

U.S. Senate,

Committee on Finance,

Washington, DC, June 4, 2008.

Elias A. Zerhouni, M.D.

Director, National Institutes of Health,
Bethesda, Maryland.

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.

Over the past number of years, I have become increasingly concerned about the lack of oversight regarding conflicts of interest relating to the almost \$24 billion in annual extramural funds that are distributed by the NIH. In that regard, I would like to take this opportunity to notify you about five problems that have come to my attention on this matter.

First, it appears that three researchers failed to report in a timely, complete and accurate manner their outside income to Harvard University (Harvard) and Massachusetts General Hospital (MGH). By not reporting this income, it seems that they are placing Harvard and MGH in jeopardy of violating NIH regulations on conflicts of interest. I am attaching that letter for your review and consideration.

Second, I am requesting an update about a letter I sent you last October on problems with conflicts of interest and NIH extramural funding regarding Dr. Melissa DeBello at the University of Cincinnati (University). In that letter, I notified you that Dr. DeBello receives grants from the NIH, however, she was failing to report her outside income to her University.

Third, the Inspector General for the Department of Health and Human Services Office (HHS OIG) released a disturbing report last January which found that NIH provided almost no oversight of its extramural funds. But your staff seemed to show little interest in this report. In fact, Norka Ruiz Bravo, the NIH deputy director of extramural programs was quoted in The New York Times saying, "For us to try to manage directly the conflict-of-interest of an NIH

investigator would be not only inappropriate but pretty much impossible."

Fourth, I am dismayed to have read of funding provided to several researchers from the Foundation for Lung Cancer: Early Detection, Prevention & Treatment (Foundation). Dr. Claudia Henschke and Dr. David Yankelevitz are two of the Foundation's board members. As reported by The New York Times, the Foundation was funded almost entirely with monies from tobacco companies, and this funding was never fully disclosed. Monies from the Foundation were then used to support a study that appeared in The New England Journal of Medicine (NEJM) back in 2006 regarding the use of computer tomography screening to detect lung cancer. The NEJM disclosure states that the study was supported also by NIH grants held by Drs. Henschke and Yankelevitz.

Regarding the lack of transparency by Dr. Henschke and Dr. Yankelevitz, National Cancer Institute Director John Niederhuber told the Cancer Letter, "[W]e must always be transparent regarding any and all matters, real or perceived, which might call our scientific work into question."

The NEJM later published a clarification regarding its earlier article and a correction revealing that Dr. Henschke also received royalties for methods to assess tumors with imaging technology. There is no evidence that the Foundation's tobacco money or Dr. Henschke's royalties influenced her research. But I am concerned that the funding source and royalties may have not been disclosed when the NIH decided to fund Dr. Henschke.

Fifth, I sent you a letter on April 15, outlining my concerns about a report on the National Institute of Environmental Health Sciences (NIEHS). That report found 45 cases at the NIEHS where extramural grants had not receiving sufficient peer review scores but were still funded. This finding is yet another example that the NIH provides little oversight for its extramural program.

Dr. Zerhouni, you faced similar scandals back in 2003 when it came to light that many NIH intramural researchers enjoyed lucrative arrangements with pharmaceutical companies. It took you some time, but you eventually brought some transparency, reform and integrity back to NIH. As you told Congress during one hearing, "I have reached the conclusion that drastic changes are needed as a result of an intensive review by NIH of our ethics program, which included internal fact-finding as well as an external review by the Blue Ribbon Panel."

NIH oversight of the extramural program is lax and leaves people with nothing more than questions--\$24 billion worth of questions, to be exact. I am interested in understanding how you will address this issue. American taxpayers deserve nothing less.

In the interim, 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. Your responses should encompass the period of January 1, 2000 to April 1, 2008. I would appreciate receiving responses to the following questions by no later than June 18, 2008:

1. Please explain what actions the NIH has or will initiate to provide better oversight and transparency for its extramural funding program.
2. Please explain how often the NIH has investigated and/or taken action regarding a physician's failure to report a "significant financial interest," as defined by NIH regulation. For each investigation, please provide the following information:
 - a. Name of the Doctor(s) involved;
 - b. Date investigation began and the date ended;
 - c. Specific allegations which triggered investigation;
 - d. Findings of the investigation; and
 - e. Actions taken by the NIH, if any.
3. Since receiving notice that the University of Cincinnati was provided incomplete information from Dr. DelBello regarding her outside income, what steps has/will NIH take to address this issue? Please be specific.
4. Please provide a list of all NIH grants received by Dr. DelBello. For each grant, please provide the following:
 - a. Name of grant;
 - b. Topic of grant; and
 - c. Amount of funding for grant.
5. Please provide a list of any other interactions that Dr. DelBello has had with the NIH to include membership on advisory boards, peer review on grants, or the like.
6. Since reports appeared in the press regarding the undisclosed funding of the Foundation for Lung Cancer: Early Detection, Prevention & Treatment, what steps has/will NIH take to address this issue? Please provide all external and internal communications regarding this issue.
7. Please provide a list off all NIH grants received by Dr. Claudia Henschke. For each grant, please provide the following:
 - a. Name of grant;
 - b. Topic of grant; and
 - c. Amount of funding for grant.
8. Please provide a list of any other interactions that Dr. Henschke has had with the NIH to include membership on advisory boards, peer review on grants, or the like.
9. Please provide a list off all NIH grants received by Dr. David Yankelevitz. For each grant, please provide the following:

- a. Name of grant;
- b. Topic of grant; and
- c. Amount of funding for grant.

10. Please provide a list of any other interactions that Dr. Yankelevitz has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

11. Please provide a list off all NIH grants received by Dr. Joseph Biederman. For each grant, please provide the following:

- a. Name of grant;
- b. Topic of grant; and
- c. Amount of funding for grant.

12. Please provide a list of any other interactions that Dr. Biederman has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

13. Please provide a list off all NIH grants received by Dr. Timothy Wilens. For each grant, please provide the following:

- a. Name of grant;
- b. Topic of grant; and
- c. Amount of funding for grant.

14. Please provide a list of any other interactions that Dr. Wilens has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

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. If you have any questions please contact my Committee staff, Paul Thacker at (202) 224-4515. Any formal correspondence should be sent electronically in PDF searchable format to [brian--downey@finance-rep.senate.gov](mailto:brian-downey@finance-rep.senate.gov).

Sincerely,

Charles E. Grassley,
Ranking Member.