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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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June 21, 2005

Via Facsimile: (301) 496-0840

Original via USPS Mail

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

Dear Director Zerhouni:

Pursuant to our authority under the Constitution and the Rules of the United States Senate and as Chairman and Ranking Member of the Committee on Finance (Committee), we are conducting a review of allegations involving the National Institutes of Health (NIH), the National Institute of Allergy and Infectious Diseases (NIAID), Division of Acquired Immunodeficiency Syndrome (DAIDS).

Last July, Dr. Jonathan Fishbein, former director of DAIDS's Office for Policy in Clinical Research Operations (OPCRO), brought allegations of scientific and employee misconduct to the attention of the Committee. Thank you for briefing our Committee staff on June 9, 2005, on the status of NIH's review of these allegations.

According to Dr. Fishbein, the NIH recruited him in July 2003 because of his experience with clinical trials to ensure that DAIDS-sponsored clinical research is in compliance with applicable regulations and good clinical practice and meets established standards of quality, integrity, and ethics. He was removed from his position as director of OPCRO on April 7, 2004, and has been on administrative leave since August 7, 2004. We are bringing to your attention some issues related to Dr. Fishbein's removal that we find disturbing. Attached for your consideration are some relevant source documents for the allegations and issues discussed in this letter.

According to NIH staff, the NIH initiated action against Dr. Fishbein because of his poor performance. Dr. Edmund Tramont, director of DAIDS, and Dr. Jonathan Kagan, deputy director of DAIDS, allegedly received negative feedback from other NIH staff regarding Dr. Fishbein in the months preceding the decision to initiate action against

Dr. Fishbein. However, and as an initial matter, there was no documentation of Dr. Fishbein's poor performance prior to his mid-year performance evaluation in late February 2004 and the issuance of the memorandum of termination in April 2004. (See Attachments 1 and 2). Furthermore, documentation of negative feedback from other NIH staff occurred after Dr. Fishbein filed his complaint in April 2004 with NIH's Office of Equal Employment Opportunity and Diversity Management (OEEODM). In addition, none of the documents obtained by the Committee to date show that Dr. Tramont, Dr. Fishbein's immediate supervisor, discussed such feedback with Dr. Fishbein or criticized Dr. Fishbein's job performance in their one-on-one meetings. An e-mail message from Dr. Tramont to Dr. Fishbein dated February 14, 2004, stated that he had not heard a single complaint regarding OPCRO since Dr. Fishbein's arrival and the reason for that was the change brought by Dr. Fishbein. (See Attachment 3). The following week Dr. Fishbein received a scathing mid-year evaluation from Dr. Kagan, and Dr. Tramont initiated the process necessary for terminating Dr. Fishbein. Specifically, Dr. Tramont issued a memorandum of termination on April 7, 2004, about six weeks after Dr. Kagan informed Dr. Fishbein that he would now be his direct supervisor and about nine weeks after Dr. Fishbein complained to Dr. Tramont regarding Dr. Kagan.

What we find particularly troubling is that the individuals included in Dr. Fishbein's allegations, i.e., Drs. Kagan and Tramont, were the same individuals responsible for preparing the justification for terminating Dr. Fishbein's employment with the NIH. In an e-mail to Dr. Kagan dated February 23, 2004, Dr. Tramont said, "Let's start working on this – Tony [Fauci] will not want anything to come back to us, so we are going to have to have ironclad documentation,... In Clauswitzian style, we must overwhelm with 'force'." (See Attachment 4).

Additional documents and information provided to and obtained by the Committee to date raise questions about the events associated with the removal of Dr. Fishbein as director of OPCRO. Dr. Fishbein asserts that he was told, unexpectedly, that his employment would be terminated because he had complained to Dr. Tramont about the inappropriate and unprofessional conduct of Dr. Kagan and acted on his concerns regarding the conduct of DAIDS-sponsored clinical research. Interestingly, it appears that only after Dr. Fishbein complained about Dr. Kagan to Dr. Tramont in early February 2004 was Dr. Kagan given supervisory responsibility for Dr. Fishbein.

Documents available to the Committee show that on February 4, 2004, Dr. Fishbein sent Dr. Tramont a letter reiterating his allegations that Dr. Kagan was creating a hostile work environment for him and his staff and requesting that Dr. Tramont address the problems highlighted in his letter. For example, Dr. Fishbein alleged that Dr. Kagan intimidated him and his staff through written and verbal communications and imposed his ideas on OPCRO. (See Attachment 5). A recent statement taken during the deposition of Dr. Mary Anne Luzar, chief of DAIDS's Regulatory Affairs Branch, corroborates allegations of Dr. Kagan's unprofessional conduct. Less than two weeks after Dr. Fishbein's complaint to Dr. Tramont regarding Dr. Kagan's behavior, Dr. Kagan inquired about terminating Dr. Fishbein and requested that the recommendation for a

\$2500 award be withdrawn. (See Attachment 6). Perhaps Dr. Kagan recognized the inconsistency of firing an employee for poor performance and giving that employee a performance award. This raises a couple of questions: (1) If Dr. Fishbein's job performance was so poor, why was he recommended for the award? and (2) If his performance was not poor and merited the award, why did Dr. Kagan want to terminate him?

