

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

June 25, 2008

## Hand Delivered

The Honorable Robert C. Byrd  
Chairman  
Committee on Appropriations  
United States Senate  
Hart Senate Office Building – Room 311  
Washington, DC 20510

The Honorable Thad Cochran  
Ranking Member  
Committee on Appropriations  
United States Senate  
Dirksen Senate Office Building – Room 113  
Washington, DC 20510

Dear Chairman Byrd and Ranking Member Cochran:

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 Centers for Medicare and Medicaid programs (CMS). Many of the actions and decisions taken by CMS are guided by research and studies funded by the National Institutes of Health (NIH/Agency). Accordingly, it is imperative that we 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.

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. As you know, institutions are required to manage a NIH grantee's conflicts of interest.<sup>[1]</sup> However, I am discovering that these regulations may be nothing more than words with little if any teeth.

Last January, the Inspector General for the Department of Health and Human Services Office (HHS OIG) released a disturbing report which found that NIH provided almost no oversight of its extramural funds.<sup>[2]</sup> But when this report was detailed in *The New York Times*, Norka Ruiz Bravo, the NIH deputy director of extramural programs stated, "For us to try to manage directly

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<sup>[1]</sup> Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995).

<sup>[2]</sup> Department of Health and Human Services OFFICE OF INSPECTOR GENERAL, "NATIONAL INSTITUTES OF HEALTH: CONFLICTS OF INTEREST IN EXTRAMURAL RESEARCH," January 2008.

the conflict-of-interest of an NIH investigator would be not only inappropriate but pretty much impossible.”<sup>[3]</sup>

Even prior to the issuance of this report, I began pressuring NIH to become more accountable for its share of American tax dollars. Last October, I sent Dr. Elias Zerhouni, the director of the NIH, a letter detailing problems with a psychiatrist at the University of Cincinnati. In that letter, I notified Dr. Zerhouni that this particular physician received grants from the NIH, however, she was failing to report her outside income from Astra Zeneca to her University.

Earlier this month, I sent Dr. Zerhouni a second letter outlining concerns about several researchers in psychiatry at Harvard University and Mass General who had not reported millions of dollars in payments from drug companies. I have questions regarding whether or not these two researchers violated NIH rules on disclosure. I am awaiting a complete response from the NIH.

Recently, Dr. Zerhouni told me that he shared my concerns about the extramural program. He wrote, “The NIH is undergoing a comprehensive review of our oversight of extramural institution’s conflicts of interest. As a result of this intensive effort, the NIH has identified and is reviewing several areas for oversight enhancement.”<sup>[4]</sup> Dr. Zerhouni also wrote that he is considering gathering public comment on whether to modify the regulations for 42 CFR Part 50, Subpart F. I would submit that the time is now to modify these regulations and add some teeth to them. Researchers need to be put on notice that government grants come with obligations of financial disclosure.

As is well known, in 2003 the NIH became immersed in scandal when it was revealed that NIH intramural researchers enjoyed lucrative arrangements with pharmaceutical companies. During a congressional hearing on the matter, Dr. Zerhouni testified, “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.”<sup>[5]</sup> Dr. Zerhouni eventually brought transparency, reform and integrity back to NIH. But he now needs to solve the much bigger problem with the extramural dollars.

NIH oversight of the extramural program is lax, creating a \$24 billion problem. To borrow from Dr. Zerhouni’s prior testimony, “drastic changes are needed.” I am asking you to join me in holding the NIH accountable until it addresses this issue in a prompt and complete manner. Accordingly, I am suggesting that as part of the appropriations process, language be considered ensuring that the NIH is fully apprised of any conflicts existing among those individuals receiving NIH funds. American taxpayers deserve nothing less.

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<sup>[3]</sup> Gardiner Harris, “Researchers Go Unchecked, Report Says,” *The New York Times*, January 19, 2008.

<sup>[4]</sup> Letter from Dr. Elias Zerhouni to Senator Chuck Grassley, dated June 20, 2008.

<sup>[5]</sup> Dr. Elias Zerhouni, Testimony, May 12, 2004

I have attached Dr. Zerhouni's letter as well as several news articles covering the problems with the NIH extramural program. Please have your staff contact Paul Thacker at 224-4515 if you have any other further questions. Thank you for your attention to this matter.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley  
United States Senator

Cc: Members of the Committee on Appropriations  
The Honorable David Obey, Chairman House Committee on Appropriations  
The Honorable Jerry Lewis, Ranking Member House Committee on Appropriations