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Grassley works to safeguard NIH resources

WASHINGTON — Sen. Chuck Grassley is asking for an accounting of various actions and expenditures at the National Institute of Environmental Health Sciences, one of the 27 institutes and centers of the National Institutes of Health.

“Leaders of government agencies hold a public trust,” Grassley said. “They need to conduct themselves in a way that honors that trust and goes the extra mile to respect both the taxpayers and the mission of their institution.”

Grassley has been conducting a broad-based review of agencies whose medical research and use of public funds help to advance public welfare.

Grassley is the Ranking Member of the Senate Committee on Finance. The text of Grassley’s letter to Elias Zerhouni, Director of the National Institutes of Health is below.

June 21, 2007

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). 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 responsible use of the public funding provided to accomplish this task. Often, the work of the NIH forms the basis for action taken by the Medicaid and Medicare

programs.

This letter is in response to documents provided to the Committee following a request sent to you on April 9, 2007, regarding Dr. David A. Schwartz, Director (Director Schwartz) of the National Institute of Environmental Health Sciences (NIEHS). The Committee has reviewed hundreds of pages of documents and a report by NIH's Office of Management Assessment (OMA) on alleged mismanagement by Dr. Schwartz. Of course, we need to recruit and retain the best leaders and scientists for the federal government, but we also must ensure that they comply with ethics rules and all applicable policies and procedures.

It appears, based on the information reviewed to date, that Dr. Schwartz has been granted numerous waivers to provide expert testimony and/or medical opinions for at least two different law firms involved in asbestos lawsuits. As far back as the summer of 2005, numerous ethics officials at NIH raised red flags about this activity, yet it was allowed to continue.

I note also that the OMA conducted an ethics inquiry into alleged mismanagement by Dr. Schwartz. That inquiry determined that Dr. Schwartz:

- violated federal travel policies in paying for a limousine ride with federal funds.
- inappropriately used members of his staff to take his car to a dealership for service.
- used government funds to frame personal pictures.

That OMA report also made a number of determinations regarding lab space that NIEHS provided to "guest researchers" from Duke University. Dr. Schwartz was on tenured leave from Duke University throughout his first year and a half at NIEHS and was warned continuously by NIH ethics officers of the potential conflicts of working with Duke University and its researchers. Yet OMA did not find that NIEHS acted inappropriately. This finding by OMA seems inconsistent with recent actions initiated by the NIH. Just months ago, NIH instructed numerous Duke researchers in Dr. Schwartz's lab to return to Duke. In an email dated March 13, 2007, one ethics officer referred to this process as "de-Duking."

Further, I am concerned by gaps in documents that the NIH provided to the Committee. In the initial letter signed by Chairman Baucus and I, we asked for all communications between you and other NIH/NIEHS officials regarding reported problems with Dr. Schwartz from the time of his initial hire to present. However, the documents we received contained only a single email from you. Further, we did not receive any emails or documents covering the time period of April through October of 2006.

The following sets forth in greater detail the allegations and OMA findings regarding mismanagement by Dr. Schwartz. In addition, I am requesting that the NIH provide responses to questions regarding the extent of other inappropriate actions or questionable behavior at the NIH. Please respond by repeating the enumerated question, followed by the accompanying response.

DAVID SCHWARTZ'S ACTIVITIES WITH LAW FIRMS

According to emails provided to the Committee, after Dr. Schwartz was hired he immediately filed outside activity requests for expert witness service with two law firms involved in asbestos cases. In emails, several people at NIH raised questions about this outside activity. According to these emails, one of the firms wanted to use Dr. Schwartz as an expert witness in as many as 155 cases.

In discussing Dr. Schwartz's requests to testify, an ethics counsel wrote in an email on July 21, 2005 that "it appears Dr. Schwartz may not be sensitive to the implications of his and his staff members' involvement in private litigation involving subject matters and substances that are within the NIEHS portfolios... I can't imagine that testifying under oath on the subject is not a conflict of interest for him as the NIEHS/NTP Director."

