

- For the 81 individuals on the list provided by the Subcommittee, the NIH Office of Management Assessment (OMA):

  a. Obtained a copy of the institute's file for each individual, including all requests for approval for outside activities for the 1999-2004 period, financial disclosure reports, leave records, information relating to approved official duty activities, listings of all current major projects and papers published since January 1, 2003, and copies of Cooperative Research and Development Agreements where the individual served as the Principal Investigator;
  b. Interviewed each individual (except as noted in Question #4 above) and provided a summary of the interview to the individual for comment;
  c. Consulted with the DEC for each individual's institute as well as the NIH Office of Human Resources and the NEO, where appropriate;
  d. Worked with the pharmaceutical or biotechnology company that reported the activity to the Subcommittee to obtain additional information to clarify or corroborate information received from the Subcommittee or the individual;
  e. Prepared a draft report that was given to the individual for comment; and
  f. Incorporated comments, as appropriate, into a final report for each individual.

- For the remaining individuals not on the Subcommittee list, NIH conducted a similar analysis; although we did

not have supporting documentation of the nature that had been provided by the pharmaceutical and biotechnology companies for the Subcommittee list of 81 individuals. The NIH reviewers collected all available information on the activities self-reported by the individuals, the newspaper articles, and the activities identified in the congressional hearings, and performed their analyses based on that information.

- Cases in which documentation of prior approval is not found are referred to the NEO. The NEO is coordinating an analysis by a committee of senior scientists to determine whether there was a conflict between the activity and the individuals' official duties at NIH.

6. Restrictions on the Review

There were no restrictions on the review. The reviewers were able to contact anyone in the agency to obtain and clarify information and they had access to all documents within the agency. The reviewers also contacted pharmaceutical and biotechnology companies and other outside sources for the same purpose. Their work was conducted using the Government Auditing Standards established by the Government Accountability Office as guidance.

7. Number of Individual Cases Reviewed [That] Have Been Completed

The fact finding portion of the review has been completed for all 81 cases on the Subcommittee's list. The fact finding portion of the review was comprised of a determination of whether the employee received prior approval; took the requisite leave, if necessary; and disclosed the outside position and any income received from the activity on his or her financial disclosure report, if the individuals were filers. For those cases where prior approval was not obtained, the review also included the conflict of interest analysis described in the response to Question #5.

8. How Many Individual Cases Have Not Been Completed?

In the cases involving individuals other than those on the Subcommittee list, determinations of whether the employee received prior approval, took the requisite leave, and disclosed the outside position and any income received on his or her financial disclosure, if the individual was a filer, have been made and the reports are being completed. Once the reports are completed, the cases will be forwarded to the NIH Office of Human Resources (HR) and NEO, as appropriate.

9. How Many Individual Cases Have Been "Cleared" and on What Basis Were Those Cases "Cleared"?

Thirty-seven individuals on the Subcommittee list were determined to have had prior approval for the activity (either an outside or official duty activity); the activity was properly reported on their annual financial disclosure report, if the individuals were filers; and they were on approved leave for the activity, if necessary.

The cases identified that were not on the Subcommittee list are still under review, as described in the response to Question #8

10. How Many Individual Cases Resulted in a Determination of Inappropriate or Questionable Conduct that was not a Violation?

We did not make such a determination. The primary purpose of the reviews is to determine whether documentation was available showing that prior approval was obtained for the activity, whether the activity was reported on the individual's financial disclosure reports, if the individuals were filers, whether the individual was on approved leave when participating in the activity, if necessary, and, where prior approval was not documented, whether the activity conflicted with the employee's official duties. If the documentation was not found, individuals were cited as violating regulations or agency policy. An identified conflict with official duties also constitutes a violation.

11. How Many Individual Cases Resulted in a Determination of a Violation?

NIH determined that thirty-six individuals on the Subcommittee list violated policies or regulations and were referred for administrative action. In addition, eight reviews found violations of policies or regulations by individuals who are no longer NIH employees, and are not subject to administrative action by NIH.

The cases identified that were not on the Subcommittee list are still under review, as described in the response to Question #8.

12. Description of Any Violations Determined by the Review

The OMA found three types of violations which resulted in recommendations for administrative action. The violations are:

1. Documentation was not available to show that prior approval had been obtained for the activity;
2. The activity was not reported on the individual's financial disclosure report (if the individual was a filer); and
3. The individual was not on approved leave when participating in an outside activity, if necessary.

In cases where documentation was not available showing that an individual obtained prior approval for an outside activity, the NEO is coordinating an analysis by a committee of senior scientists to determine whether there was a conflict between the activity and the individual's official duties at NIH.

13. How Many Individual Cases Resulted in Disciplinary Actions and a Description of Those Actions?

As stated in #11 above, 36 individuals from the Subcommittee list violated policies or regulations and were recommended for administrative action. The NIH Office of Human Resources is assessing the findings and conclusions to ensure consistency in the disciplinary actions that will be taken by management officials. NIH will move ahead with specific actions when that consistency assessment is completed.

14. How Many Individual Cases Were Referred to the Office of Inspector General, DHHS, to Investigate Allegations of Criminal Violations and the Dates of those Referrals?

Nine individuals were referred to the HHS Office of Inspector General for investigation. The referrals were made on August 10, 2004, August 12, 2004, September 24, 2004, November 2, 2004 (2), January 25, 2005, and February 23, 2005 (3).

15. What Factors Led You to Believe There Was a Need for Stricter Ethics Rules at NIH?

I have closely followed emerging conflict of interest issues and the progress of NIH reviews of potential conflicts of interest involving NIH scientists. As it became clear that problems were being identified, I decided it was necessary to move aggressively to protect the integrity of the science conducted at NIH and to maintain public confidence in the nation's premier medical research institution.