



<http://finance.senate.gov>
Press_Office@finance-rep.senate.gov

For Immediate Release
Monday, July 30, 2007

Grassley seeks more information about problems at NIH

WASHINGTON - Sen. Chuck Grassley is broadening his inquiry into allegations of mismanagement at the National Institutes of Environmental Health Sciences, one of the 27 institutes and centers of the National Institutes of Health.

“We need to attract and keep the best minds for government research, but we can’t do it at the expense of high ethical standards and fidelity to the public good,” Grassley said. “It’s hard to see how making thousands of dollars to testify in court cases advances the interest of the American taxpayer.”

The senator has ongoing reviews of several agencies whose medical research and use of public funds help to advance public welfare. He is 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.

July 25, 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" or "the Institute"). 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.

First, I would like to thank you for cooperating with this inquiry regarding allegations of mismanagement at the National Institute of Environmental Health Sciences (NIEHS or Institute). I also appreciate the sworn congressional testimony you gave on June 22, 2004 regarding conflicts of interest at NIH. During that oversight hearing, you stated that, "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 Committee has received additional information that requires me to broaden my inquiry and request additional documentation. My investigators have had discussions with several NIH employees who have voiced concerns and provided documents regarding actions by Dr. David Schwartz, Director of NIEHS.

You are probably unaware of the fact that a number of employees at NIEHS are unhappy with the leadership of Dr. Schwartz, and morale at the Institute appears to be less than stellar. This assessment is based upon individuals currently employed by NIEHS. One employee, who spoke confidentially with my investigators, likened Dr. Schwartz's behavior at the Institute to that of "a child in a candy store." Several other employees told my investigators that Dr. Schwartz has brought pressure on subordinates to engage in behavior that they perceived as unethical.

Due to the specificity of certain questions and documents being requested, I ask that Dr. David Schwartz, Joyce Martin, Dr. William Martin, Marc Hollander, and others from the NIEHS Office of the Director be recused from participating either directly or indirectly in gathering responses to my inquiries, other than supplying documents. To further ensure the integrity of this inquiry, please: (1) identify the individual(s) at NIEHS responsible for supervising the coordination of this request for information and (2) please ensure that the documents they gather remain under their custody and control at all times until they are delivered to NIH.

I am also requesting that you provide additional responses to the Committee regarding NIEHS. For all questions identified in this letter, please be sure to repeat the enumerated question and then have it followed by the accompanying response.

A. EXCESSIVE SPENDING ON PERSONAL LAB

Documents provided to the Committee show that Dr. Schwartz exceeded his budget and tapped into the Institute's intramural budget and other revenue streams to fund his own research. This re-direction of resources could have a detrimental impact on other NIEHS investigators, who may have lost funding for their own projects.

In the Memorandum of Understanding (MOU) given to Dr. Schwartz, he agreed to spend

\$1.8 million of the NIEHS budget on his own laboratory. However, on November 2, 2006, the NIH Director of Extramural Research sent Dr. Schwartz an email stating, "I've become aware that you have budget requests above the \$1.8 million in the MOU that established your intramural lab at NIEHS...."

Based upon inquiries made to date, the Committee learned that the budget over-run by Dr. Schwartz may have exceeded the budget for his personal lab by millions of dollars. A slide show presentation prepared on March 16, 2007 for Dr. Schwartz's lab gives the Committee some idea of how much money was spent. For example, one slide reads, "Challenge - Get Dr. Schwartz's lab budget within \$1.82 M per year allocation?" A spreadsheet that accompanied the presentation shows that the operating expenses for Dr. Schwartz's intramural lab for FY2006 were \$5,982,488. The estimate for FY2007 was \$2,650,982 and the estimate for "FY2008 (right-sized)" was \$1,818,049. In light of this information, I am confident that you understand my concern.

