

**PRESS RELEASE**

**July 7, 2009**

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## **SENATORS GRASSLEY, KOHL WORK TO BRING TRANSPARENCY TO BIOMEDICAL RESEARCH FUNDING**

WASHINGTON – Today Senators Chuck Grassley and Herb Kohl sent a letter to the National Institutes of Health (NIH), urging the federal agency to take steps to increase transparency of federally funded biomedical research. NIH is seeking public comment as it considers changes to its disclosure policy, and the senators made specific recommendations related to both individual researchers and academic institutions who receive NIH grants.

“In January 2008, the HHS OIG released a disturbing report which found that NIH provided almost no oversight of its extramural funds. It is clear that this is a pervasive problem that requires an immediate change in NIH requirements for disclosure of potential conflicts of interest by their grantees,” the letter reads. “With almost \$24 billion in extramural funds distributed by NIH each year, and in light of the additional \$10 billion provided by the American Reinvestment and Recovery Act to fund research grants, it is imperative that NIH properly fulfills its mission to advance the public’s welfare and makes responsible use of the funding provided.”

The senators suggested that researchers be required to report their outside income to the nearest \$1000, and that universities be required to complete a plan to manage the researcher’s potential conflicts of interest. Finally, they maintained that both the disclosures and the plan be available to the public via the NIH website.

In February, Grassley and Kohl filed an amendment to the American Reinvestment and Recovery Act (ARRA) which would have placed new requirements on institutions receiving NIH grants. NIH awards almost \$24 billion annually in grants for biomedical research, and the ARRA increased that figure by \$10 billion. In addition to provisions similar to the suggestions made in today’s letter, the amendment would have required the agency to actively enforce its conflict of interest policies and respond in a timely manner when those policies have been violated by grantees. The amendment was not included in the final bill.

For the past two years, Grassley and Kohl have collaborated to push for increased transparency in financial relationships between physicians and the drug, device and biologic industries. As part of that effort, they have championed the Physician Payments Sunshine Act (S. 301) to require these industries to publicly report payments and gifts to doctors. Recently, identical provisions to those in S.301 were included in the health care reform discussion documents released by the Senate Finance Committee. Similar provisions were included in the House draft bill as well.

Grassley is Ranking Member of the Senate Committee on Finance. Kohl is Chairman of the Senate Special Committee on Aging. Below is the text of their letter to NIH.

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July 7, 2009

**Via Electronic Transmission**

Raynard Kington, M.D., PhD.  
Acting Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Acting Director Kington:

In response to the request for public comment on the proposed regulation changes to the National Institutes of Health (NIH)'s disclosure policy, we would like to submit our initial recommendations.

As you know, for two years we have worked together as part of a continued effort to achieve public disclosure of financial relationships between physicians and the drug, device and biologic industries. As part of that effort, we have championed the *Physician Payments Sunshine Act* to require these industries to publicly report payments and gifts to doctors. In addition, beginning in the summer of 2008, Senator Grassley began releasing information to demonstrate that universities are not managing their professors' financial conflicts of interest and that change is needed at the NIH to ensure that the agency's funding is used for legitimate purposes. Specifically, we found:

1. The Chair of the Psychiatry Department at Emory University failed to report hundreds of thousands of dollars in payments from a pharmaceutical company while researching that same company's drugs with an NIH grant. The Health and Human Services Office of the Inspector General (HHS OIG) is now investigating the matter.
2. The Chair of the Psychiatry Department at Stanford University received an NIH grant to study a drug, while partially owning a company that was seeking FDA approval of said drug. He was later removed from the grant.
3. Three professors at Harvard University failed to report almost a million dollars each in outside income while heading up several NIH grants. Harvard plans to release a report on the matter.
4. The host of a show that ran on an NPR satellite station received over a million dollars from pharmaceutical companies to give promotional talks. The show had received funding from the NIH and has been cancelled.
5. The Chair of Orthopedic Surgery at the University of Wisconsin reported taking more than \$20,000 from a company every year, for five years. The actual amount was around \$19 million. The University of Wisconsin is revising its rules.

6. A professor at the University of Texas received an NIH grant to study Paxil in children, while also giving dozens of promotional talks on Paxil. The HHS OIG is now investigating.

Further, in January 2008, the HHS OIG released a disturbing report which found that NIH provided almost no oversight of its extramural funds. As *The New York Times* reported, "The agency provides little direct oversight over this sea of scientists, and it has little interest in doing so."

It is clear that this is a pervasive problem that requires an immediate change in NIH requirements for disclosure of potential conflicts of interest by their grantees. With almost \$24 billion in extramural funds distributed by NIH each year, and in light of the additional \$10 billion provided by the American Reinvestment and Recovery Act to fund research grants, it is imperative that NIH properly fulfills its mission to advance the public's welfare and makes responsible use of the funding provided.

Therefore, we make the following recommendations:

1. Researchers on an NIH grant must report their outside income to the nearest \$1000;
2. Universities must complete a plan to manage the researcher's potential conflicts of interest;
3. Both pieces of information will be made public on the NIH's website.

We feel that these are reasonable initial steps to provide more transparency to the billions of dollars that the government spends on biomedical research. Of course, we would support any additional protections enacted by NIH. American taxpayers deserve nothing less.

Sincerely,



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Charles Grassley  
Ranking Member  
U.S. Senate Finance Committee



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Herb Kohl  
Chairman  
U.S. Senate Special Committee on Aging

Cc: Mr. Jerry Moore  
National Institutes of Health, Office of Management Assessment