## United States Senate Committee on Finance

Sen. Chuck Grassley · Iowa Ranking Member

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For Immediate Release Tuesday, August 28, 2007

Grassley questions NIH leader about his response to questionable actions of division head

WASHINGTON — Sen. Chuck Grassley is asking the director of the National Institutes of Health to address concerns that an internal review he supervised of actions by an NIH division head glossed over problems and failed to answer a number of obvious questions.

Grassley made his inquiry this week in a letter this week to director Elias Zerhouni. Last week, Dr. David Schwartz stepped down from his position as director of the National Institute of Environmental Health Sciences while his management practices are reviewed.

"I'm urging the top leader at the National Institutes of Health to take responsibility for what's happened at the Environmental Health Sciences division, where allegations have been made about violations of the public trust and subsequent damage to employee morale," Grassley said.

The text of Grassley's letter to Zerhouni follows here.

August 27, 2007

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

Dear Director Zerhouni:

As a senior member of the United States Senate and as Ranking Member of the Committee on Finance ("Committee"), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities of the National Institutes of Health ("NIH"). In this capacity, I must ensure that NIH, as the primary federal agency responsible for conducting and supporting medical research, properly fulfills its mission to advance the public's welfare and makes ethical and responsible use of the public funding provided to accomplish this task.

The purpose of this letter is to update you about my inquiry into the National Institute of Environmental Health Sciences ("NIEHS" or "Institute"). First, I am concerned about the Office of Management Assessment (OMA). Last year, the OMA examined problems with mismanagement by Dr. David Schwartz, director of the NIEHS. But my investigators uncovered evidence that the OMA either missed and/or ignored when it investigated Dr. Schwartz's use of government staff to provide computer services for his family. More seriously, my investigators have been advised by some NIH employees that the OMA report is nothing more than a "white wash." Second, I am concerned that Dr. Schwartz created policies for extramural funding at NIEHS that may differ from yours. Several employees at NIEHS advised my investigators that Dr. Schwartz may be improperly meddling in the process for awarding grants to outside researchers. When my investigators examined the issue, they discovered evidence supporting that allegation. Finally, I am aware that you have announced that NIH will convene a panel of senior management to conduct a review of NIEHS. I understand that this instruction is apparently a response to language in a House of Representatives Report.

Let me also take this opportunity to apprise you of the current situation. My first letter of inquiry was sent to NIH on April 22, which asked for information regarding allegations of mismanagement by Dr. Schwartz. A second letter was sent on July 21 which laid out some of the problems I had uncovered.

In this second letter, I expressed grave concerns about leadership choices and ethical decisions made by Dr. Schwartz. I asked you to answer several questions and to provide the Committee with documents by no later than July 10. It is now five weeks past that due date and I still have not received a complete response.

For instance, in my first letter, I asked for any correspondence you may have regarding problems with Dr. Schwartz or the NIEHS. However, you provided the Committee with only one, lone email in which you were discussing Dr. Schwartz. As I mentioned to you in my subsequent letter, I find it very hard to believe that over the last couple of years, with all the problems at NIEHS, you have sent or received only one piece of correspondence regarding Dr. Schwartz. Because of this, I asked in my second letter that you confirm to me in writing that you had given me all communications, records and/or documents regarding my first request. I continue to await your assurance on this matter.

The slow pace of NIH's response leads me to believe that either you do not appreciate or perhaps do not respect the need for effective congressional oversight of government agencies. I hope that is not the case.

This past Monday afternoon, August 20th, Dr. Schwartz stepped aside as director of NIEHS until NIH completes this second investigation into his activities. Later that same day, a group of scientists at NIEHS, called the Assembly of Scientists, released the results from a poll on three questions they had asked of their members. I received an email that contains those results and I would like to share them with you.

Of the 206 assembly members, 146 responded to the poll.

On the question "How have the actions and decisions of the Director, David Schwartz, affected your

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morale?"
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99 out of 146 responded, "Negatively."
6 out of 146 responded, "Positively."
36 out of 146 responded that they were "not affected."
1 chose not to respond, but voted on other questions.
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On the question "At this time, does the NIEHS Director have your continued support?"

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36 out of 146 responded, "Yes."
91 out of 146 responded, "No."
15 people chose not to respond, but voted on others questions.
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On the question "Do you have confidence in the leadership of the NIEHS Director?"

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25 responded, "Yes."
107 responded, "No."
10 people chose not to respond to this question, but voted on others.
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Four members responded to the ballot, but abstained from voting.

