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MEMORANDUM

TO: Reporters and Editors  
FR: Jill Kozeny, 202/224-1308  
for U.S. Senator Chuck Grassley of Iowa  
RE: National Institutes of Environmental Health Sciences  
DA: Tuesday, April 15, 2008

Last summer, Senator Chuck Grassley began an inquiry into allegations of mismanagement and ethical lapses at the National Institutes of Environmental Health Sciences, one of the 27 institutes operated by the National Institutes of Health. His inquiry revealed allegations of missapropriated funds, conflicts of interest and mismanagement by the Director of the National Institutes of Environmental Health Sciences, Dr. David Schwartz. In response, the Director of the National Institutes of Health, Dr. Elias Zerhouni, told Senator Grassley that he would empanel a group of internal and external experts to conduct an independent review of problems at the National Institutes of Environmental Health Sciences.

Yesterday, Senator Grassley obtained a copy of that panel's report. Today, Senator Grassley is asking Dr. Zerhouni to respond to its findings that 45 grants were funded out of order between 2005 and 2007 from the extramural program of the National Institutes of Environmental Health Sciences. Senator Grassley said he is also asking the Inspector General for the Department of Health and Human Services to investigate. Last fall, Senator Grassley asked the Government Accountability Office to conduct a review.

Senator Grassley said this activity is of concern because it breaches the peer review process, which provides an objective measure of grant applications. When a grant request is funded without having received a peer review that recommended funding, then the decision to fund the grant should be documented. In addition to 45 grants being funded out of order, according to the new report, Grassley said it appears that the actions were undocumented. He said he wants to know if this activity is also occurring at other institutes of the National Institutes of Health.

The text of the letter sent today from Senator Grassley to Dr. Zerhouni is below. The report of the panel and an email discussing approval of the NIEHS director's outside activities are posted at <http://finance.senate.gov>. To find them, go to press releases and click on Senator Grassley's name.

April 15, 2008

Elias A. Zerhouni, M.D.  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Director Zerhouni:

As a senior member of the United States Senate and the Ranking Member of the Committee on Finance (Committee), I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the National Institutes of Health (NIH/Agency). In this capacity, I must ensure that NIH properly fulfills its mission to advance the public's welfare and makes responsible use of the public funding provided for medical studies. This research often forms the basis for action taken by the Medicare and Medicaid programs.

Last year, I sent you several letters about serious mismanagement problems plaguing the National Institute of Environmental Health Sciences (NIEHS). In particular, my investigation demonstrated that the NIEHS director was giving expert testimony in court cases regarding asbestos while also leading the National Toxicology Program, overspent his lab budget by millions of dollars, used government staff for personal purposes, and allegedly meddled in the extramural funding process, among other things.

At that time NIEHS was being run by Dr. David Schwartz, who will depart NIEHS shortly. In response to these letters, you graciously met with me and my staff and informed us that you were creating a panel to perform an independent and in-depth assessment of problems at the NIEHS.

A copy of that report was provided to my staff just a short time ago by a government employee (See attachment #1). The report is entitled: "Management Review National Institute of Environmental Health Science Office of Management Assessment National Institute of Health Department of Health and Human Services April 9, 2008: Final Report." (Report).

A review of this Report raises several issues of concern. First, I am troubled that this Report places blame for many of the NIEHS problems on the NIEHS ethics office. While we do not disagree that the NIEHS ethics office is understaffed and may have some problems, that office lacked general authority to approve Dr. Schwartz's outside activities. Based upon a review of the internal emails provided to me, it is apparent that Dr. Schwartz had many of his outside activities approved by Dr. Raynard Kington at the NIH rather than the NIEHS ethics office (See attachment #2: email from Dr. Kington to Dr. Schwartz). That fact is not addressed in the Report.

Second, I am very worried that there continue to be allegations that Dr. Schwartz was

involved in selecting individuals/organizations for extramural grants. Of the \$700 million appropriated to the NIEHS, around 80% of that money funds extramural grants. Specifically, I note that the Report found that "decisions to award extramural grant applications out of rank order are not properly documented, as required by NIH policy."

The Report notes that between fiscal years (FY) 2005 to FY 2007-2,516 grants were funded through the NIEHS extramural program, and that "45 applications that scored beyond the payline were funded." This seems to mean that Dr. Schwartz was manipulating extramural funding at the NIEHS and not properly documenting his decisions as required.

I would also like to inform you that I have asked the Government Accountability Office to conduct an inquiry of the NIH oversight process. I am concerned that many of the problems I have uncovered at NIEHS, including meddling with extramural grants, may be found at other NIH institutes.

Further, I note that this Report also found:

- 1) Several grants to the NIEHS from outside organizations were not documented;
- 2) Staff did not comply with NIH policy on travel and;
- 3) NIEHS managers showed intent to hire before receiving best qualified lists.

To add to this final point, according to emails that I have received, a husband and wife were negotiating their combined salaries with NIEHS before the job for the wife had even been posted.

Therefore, and through this letter I am asking the Health and Human Services Office of the Inspector General to perform an audit of extramural grants and all expenses coming out of the NIEHS office of the director for the fiscal years 2005 to FY 2007.

Accordingly, I ask you to respond to the following requests for information and documents. In responding to each request, first repeat the enumerated question followed by the appropriate response.

- 1) Why did the Report fail to address the fact the Dr. Raynard Kington approved many of Dr. Schwartz's outside activities? In addition, and in light of this fact, what action(s) will be instituted, if any, against Dr. Kington?
- 2) I began my investigation, in part, because of allegations that Dr. Schwartz was engaged in outside activities that conflicted with his job as director of the NIEHS. If the NIEHS ethics office did not have final approval of Dr. Schwartz's outside activities, then why was this not identified in the Report?
- 3) I sent a letter to you on August 27, 2007; I identified several problems with a report completed on the NIEHS by the NIH Office of Management Assessment (OMA). For instance, OMA found that Dr. Schwartz had not used computer staff for his own needs, but my investigators found credible evidence to the contrary. Why was this issue not addressed in this recent report?
- 4) Please provide a list of all 45 grants that scored beyond the payline, but were funded. For

each grant, provide the following information:

1. Grant title;
2. Brief description of the grant proposal;
3. Score of the grant and ranking in the payline;
4. Amount of funding for the grant;
5. Score of the last grant in the payline and its rank in the payline;
6. Number of grants that were bumped to provide funding for this particular grant and;
7. Rationale for funding those grants scoring below the payline.

I request your prompt attention to this matter and your continued cooperation. I also request that the response to this letter contain your personal signature. Also, I am sending you a copy of the Report that prompted this letter.

Sincerely,

Charles E. Grassley  
United States Senator  
Ranking Member of the Committee on Finance

cc: The Honorable Daniel R. Levinson  
Inspector General  
U.S. Department of Health and Human Services

Attachment