In an email sent the very next day to the NIH Deputy Director, another ethics officer commented, "[Schwartz] already has an outside clinical practice and a gig with one law firm (one weekend a month). Would another busy relationship with a law firm be too much - conflict of commitment?"

Apparently, in response to pressure from Dr. Schwartz to get clearance for his testimony, the NIH Deputy Director sent him an email on July 29, 2005 stating, "We are bending the process a bit to get you an answer as soon possible for this next one, but may not be able to do this again. It is primarily a matter of fairness."

On August 2, 2005, an NIH employee sent an email to the NIH Director of Extramural Research stating, "[T]he expert witness role can lead to trading on the reputation of the NIH. I think it's almost inevitable. I don't think I'm being too cynical in suggesting that an expert witness from NIH is attractive to an attorney just because it's easy to leave the implication that the NIH in some sense stands behind the testimony. Later on, it will be easy for someone to attack NIH on this ground."

Two days later, on August 4, 2005, the Deputy Director of NIH wrote another email to Dr. Schwartz stating that the, "[Office of the Secretary] had major concerns about your doing these activities. I pushed back, and they eventually deferred to my call. I know I have said this before, but you should be extremely careful about any of your outside activities....There is also the possibility that the opposing attorneys may also cry 'foul' and write the Secretary or a member about why you were allowed to serve as an expert witness."

On November 17, 2005, the early concerns by many staff members were realized. In an email to you, Dr. Zerhouni, the Deputy Director of NIH wrote, "We have received a FOIA request re David's outside activity as expert witness in a case, apparently from an opposing counsel who wants to know more about how the director of NIEHS can testify against his client." You responded hours later, "Wow. Your powers of prediction are amazing!" The Deputy Director at the NIH then replied, "I am surprised it happened this fast."

In light of this series of events, please respond to the following questions:

1. Was Dr. Schwartz compensated for his outside activities with laws firms while employed

at NIEHS? If so, please provide all documents, records, and communications regarding Dr. Schwartz's compensation for any outside activities.

2. Provide a copy of the NIH policy allowing employees to testify in court cases, including modifications, and deletions for the period between January 1, 2003 to the present.
3. Did Dr. Schwartz comply with all applicable policies and procedures with regard to his outside activities? If yes, please so state. If not, please discuss in detail the corrective action taken.
4. Please identify by name and position all NIH employees who have engaged in outside activities with law firms for the period between January 1, 2003, to the present.

FINDINGS FROM THE OFFICE OF MANAGEMENT ASSESSEMENT

A. Limousine rental

A recent OMA report on alleged mismanagement at NIEHS raised questions about the actions of Dr. Schwartz. According to the OMA report, in September 2005, Dr. Schwartz used a limousine service to drive himself from the NIEHS in Research Triangle Park, NC, to a meeting in Washington, DC. The car was hired because none of the available flights allegedly "fit" into Dr. Schwartz's itinerary. The limousine service cost \$780 with a \$156 tip, making the total car fare \$936.

1. Please explain how often Dr. Schwartz and/or other NIEHS officials used a car service/limousine for long-distance travel from January 1, 2003 to the present. Please provide receipts for such travel.
2. Please explain what corrective action, if any, was taken in light of this finding with the regard to Director Schwartz and/or others if applicable.
3. Please provide a copy of all pertinent NIEHS travel policies, including changes and modifications, which have been effective since January 1, 2003.

B. Subordinates used for personal purposes

The OMA report also identified three instances in which NIEHS employees and a contractor drove the Director's car to a dealership for service and to the airport so he would have the car when he returned from a business trip. According to the OMA report, three employees were found to have spent 40 minutes each transporting Dr. Schwartz's car to a dealership in Chapel Hill, NC. In the OMA report, an ethics officer stated that "it is likely that Dr. Schwartz misused the authority associated with his public office for his own private gain and misused his subordinate's time."

1. Please explain what corrective action, if any, was taken in light of this finding and please

apprise me of any allegations that such activities are still occurring.

2. Have there been other allegations from January 1, 2003 to the present where Directors at any other NIH institute/center misused their authority for personal gain? If so, please elaborate.