In addition, Science Magazine (Science) reported that in relation to other institute leaders, Dr. Schwartz's "supersized" lab had 26 people at one time. However, expired NIEHS web pages of Dr. Schwartz's lab showed that he had up to 33 people in his lab. This is well over twice the size of the labs of other NIH institute leaders, such as Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases. Science reported that he has 15 people in his lab.

In this same Science article, NIH Deputy Director Raynard Kington attributed the cost over-run to a, "mistaken assumption that [Schwartz's] group would not be charged for using the NIEHS core facilities." However, my investigators have acquired evidence suggesting that core facility charges were not the reason that Dr. Schwartz's lab ballooned in cost. According to documents provided to the Committee, we learned that Dr. Schwartz transferred over \$1 million from his Office of Director account to buy supplies for his personal lab.

Certainly, people must be perplexed at how Dr. Schwartz was able to find an extra \$4 million to fund his personal lab. Indeed, my investigators have spoken to both current and former employees of the Institute who say that they have not been allowed to exceed their lab budgets. Accordingly, please respond to the following questions regarding Dr. Schwartz's expenditures on his personal lab:

1. Where and how did Dr. Schwartz obtain an extra \$4 million to fund his lab for FY 2006? Please provide an itemized account of all monies that went into Dr. Schwartz's lab and include the various accounts from which the money came for FY 2006 and FY 2007.
2. By using Institute money for his lab, did Dr. Schwartz deny other NIEHS scientists the ability to support their own research? Please describe NIH's checks and balances system for ensuring that a director does not take a disproportionate share of Institute money for personal research. If no such system exists, please so state.
3. Has there been any disciplinary action initiated or taken against Dr. Schwartz for alleged breaches of his MOU on financial support for his lab?
4. Please advise the Committee whether or not Dr. David Schwartz was recruited and hired according to all applicable policies and procedures used by NIH.

5. The Committee learned that one of the researchers who may have suffered a funding cut to provide monies for Dr. Schwartz is Ms. Retha Newbold. Please provide the Committee with documents and/or communications regarding the funding of work by Ms. Retha Newbold. Please include copies of her annual reviews and/or performance reviews from 2004 to the present.

B. DR. SCHWARTZ'S TESTIMONY IN ASBESTOS CASES

In August 2005, several NIH officials were troubled that Dr. Schwartz should be allowed to testify in court cases. In one instance, 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."

The Committee acquired several depositions of Dr. Schwartz, which show that the concerns voiced internally merited further review. In fact, even before Dr. Schwartz assumed leadership at the Institute, trial attorneys began highlighting his future connection to NIH. It seems apparent that these lawyers intended to repeatedly remind the court and others of Dr. Schwartz's leadership position at NIEHS perhaps in order to increase his credibility and help influence the case. The following is a portion of the testimony given by Dr. Schwartz on an asbestos matter on February 24, 2005. Note how the lawyer repeatedly telegraphs to readers the position that Dr. Schwartz has within the NIH:

12 Q Now, I guess I should have started by letting the
13 ladies and gentlemen of the jury know why you're here on the
14 videotape at Duke University, or right here by Duke rather
15 than coming to a courtroom in the state of Texas and talking
16 to them in person.

17 Would you tell the ladies and gentlemen of the
18 jury why you're not going to be able to get away and come to
19 Texas and talk to them in person.

20 A In April of 2005, in about a month, I'll become
21 the director of an institute at the NIH, the National
22 Institute of Environmental Health Sciences. And as director
23 of the Institute of Environmental Health Sciences, I'll be
24 very busy. This is one of the major institutes within the
25 National Institutes of Health. There are only 19 institutes
0013

1 in the National Institutes of Health, and I'll be directing
2 one of them. It will be a very demanding schedule and I
3 just simply won't have the time to come to Texas.

4 Q If you'd like to, if you weren't heading up one of
5 the major institutes of the National Institutes of Health,
6 specifically in the environmental health sciences division
7 and getting ready to go there right now, would you like to
8 come and talk to the ladies and gentlemen of the jury in
9 person?