These appear to be uncomplimentary numbers and seem to be the equivalent of a vote of "no confidence" against Dr. Schwartz. Indeed, this ballot seems to indicate that the problems brought upon NIEHS and NIH by Dr. Schwartz are perhaps far beyond the ability of a panel of senior NIH executives to address. Nonetheless, I look forward to receiving the results of that review.

I am equally concerned that, until recently, you seemed to have little involvement in the problems gripping NIEHS. For example, NIH letters addressed to me are typically signed by one of your subordinates. Moreover, the tone of NIH responses to my letters leads me to believe that your subordinates are addressing these problems with Dr. Schwartz, even though you are his direct supervisor.

Dr. Zerhouni, you are responsible for Dr. Schwartz and I want to hear from you on this matter. Congress provides the NIH with over \$28 billion every year to support research that is vital for the health of Americans. While the pay for government service may not be as high as private industry, and we do not provide perks such as stock options like some companies do, most scientists feel a sense of pride in serving the public while working at NIH. Leading NIH or one of its institutes is a high honor that should not be taken lightly. Like you, I am proud of the research that NIH conducts, and I am grateful for federal scientists who work hard to protect American lives. In fact, it is the importance of NIH scientists which requires me to ensure that Americans maintain their trust of NIH and taxpayer funded research.

The following sets forth in greater detail some of the findings of my inquiry. In addition, I am requesting that you answer the following questions. Please respond by repeating the enumerated question, followed by the accompanying response.

I. Dr. Schwartz's use of government staff for personal reasons

Last year, OMA investigated seven allegations of mismanagement by Dr. Schwartz . On issue number four, OMA inquired, "Did the Director of NIEHS inappropriately obtain four laptop computers and use computer staff for his own needs?" On that issue, OMA staff concluded, "No, the Director of the NIEHS did not inappropriately receive four laptop computers or use computer staff for his own needs."

During that investigation, OMA staff interviewed several people including at least one computer support specialist. The record of that interview states that this particular computer support specialist told your OMA staff that "Dr. Schwartz wanted all his machines to have the Internet access and the ability to print, and he wanted his wife to have a working computer."

In the course of my inquiry, NIH has provided my investigators with hundreds of emails and other documents. In an email dated June 27, 2005, Dr. Schwartz responded to an NIEHS computer specialist who was updating him about work he was doing on Dr. Schwartz's laptop and home printer. In responding, Dr. Schwartz copied the email to his wife. Dr. Schwartz wrote, "Thanks very much. It might be helpful to check with WIFE'S NAME REDACTED to make sure everything else is working. Thanks again."

In another email that Dr. Schwartz sent in August 2005, he wrote to an NIEHS computer specialist, "You set up my old dell laptop for my [child], NAME REDACTED. However, she can't sign on because it requires a password. Could you give her the password?"

The next day, NIEHS computer support specialist, Rob LeVine responded with the passwords for Dr. Schwartz's child. Mr. LeVine then wrote, "On the new laptop for her, Keith did does not remember a password for her profile on that computer."

Further, when my investigators interviewed an NIEHS computer support specialist a few weeks ago, they learned that Dr. Schwartz has four government computers in his possession: two lap tops, one desktop in his home office, and another government desk top in an undisclosed location in his home.

In light of these facts, please respond to the following questions.

- 1. Why did OMA staff not probe further upon learning from the computer support specialist that Dr. Schwartz "wanted his wife to have a working computer?" Did they not think to ask if Dr. Schwartz had acquired government equipment for his family's use?
- 2. Do you feel that it is appropriate for Dr. Schwartz to have federal employees provide computer support for his child?
- 3. Why did OMA staff conclude that Dr. Schwartz did not "use computer staff for his own needs" even though computer staff did so?
- 4. Have government employees ever assisted your family members with their personal computer needs?
- 5. Are all four government computers in Dr. Schwartz's possession for his use as a government employee? If so, please explain.

- 6. Please provide my investigators with all communications, records, and documents regarding the OMA report on allegations of mismanagement at the National Institute of Environmental Health Sciences. This should include drafts of the report.
- 7. Please provide the name and title of every person who worked on the OMA report. Please include the name of each person's direct supervisor.
- 8. Several allegations have been made about the behavior of Dr. Schwartz that were not addressed by the OMA. Please describe the process by which OMA determined the seven issues that it chose to investigate, to include the names of all people involved. Who determined the exact wording of these seven issues?
- 9. During the course of the OMA investigation, did OMA investigators apprise you or Dr. Raynard Kington of what they were finding?
- 10. Did you or Dr. Kington have any influence on determining the parameters of the investigation, the course of the investigation, or the outcome of the investigation?
- II. Dr. Schwartz's conflicts of interest and extramural funding.