In addition, while e-mails from Dr. Kagan to Dr. Fishbein show that Dr. Kagan had offered advice and feedback to Dr. Fishbein regarding Dr. Fishbein's interactions, or lack thereof, with DAIDS staff and others outside OPCRO, throughout most of Dr. Fishbein's tenure as director of OPCRO, Dr. Kagan also sent messages expressing his support and satisfaction with Dr. Fishbein's work. (See Attachments 7-15). For example, in an e-mail dated July 8, 2003, Dr. Kagan defended Dr. Fishbein to Dr. Tramont, stating that Dr. Fishbein is "good at what he does. Better than anyone at DAIDS, ...including you. This is why we brought him on." (See Attachment 16). Furthermore, Dr. Fishbein was recognized for his accomplishments. In November 2003, he received a certificate of appreciation from NIAID. (See Attachment 17). A recent statement from the deposition of Dr. Jacklyn Burns, deputy director of OPCRO, corroborates the list of OPCRO accomplishments under Dr. Fishbein's leadership. (See Attachment 18).

A series of e-mail communications also show that Dr. Fishbein opposed actions taken by Drs. Tramont and/or Kagan, prior to his termination. For example, Dr. Fishbein claims that he was instructed to reprimand Dr. Luzar for submitting an "erroneous" IND safety report related to a DAIDS-sponsored perinatal HIV prevention trial (HIVNET 012) without consulting the study's medical officer as required by DAIDS's standard operating procedures.¹ However, he disagreed with the decision to reprimand Dr. Luzar. Dr. Fishbein states in an e-mail message that it was his impression that Dr. Luzar was vindicated, and he urged Drs. Tramont and Kagan not to take disciplinary action against Dr. Luzar. (See Attachments 19).

An e-mail message from Dr. Kagan to Dr. Tramont shows that Dr. Fishbein disagreed with Dr. Tramont regarding the re-opening of clinics in Kampala, Uganda. Dr. Kagan tells Dr. Tramont that Dr. Fishbein should have the opportunity to determine whether or not deficiencies at the sites had been corrected before the sites are re-opened. (See Attachment 16). Dr. Fishbein also alleges that the NIH tried to withhold filing of a safety report on the death of a pregnant HIV-positive woman from Memphis, Tennessee, who was enrolled in an NIH-funded clinical trial testing a drug therapy that included the use of an HIV/AIDS drug called nevirapine.

Finally, the decision to terminate Dr. Fishbein may also be related to a letter that he sent to the executive committee of ESPRIT, a DAIDS-sponsored clinical trial using technology, which was invented by the director and deputy director of NIAID, for

¹Dr. Fishbein also raised allegations of misconduct involving a high level NIH official and HIVNET 012 after he was informed by Dr. Kagan that his employment with the NIH would be terminated.

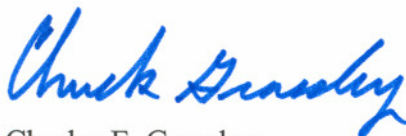
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administering the study drug, interleukin-2 (IL-2). Several e-mail communications suggest that Drs. Kagan and Tramont decided to terminate Dr. Fishbein soon after Dr. Fishbein issued the letter, dated February 6, 2004. Dr. Fishbein's letter expressed his concern about delays in providing patients new safety information associated with the IL-2 and directed the executive committee to promptly update the study protocol and informed consent. (See Attachment 20). Specific risks allegedly associated with that trial include cardiac events, diabetes, and suicidal tendencies among HIV-infected individuals generally considered healthy because they have not yet exhibited any AIDS-defining illnesses. According to Dr. Luzar's statement, the "backlash to that letter was astounding." (See Attachment 21).

The aforementioned sequence of actions and events not only raises the appearance of retaliation against Dr. Fishbein, but also suggests broader, more systemic problems related to the management and functioning of DAIDS. In fact, your senior advisor concluded after her review of OEEODM's investigative report that "DAIDS is a troubled organization" and "the overall management of this Division needs careful review." (See Attachment 22). As Chairman and Ranking Member of the Committee, we request that the NIH keep our Committee staff apprised of any developments and actions related to Dr. Fishbein and his allegations and concerns regarding HIVNET 012 and ESPRIT as well as the operation of DAIDS. In particular, please state what actions the NIH has taken to date. We would appreciate being advised quarterly of this information beginning July 5, 2005.

Thank you for your attention to this important matter. We look forward to hearing from you regarding the issues, allegations, and questions set forth in this letter and would appreciate a timely response to our inquiries no later than July 5, 2005. Should you have any questions regarding this letter, please do not hesitate to contact our Committee staff, Angela Choy (majority) at (202) 224-4515 or David Schwartz (minority) at (202) 224-5315. All correspondence should be sent via facsimile to (202) 228-2131 (majority) and (202) 228-2316 (minority). All original material should be sent via USPS mail.

Sincerely,



Charles E. Grassley
Chairman



Max Baucus
Ranking Member