C. Personal decorations

According to the OMA report, Dr. Schwartz had 16 personal items framed for his office for a total of \$2,000 in expenses. In an expert opinion, a contracting officer stated that the NIEHS Director "should have known these items were personal in nature and should be held responsible for reimbursing the government." The OMA also recommended that Dr. Schwartz reimburse the government for framing the items, which included his high school diploma, college diploma, medical degree, numerous medical certificates, and various pictures.

1. Did the Director reimburse the government for the full \$2,000, and if not, why not?
2. Please describe in detail any other corrective actions taken at the NIH to ensure that Director Schwartz, as well as other Directors understand the appropriate protocol with regard to spending government funds for personal purposes.

TIES TO DUKE UNIVERSITY

It is vitally important that NIH executives and directors of the institutes/centers be seen as impartial in awarding grants or engaging in collaborations with any particular university or researcher. Dr. Schwartz assumed the directorship of the NIEHS without giving up his tenured position at Duke University. Emails reviewed by the Committee show that Dr. Schwartz was warned multiple times about avoiding conflicts of interest with Duke. A draft of his ethics agreement that was provided to the Committee reads, "You will be on a leave of absence from Duke University, and as such, for purposes of the criminal conflict of interest statute, 18 U.S.C. 208, you are an employee of Duke University and must not participate in specific party matters that that (sic) will directly and predictably affect Duke's financial interests unless a waiver is granted to allow such participation."

However, emails show that Dr. Schwartz's connections to Duke were a concern for ethics officers and other NIH personnel. Eventually, nearly a dozen Duke researchers had to return to the University because of concerns over conflicts. In fact, the lab itself was forced to close down temporarily.

A careful review of the material provided to the Committee demonstrates that as Dr. Schwartz began seeking waivers to transfer students and staff from his Duke lab to NIH facilities in 2005, one ethics officer warned the Deputy Director of the NIH in a December 15, 2005, email: "He's suppose (sic) to be recused from Duke. Exceptions are swallowing the rule." NIH Deputy Director for Extramural Research sent an email to Dr. Schwartz that again emphasized the need to avoid such entanglements. On January 26, 2006, an ethics officer wrote in an email to Dr. Schwartz, "You must recuse yourself from all matters that are under discussion or that will impact any institution with which you are collaborating."

Yet on November 29, 2006, Dr. Schwartz sent an email to the Deputy Director of the NIH stating that he was a co-investigator on two grants with Duke researchers. In response, an ethics office wrote that the researchers for both "referenced grants are Duke researcher (sic) (no waiver on file or even pending), and neither of these grants is the grant I showed you earlier today...."

On December 1, 2006, Dr. Schwartz sent an email to the Deputy Director of the NIH listing all the employees in his lab. He wrote, "Attached is a list of the personnel in my lab - divided by NIEHS employees and Duke employees." The attached list contains the names of 14 Duke researchers.

On December 15, 2006, another NIH employee sent an email that identified two pending NIH grants by Duke researchers listing Dr. Schwartz as a collaborator. Notes regarding a grant for one Duke researcher read "I have asked Dr. [redacted] to have pending application reviewed quietly to see if removal of the participation of Dr. Schwartz would require a major restructuring..."

On January 9, 2007, the former NIEHS Scientific Director lodged a complaint stating that he did not know that Dr. Schwartz had four waivers for Duke employees and that numerous Duke researchers had been brought to the NIEHS. That same day an ethics officer sent an email to NIH's Deputy Director stating, "NIH determined that waiver only permitted [David Schwartz's] collaboration with these researchers; not their appointments in his lab." She then listed several Duke researchers that would have to leave Dr. Schwartz's lab and several collaborations for which he had no waiver.

On January 25, 2007, the NIH Deputy Director sent an email asking "In anticipation of having to ask some or all of the Duke folks currently working in David's lab to return to Duke, I would like for you to send me copies of all of the documents/agreements (and I am just assuming that such agreements exist) that set the terms of their 'guest' appointments at NIEHS."