Since beginning this inquiry in April, my staff has received credible allegations that Dr. Schwartz may have been ignoring, among other things, ethical considerations when NIEHS awards extramural grants. Several scientists in both the private and public sector have raised this issue and are worried that if they speak out publicly they might see their funding cut in retaliation. Dr. Schwartz has collaborations with several outside academics and institutions, which require him to recuse himself from certain situations in the grant awarding process.

Because NIEHS provides hundreds of millions of dollars every year in funding to outside researchers, it is vital that the process for allocating these dollars is above reproach. The scientists of this country must trust that NIH is handling the grant process in a clear and transparent manner and in compliance with all applicable law. The actions of the director of NIEHS must be held to the highest scrutiny.

However, my Committee staff has learned that Dr. Schwartz does not seem to enjoy such scrutiny and has attempted to create his own process for vetting his ethics and conflicts of interest. In fact, Dr. Schwartz may have created a separate process for vetting his conflicts of interest that involves neither staff at NIH (Building 1) nor ethics officers at NIEHS in Research Triangle Park (RTP). This is extremely problematic as it creates an environment where scientists at NIEHS and at outside institutions begin to worry that grants will be given for reasons other than merit.

For instance, on November 15, 2006, NIEHS executive officer Marc Hollander sent an email detailing the minutes from an NIEHS meeting where Dr. David Schwartz expressed concerns to his staff about the difficulties he faces with ethics and conflicts of interest policies. Dr. Schwartz's concerns included the process for working out his personal conflicts of interest and his involvement with extramural grants.

Specifically, Mr. Hollander wrote that Dr. Schwartz "was concerned that we (NIH) are making up

the rules as we go along. That the decisions he receives appear to be opinions, not rules-based." Further down in the letter, Mr. Hollander wrote, "David restated that we need to develop what works for us in RTP without any interaction with Building 1 and out [sic] internal ethics office. It was validated that these exclusions are not negotiable." (emphasis added)

Please respond to the following questions.

- 1. Please describe the safeguards that are in place to ensure that Dr. Schwartz has not unduly influenced awards for extramural funding.
- 2. As Dr. Schwartz's immediate supervisor, do you feel it is appropriate for him to "develop what works for [him] in RTP without any interaction with Building 1 and [NIEHS] internal ethics office?"
- 3. Please look into the matter of the minutes that were recorded for this meeting and explain to me how you will handle this matter.
- 4. Also, in my last letter I asked you about a form that was passed around NIEHS to get employees to inform management when they are contacted by Congress. Whose idea was this and who specifically asked for that form to be handed out?
- III. Dr. Schwartz's ties to Duke University not captured in the OMA report

In my letter dated July 21, 2007, I asked NIH to "provide all supporting documents, records, and communications found by the OMA regarding its investigation of funding for Duke researchers at NIEHS." In response, NIH answered:

OMA reviewed only the allegation that NIEHS provided office space to two Duke University employees and two employees of the World Health Organization. It did not review issues related to the funding of those guest researchers. Documentation regarding this investigation will be transmitted to the Committee under separate cover. After issuing its report on this allegation, OMA received additional allegations involving the funding of Duke University guest researchers at Dr. Schwartz's NIEHS laboratory OMA referred the additional allegations to the Special Investigations Unit of the HHS Office of the Inspector General (OIG) for investigation. Any additional inquiries should be referred to the OIG.

After requesting this information, my investigators acquired compelling evidence that Dr. Schwartz has maintained almost constant contact with Duke since taking over leadership of NIEHS. Some of this contact does not appear to be covered by the multiple waivers granted earlier to Dr. Schwartz by NIH. Even after Dr. Schwartz cut his ties to Duke last spring, he continued to try and involve himself with the university, even though he apparently was supposed to have a one year cooling-off period. Dr. Zerhouni, you may want to look into this matter further. As you requested, I will let the Health and Human Services OIG know that the OMA investigation missed this vital information. Additionally, I will begin forwarding documents to the HHS OIG.

In closing, I look forward to greater attention to this matter on your part. In responding to this letter, please provide answers and documents by no later than September 10th, 2007, in accordance with the attached definitions.

Sincerely,

Chuck Grassley United States Senator Ranking Member, Committee on Finance