10 MS. MCALISTER: Objection to form.

11 A I'd be happy to.

12 Q Okay. What are some of the -- so the ladies and
13 gentlemen of the jury understand -- the impact of that
14 position, the National Institutes of Health, could you tell
15 them what the National Institutes of Health, Environmental
16 Health Sciences Institute does, and what are some of the
17 other major institutes within that organization that the
18 jury might have heard of.

19 A The National Institutes of Health is the largest
20 research institute around the world that focuses on human
21 health. And the basic mission of the National Institutes of
22 Health or the NIH is to do research to improve human health
23 and understand human disease.

24 And so the way the NIH is --
25 (Telephone interruption.)

1 (Discussion off stenographic record.)

2 (Pause.)

3 THE VIDEOGRAPHER: Stand by. We're off the record
4 at 9:39 a.m.

5 (Discussion off the record.)

6 THE VIDEOGRAPHER: Stand by. We're back on the
7 record. The time is 9:43 a.m.

8 Q All right. Doctor, before the phone rang, you
9 were describing the National Institutes of Health. If you
10 can go ahead and continue that answer.

11 A The -- so the National Institutes of Health is
12 part of the Department of Health and Human Services. And
13 its budget is about \$29 billion each year. It's a major
14 part of the federal government.

15 The way the National Institutes of Health are
16 organized, is they're organized by institute. And there are
17 19 institutes and nine centers within the National
18 Institutes of Health.

19 The 19 institutes focus on different diseases or
20 different types of major problems that Americans face that
21 cause disease.

22 So the institutes that you might be familiar with
23 are the National Cancer Institute, is one of the National
24 Institutes of Health; the National Heart, Lung and Blood
25 Institute is another institute of a health within the NIH;

0015

1 the National Institute of Allergy and Infectious Diseases is
2 another institute within the NIH.

3 There are variety of institutes, and one of the

4 institutes is the National Institute of Environmental Health
5 Sciences, which I'll be directing in April of 2005.

6 The National Institutes of Environmental Health
7 Sciences focuses on trying to understand how environmental
8 exposures are affecting human health and how environmental
9 exposures cause disease as a way of trying to prevent
10 disease development and as a way of trying to understand
11 disease mechanisms that could lead to new treatments and
12 prevention of disease among persons.

13 Q Dr. Schwartz, thank you for that description. We
14 appreciate you taking on the responsibility of heading up
15 the Environmental Health Sciences Institute for the National
16 Institutes of Health. We really do.

Later in the deposition, Dr. Schwartz and the lawyer continued:

17 A Yes, it is. I have a number of other articles
18 that were requested as either editorials or reviews and then
19 several book chapters as well.

20 Q You've got some -- even some papers that are out
21 being reviewed by people that will still hit the medical and
22 scientific literature while you're with the National
23 Institutes of Health; don't you?

24 A Oh, yes. Yeah. I'll be continuing to have -- at
25 the NIH, National Institutes of Health, I'll continue to
0033

1 have an active laboratory and will continue to publish.

2 Q Now, in addition to submitting articles to
3 journals to have them reviewed and criticized and, you know,
4 held up to scrutiny before they get published, have you also
5 served on the boards of those editors to review other
6 papers?

7 A I have.

8 Q And do you sit today on any editorial boards that
9 goes through this process of reviewing medical and
10 scientific literature to make sure it's scientifically sound
11 and consistent with conservative principles of science and
12 medicine?

13 A I do. I believe I sit on two editorial boards,
14 one in the American Thoracic Society, the American Journal
15 of Respiratory and Cell Biology, and another at -- that's
16 part of the NIH, a journal called Environmental Health
17 Perspectives.

In another deposition on March 24, 2005, a lawyer once again felt the need to continually remind readers of Dr. Schwartz's position with the federal government.

6. Q. All right. Now, let me kind of switch gears
7 just a moment with you and ask you a little bit about your
8 appointment with the National Institute of Health.