On February 1, 2007, the NIH Deputy Director sent an email announcing that Dr. Schwartz was stepping down from his lab. That same day, another high ranking researcher at the NIH sent an email to the NIH Deputy Director and others at NIH stating, "I suggest that we be totally transparent regarding to (sic) what happened. I say this because this is what I feel and because it will become known, sooner or later, and I do not want to be pa (sic) of a 'cover-up'."

On February 12 and 13, several executives at NIH including the Deputy Director and the Director for Extramural Funding discussed contacting Duke officials to get all the protocols at Duke that involved Dr. Schwartz. The Deputy Director wrote, "Perhaps (deleted) could call the contact in the Dean's office and ask for this information to be discreetly obtained for us?" The Director for Extramural Funding responded, "Discreet would be the operative word." An ethics officer wrote, "Sure. Who has the name and number of the contact person?"

On March 13, 2007, an ethics officer sent an email stating, "The new hirers (sic) (former Duke employees) would have a one year (regulatory) cooling off period from Duke matters but

that could be allowed with an authorization. Once the 'de-Duking' process is complete, the number of Duke projects/personnel in the lab will be very low, if any."

On April 5, 2007, the Deputy Director sent an email stating, "Your summary hit the major points. I think that for this matter, DAS will remain recused for the full 1-year cooling-off period following his resignation from Duke."

In light of the issues raised in these emails, I have questions about NIH's handling of the conflicts of interest involving Dr. Schwartz and Duke University. NIH officials were still confused about the financial arrangements for the Duke researchers in Dr. Schwartz's lab as late as January 2007, many months after those researchers had begun work in the Director's lab.

1. How many times has NIH permitted new employees to maintain their tenure with a former university for the period between January 1, 2003 to the present? For each situation identified please note the name, position and affiliation of the individual.
2. Did Dr. Schwartz comply with all of the applicable policies and procedures for bringing guest researchers to the NIH? If yes or if not, please elaborate in detail.
3. Why, in discussing Duke's conflicts of interest, did an NIH staff member write in an email to the Deputy Director of the NIH "I just think it's unfair for good and decent people (sic) to take a fall for those wh (sic) don't have a strong moral center." To whom was this NIH staff member referring?
4. Please provide a list of all people affiliated with Duke considered "guest researchers" and explain how each of those researchers were funded.
5. Has your office received similar complaints of conflicts of interest regarding the Directors at other NIH Institutes or Centers from January 1, 2003, to the present? If so, please provide copies of those complaints, as well as documents and communications involving investigation of the complaint as well as any corrective action responding to the complaint.

DISCREPANCIES BETWEEN OMA REPORT AND EMAILS

The OMA also reviewed numerous other allegations, including the following: "Did the NIEHS inappropriately provide office space to Duke University and World Health Organization staff?" The OMA concluded that the NIEHS did not.

In light of the concerns raised by NIH ethics officers and senior management about the Duke researchers and the eventual decision to send almost a dozen Duke researchers back to the university, this conclusion is difficult to understand. Evidence from the emails and documents provided to the Committee, as well as conversations with current and former NIH staff, raise questions about the integrity and independence of the OMA office and its investigations. Accordingly, please respond to the following questions:

1. Please provide all supporting documents, records, and communications found by the

OMA regarding its investigation of funding for Duke researchers at NIEHS.

2. Please identify the individual(s) who approved the OMA advisory report, including any drafts of the report, as well as any communications and/or documents regarding the report.
3. Please explain why the review did not capture the concerns as expressed in emails detailed above.
4. Please provide the Committee with all OMA reports for the period of January 1, 2003 through the present.

NIH PROCESS ON RESPONDING TO CONGRESSIONAL INQUIRIES

I am greatly concerned that our request for information contained only a single email from you, even though our request covered a span of about two years. In addition, there is a gap between April 2006 and October 2006 in the emails we received. This is a seven month gap in our document request. Dr. Zerhouni, please provide written confirmation to me that we have received all communications, records and/or documents as requested in our original letter.

In closing, I look forward to hearing from you regarding the questions set forth in this letter by no later than July 10, 2007, in accordance with the attached definitions and general instructions.

Sincerely,

Chuck Grassley
United States Senator
Ranking Member of the Committee on Finance