**Testimony Before the Oversight and Investigations Subcommittee**

**Committee on Energy and Commerce**
**United States House of Representatives**

# NIH ETHICS CONCERNS: CONSULTING ARRANGEMENTS AND OUTSIDE AWARDS


*Statement of*

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Mr. Chairman and Members of the Subcommittee, I am Elias A. Zerhouni, Director of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS). I am here to testify about my proposal to strengthen the ethics system at NIH by changing our rules, practices, and procedures.

I have reached the conclusion that drastic changes are needed as the result of an intensive review by NIH of our ethics program, which included internal fact-finding as well as the external review of a Blue Ribbon panel. This review was prompted in part in response to the inquiry of this Subcommittee and the bipartisan concerns of Chairman Greenwood, Ranking Member Deutsch, Congresswoman DeGette, and the full Committee Chairman, Mr. Barton, as well as the Committee's Ranking Member, Mr. Dingell, and other members of the panel.

The events and arrangements that have been the subject of the Subcommittee's oversight and NIH's reviews were rooted in a significant alteration of NIH's ethics rules and policies that occurred in 1995. These changes were the result of converging interests. The first was NIH's desire to strengthen the research enterprise through the use of innovative recruitment and retention policies. The second was a government-wide standardization of ethics policies, which resulted in a decision by NIH to change its ethics rules to conform to the new policies.

As we move forward, I regret that the reputation of NIH has been challenged over ethics concerns and that the conduct of individual scientists who have devoted their lives to battling disease and easing the suffering of millions of patients has been questioned. I believe the NIH and its employees were operating within rules that allowed or did not specifically address many of the arrangements that the Subcommittee has questioned, including lecture awards and consulting with industry. In retrospect, there was not a sufficient safeguard against the perception of conflict of interest.

As I have testified previously, our public health mission is too important to have it undermined by any real or perceived conflicts of interest. It is imperative that Congress and the American people trust that the decisions made by our scientists are motivated solely by public health priorities and scientific opportunities, not personal financial concerns.

The first step in maintaining such trust was the creation of the NIH Ethics Advisory Committee (NEAC). The NEAC, an internal NIH committee, is providing a centralized, consistent, and rigorous review of all consulting arrangements with pharmaceutical and biotechnology companies, awards valued in excess of $2500, and all outside activity requests from senior NIH officials. Composed of Institute and Center Directors and scientific leaders, and with the participation of ethics officials, the Committee provides unprecedented review by scientific peers of applications for outside activities and awards. NEAC looks carefully at each request under its jurisdiction so that, for instance, NIH employees are not consulting on matters that are related to their official duties or pose other potential concerns. Only those requests for approval that have passed muster at the Institute level, by both the employee's supervisor and the Institute's Deputy Ethics Counselor (DEC), are forwarded to the NEAC for review. Upon NEAC review, it is only those arrangements that do not pose conflict of interest concerns that are recommended for approval and forwarded to the NIH Deputy Ethics Counselor. As a result of the unprecedented review by scientific peers now applied to the ethics program, the culture at NIH is already changing.

On May 12, I testified before this subcommittee about four principles for change in the NIH ethics program:

1) Enhance public trust in NIH by preventing conflicts of interest through the restriction of financial relationships that employees may have with outside organizations;

2) Increase levels of transparency in the NIH ethics program by requiring much more internal as well as public disclosure of the details of financial relationships that employees have with outside organizations, including consulting arrangements and awards;

3) Balance NIH's ability to recruit and retain the best scientific expertise while expediting the translation of research advances;

4) Establish effective monitoring and oversight of employee activities.

Today I am announcing that NIH, working with the HHS Office of the Secretary, will seek a major reform of the Agency's ethics program by requesting restrictive rules and by seeking to increase the

public availability of information related to outside activities with industry. As you know, this process cannot happen overnight. We are aggressively working with the Office of the Secretary and OGE to make sure that we have in place a set of rules that ensures the appropriate ethical oversight while continuing to encourage scientific creativity. The following framework lays out our attempts to implement the principles described above.

**Principle One: Enhance Public Trust**

- Prohibited Holdings: We are working to prohibit the holding of stock in individual biotechnology and pharmaceutical companies as is done at the Food and Drug Administration. There, all employees that file either a public or confidential financial disclosure report are prohibited from holding stocks in significantly regulated entities. Non-filers are permitted to hold only up to $5000 of such stock, which is $10,000 below the current federal rules for *de minimis* financial interests.

- Awards: We are actively pursuing a two-step process. First, any NIH employee should be prohibited from accepting any award unless the award has been pre-screened. Such a process would include an independent advisory committee of non-government individuals, and a determination by the NIH DEC that the award meets the regulatory definition of *bona fide*. Second, even if the award has been determined to be *bona fide*, specific awards to employees still should be reviewed on a case by case basis by the NEAC, and approved by the NIH DEC to ensure that the acceptance of the award does not create a real or apparent conflict of interest for the employee in relation to official duties. As an additional restriction, NIH will seek to prohibit any official – including Institute and Center Directors – who are responsible, either directly or indirectly through subordinates, for a funding decision affecting the entity offering the award, from receiving the cash component of an award. It is my intention that this restriction will not preclude the acceptance of cash in the case of certain exceptional *bona fide* awards, such as the Nobel Prize. The list of pre-screened bona fide awards would be posted publicly, as will the NIH recipients of such awards.