9 As I understand it, Dr. Schwartz, that
10 appointment begins sometime soon, is that correct?

11 A. Yes.

12 Q. What date does it begin?

13 A. April 11th.

14 Q. And as of April 11, your title, if you will,
15 with the NIH will be what?

16 A. The Director of the National Institutes of
17 Environmental Health Sciences.

18 Q. And will that appointment with the United States
19 Government keep you here in the Durham/Raleigh area?

20 A. Yes.

21 Q. You don't have to move to Washington, D.C.?

22 A. No, I don't.

23 Q. Well good. Good for you.

24 As of April 11, 2005, what, if any, is your
25 relationship with Duke University going to be?

1 A. I am going to continue to see patients two
2 afternoons a month. And I am going to continue to
3 collaborate with investigators at Duke. But I'm going to
4 take a leave of absence from my appointment at Duke.

5 Q. With respect to conducting independent medical
6 evaluations for plaintiff's firms like Mr. Chandler's or
7 others, either in the State of Texas or anywhere else for
8 that matter, as of April 11, will you be conducting any of
9 those exams in the State of Texas?

10 A. I don't have any plans to.

11 Q. Well, is there any prohibition for you as a
12 director of NIH, Environmental Health Division from doing
13 those types of exams as of the time you go on to NIH?

14 A. I don't know the answer to that. It's a very
15 demanding job that I will be undertaking, and I don't
16 think that I am going to have the time to do it.

17 Q. Irrespective of whether or not you are going to
18 have time to do it, does the NIH have a restriction on
19 individuals such as yourself that have appointments with
20 them to restrict or have another consulting type of roles,
21 such as conducting medical examinations for plaintiff's
22 lawyers for lawsuits?

23 A. I don't think that they do restrict that.

24 Q. Have you checked into that?

25 A. I haven't, just because I don't plan to do it.

In testimony on January 23, 2006, in the Superior Court of California in San Francisco County, lawyers could not refrain from mentioning Dr. Schwartz's job as Director of NIEHS:

7 Q. Since you've joined the NIH, do you still maintain your
8 affiliation with Duke University?

9 A. Yes. In fact, it's because I enjoy teaching so much. I see
10 patients there two afternoons a month, the first and the third
11 Friday of every month. And I see patients with the pulmonary
12 fellows.

13 So the pulmonary fellows see the patients, they present them
14 to me, we go examine the patient together, and then we discuss
15 the case.

In another bit of testimony that same day, Dr. Schwartz and the lawyer continued:

10 Q. All right. And you also talked about you were -- Mr. --
11 Mr. Brady, you were convinced that he had mesothelioma.

12 Isn't it true that your employer is the one that made the
13 diagnosis of mesothelioma, the NIH?

14 A. They were one of the physicians that contributed to the
15 diagnosis of mesothelioma, yes.

16 Q. Okay. Washington Hospital had this differential diagnosis.
17 Then your employer said, "Well, we think it probably is
18 mesothelioma."

19 A. That's correct. And -- And the treating oncologist, as well
20 as the radiation oncologist that were local physicians concurred
21 with that diagnosis.

Dr. Schwartz also explained, during his testimony that he was charging \$500 an hour to give these depositions, not including expenses for travel, lodging, and meals. For court testimony, he said that he charged \$600 an hour.

In light of the information set forth above regarding Dr. Schwartz and his outside activities, please respond to the following questions:

1. Do you think that these exchanges between Dr. Schwartz and trial lawyers where his position as the Director of NIEHS was repeatedly emphasized led to "trading on the reputation of the NIH?" Please provide a detailed response to this question.

C. INTEGRITY OF PROCESS FOR EXTRAMURAL FUNDING

Based upon information provided to the Committee since our last letter, we have broadened our concerns regarding David Schwartz's possible conflicts of interest. Based on

information reviewed by the Committee, it is apparent that some in NIH also have concerns.

For instance, in October 2005, an NIH ethics officer wrote the following email about Dr. Schwartz's outside activities: "It seems he does not view himself as the director of a very broad program... These seem to be other examples of where he is not even looking at the rules, but rather just trying slip a few by us."