- Outside Activities with Industry: While we continue to encourage consultation with industry as part of official duties, I intend to prohibit senior NIH employees, as well as all employees involved in extramural funding decisions, from consulting with industry for compensation or any other form of remuneration. Other employees would be permitted to consult only if the arrangement has been reviewed by the NEAC and approved by the NIH DEC, and certain restrictions are in place. These are: 1) payment may not include stock or stock options; 2) annual compensation from all outside activities with industry must be limited, and no more than half of that limit may come from any one source; and 3) a cap on the number of hours annually that an employee can spend on all outside activities with industry.

- Participation on Industry Boards: I seek to prohibit all NIH employees from membership on corporate boards of the pharmaceutical and biotechnology industries. In addition, employees should be allowed to participate in industry scientific advisory boards as ad-hoc participants only if such participation has been reviewed by NEAC, and approved by the NIH DEC.

- Consulting (includes speaking) with Grantee Institutions: While we continue to encourage consultation with grantee institutions as part of official duties, I will seek to prohibit all NIH employees from consulting with NIH grantee institutions for compensation or any other form of personal remuneration.

- Consulting (includes speaking) with Non-profits that are not Grantee Institutions: I seek to prohibit NIH senior leadership from consulting with these entities.

- Clinical Practice: NIH seeks to control employee annual compensation for clinical practice.

**Principle Two: Increase Transparency**

- NIH, working with HHS and OGE, has already increased the number of senior managers who must publicly disclose their compensated activities with outside organizations and the amounts

received. This has been increased by 93 positions. We are hopeful that OGE will grant HHS' recent request to extend public financial disclosure to an additional 508 positions.

- I will seek authority from OGE for NIH to determine which of its employees must submit public financial disclosures.

- We are working towards requiring that outside activities with industry be publicly disclosed. This will include disclosure to CRADA partners.

- NIH employees will continue to be required to disclose the amount of compensation earned from outside activities.

- I will review the duties and responsibilities of employees who currently do not file any financial disclosure reports, specifically those involved in human subjects work, to increase the number of employees who file such reports to avoid any involvement in a real or apparent conflict of interest.

**Principle Three: Recruit and Retain Best Scientific Expertise While Expediting Translation of Research Advances**

- I will encourage NIH scientists to continue teaching, speaking or writing about their research as part of their official duties.

In order to encourage scientific interactions involving the exchange of knowledge and the exercise of intellectual leadership by NIH scientists, NIH will continue to allow certain types of outside activities – including teaching and lecturing opportunities and collaborations with the private sector – but only under clear, rigorous rules meant to eliminate conflicts of interest.

**Principle Four: Establish Effective Monitoring and Oversight Mechanisms**

- I will continue to require that supervisors fulfill their responsibilities in both reviewing proposed outside activities and, if NEAC ultimately approves the outside activity, in

monitoring the effect that the activity might have on the employee's official duties. Before any proposed outside activity is forwarded to the NEAC for review, supervisors will be asked to determine whether the activity can and should be undertaken as part of the employee's official duties, and if not, whether the proposed outside activity will cause a conflict, either of interest or of commitment. In addition, supervisors will be expected to monitor employees' compliance with the limitation on hours.

- NIH will improve its ability to manage and track approved activities with outside organizations by increasing the accountability of managers, creating a centralized system, conducting random audits of files pertaining to activities with outside organizations, and continuing the rigorous review by peers.

- NIH will develop and implement a new, more understandable method of training employees on ethics rules, and we will establish a web site that displays rules in plain language, updates employees on regulatory trends and changes and discusses – anonymously – ongoing cases as examples of best practices or unacceptable practices.

We are severely restricting the ability of NIH employees to consult with industry. However, as I have previously testified, the easiest way to approach this matter would be to ban all consulting with industry. I do not want to discourage the kind of intellectual excitement and curiosity that leads our scientists to want to work with industry. I want to provide an environment for them in which they have the same kind of professional and intellectual opportunities as their counterparts in academia. I want the intramural program to continue to attract the best and the brightest. With these principles in mind, I am working to strike a careful balance – whereby those individuals in key decision-making positions will be prevented completely from consulting, while stringent limits will apply to other employees.

Mr. Chairman, Members of the Subcommittee, in summation, I have described the three core elements of reforming the ethics process at NIH. Number one, we are applying review of applications for outside activities by scientific peers. Number two, we are requiring full disclosure and transparency in the program. And number three, NIH is working to reduce, restrict, or eliminate the types of activities about which this Subcommittee has raised concerns.

Thank you for this opportunity to speak before the Subcommittee on these matters once again. I would be happy to answer any questions you may have.