Employees at NIEHS told Committee investigators, and provided documentation to support their allegations, that Dr. Schwartz may have disregarded established internal policies and procedures during the approval process for extramural grants at NIEHS.

For example, Dr. Schwartz has multiple outside collaborations. It is my understanding that Dr. Schwartz is supposed to recuse himself from approving/disapproving grants for which he has a conflict of interest. However, after speaking to NIEHS employees, it appears that Dr. Schwartz may not have followed appropriate policy on this matter. According to typical protocol, after NIEHS collects all grant proposals, a review committee of experts scores the grants applicants. The director of extramural funding then prepares a slate of potential grantees and their priority scores for funding. This slate is presented eventually to an advisory committee or council.

In light of the information set forth above regarding Dr. Schwartz and his activities please respond to the following questions:

1. Please provide the Committee with the slate of potential NIEHS grantees that NIEHS Extramural Affairs generated from June 2005 to June of 2007. NIEHS Extramural Affairs generates these slates which list the grants and priority scores from the peer-review committees. Also, please provide a record of the advisory committee/council meeting discussions which would have discussed these slates.
2. The Committee is interested in understanding which grants were eventually funded. Please provide the Committee with the NIEHS Director's reports which describe grants that were funded. The time span for this request is June 2005 to June 2007.
3. Please provide the Committee with any communications and/or records regarding Dr. Schwartz's conflicts of interest and extramural funding, including any and all third party reports.

D. HIRING PRACTICES AT THE NIEHS

We have received numerous allegations and supporting information regarding inappropriate hiring practices conducted by David Schwartz and the NIEHS Office of the Director. From the information we have received, it appears that Dr. Schwartz and/or officials in the Office of the Director at NIEHS may have circumvented normal hiring practices with regard to Dr. William Martin, Director of the Office of Translational Research and his wife, Joyce Martin, Director of the Office of Science Policy.

In light of the information set forth above, please respond to the following questions:

1. Please provide any communications and documents regarding the hiring and/or recruiting

of Dr. William Martin and/or Joyce Martin, including any employment or personnel records signed by either individual.

2. Please provide all documents and communications in relation to the positions now held by Dr. William Martin and Joyce Martin, to include resumes of applicants for the positions, communications between NIEHS and these applicants, and the posting of the position.

3. Please provide any documents and/or communications regarding conflicts of interest and waivers for outside activity(ies) for Dr. and Ms. Martin.

E. ETHICS DOCUMENTS SIGNED BY DR. SCHWARTZ

Numerous employees at NIEHS told Committee investigators that Dr. Schwartz seems less interested in ethics than in getting what he wants. However, the Federal Times reported on July 29 that Dr. Schwartz felt that "NIH should conduct more thorough ethics training with employees new to the federal government." He also said, "I think that the solution involves establishing very clear expectations and also orienting individuals in a way that they fully understand the ethics guidelines and ethics standards at the NIH that may be different from where they are coming from. I did not receive any sort of orientation on the ethics guidelines."

In light of the information above, please respond to the following questions.

1. Please provide the Committee with documentation of any ethics package and/or training that Dr. Schwartz received including communications regarding his ethics and/or ethics training.

2. Since Dr. Schwartz became director of the Institute, who has been his Deputy Ethics Officer? Please provide dates for which any individual has served as the Deputy Ethics Officer for NIEHS from June 2005 through June 2007.

3. We have also received credible information that Dr. Schwartz attempted to have his wife travel with him on official duties, possibly as a contractor/consultant for the NIH. Please provide the Committee with any documents and/or communications regarding travel and/or the hiring of Louise Sparks, from June 2005 to the present.

In closing, I look forward to hearing from you regarding the questions set forth in this letter by no later than August 8, 2007, in accordance with the attached definitions. If you have any questions, please do not hesitate to contact Angela Choy or Paul Thacker at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to thomas_novelli@finance-rep.senate.gov.