

For Immediate Release
Tuesday, September 23, 2008

Grassley asks NIH to account for employment of expert advisor

WASHINGTON --- Senator Chuck Grassley today asked if the National Institutes of Health is trying to get around its own policies to prevent conflicts of interest by hiring medical experts as contractors rather than full-time employees.

Grassley based his questions for the Director of the NIH on the case of a senior advisor in the National Heart, Lung and Blood Institute within NIH. Here, the doctor stayed on the staff of Tufts University School of Medicine and Tufts-New England Medical Center, while also acting as a high profile advisor and advocate for a cardiac device company.

In 2006, questions raised by Grassley about the practices of an NIH institute leader led to the official's departure from the NIH. Grassley also is working to get the National Institutes of Health to meet its obligation as a trustee of tax dollars to do whatever it can to achieve accurate disclosure of the financial relationships between the pharmaceutical and device industry and doctors who conduct medical research with the \$24 billion in federal grants awarded each year.

The text of the letter sent today by Grassley to the NIH Director is below.

September 23, 2008

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

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 last few months I have sent you several letters about the lack of oversight regarding conflicts of interest relating to the almost \$24 billion in annual extramural funds that the NIH distributes. However, I now understand that NIH still has conflict of interest issues with its own intramural researchers. Let me elaborate.

Specifically, Dr. Marvin Konstam was hired by National Heart, Lung and Blood Institute (NHLBI) last January as a senior advisor to the NHLBI Director, Dr. Elizabeth G. Nabel.^[1] At the time, Dr. Konstam was the Chief of Cardiology at Tufts-New England Medical Center and Professor of Medicine and Professor of Radiology at Tufts University School of Medicine. When he was hired by NHLBI, Dr. Konstam was also the medical director for Orqis, a company that develops medical devices related to congestive heart failure. Dr. Konstam joined Orqis back in 2003.^[2]

What concerns me is that after joining the NHLBI as a senior advisor to Dr. Nabel, it appears that Dr. Konstam retained his position with both Tufts and Orqis. As you may well remember, together we dealt with a similar problem with Dr. David Schwartz, the former director of the National Institute of Environmental Health (NIEHS). Dr. Schwartz became director of NIEHS, but never resigned his position from Duke University, which resulted in several conflict of interest issues as Dr. Schwartz refused to relinquish his close relationship with Duke. Dr. Schwartz hired several scientists from Duke who were forced to return to Duke, and your office had to investigate several NIEHS grants awarded to Duke for possible conflict of interest violations.

Further, I would like to remind you of the scandals faced by NIH back in 2003 when it came to light that many NIH intramural researchers enjoyed lucrative arrangements with pharmaceutical companies. During a hearing on this matter you told Congress, "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."^[3]

While I thank you for the changes that you brought to the NIH, I am concerned that others at your Agency might not share your views. Perhaps others at NIH do not recognize how critical it is to maintain the integrity of the NIH.

Just last week, Orqis sent out a press release about one of its products. In that press release, Dr. Konstam praised the product and was quoted as the "Medical Director, Orqis Medical, and Professor of Medicine, Tufts University."^[4] Furthermore, Dr. Konstam submitted a paper to the journal *Circulation* last February, one month after he was hired by NHLBI.^[5] This study reported on a multicenter trial of an Orqis product that tries to improve cardiac flow. Dr. Konstam is listed as a corresponding author and the contact information lists his address and email at Tufts. In light of these facts, I would appreciate your insights into how Dr. Konstam, who appears to be a full-time federal employee, kept an office at Tufts and was publishing studies on behalf of Orqis while at the same time the Health and Human Services Website listed him as a Senior Advisor with an NHLBI phone number and email account.

^[1] NHLBI Meeting Minutes, dated October 30, 2007.

^[2] Business Wire, "Marvin Konstam, M.D. Joins Orqis Medical As Medical Director," Jan. 13, 2003.

^[3] Dr. Elias Zerhouni, Testimony, May 12, 2004.

^[4] Orqis Medical Corporation Press Release, "Orqis(R) Medical Completes First in Man Implant of Revolutionary Exeleras Product," September 15, 2008.

^[5] Greenberg, Barry et. al. "Effects of Continuous Aortic Flow Augmentation in Patients With Exacerbation of Heart Failure Inadequately Responsive to Medical Therapy," *Circulation*, September 2, 2008. (Received February 13, 2008; accepted July 1, 2008.)

Furthermore, the *Journal of the American Medical Association* (JAMA) released a study on April 16, 2008, about the ghost writing of medical studies.^[6] This study named Dr. Konstam as one of the researchers involved. When the *Boston Globe* interviewed Dr. Konstam about the allegations, he was quoted as a senior advisor for NHLBI.^[7] But three months later in July, Dr. Konstam was on a Food and Drug Administration safety panel on diabetes drugs and a news report listed his affiliation as Tufts Medical Center.^[8]

Obviously, anyone would be confused about who is Dr. Konstam's employer—Tuft's? The National Heart, Lung, and Blood Institute? Orqis?

I understand that NIH informed my staff last week that Dr. Konstam is a contractor with NIH. I'm concerned that the NIH may be avoiding intramural conflict of interest policies by hiring experts as contractors instead of as full time employees.

In light of this letter, I would appreciate a staff briefing to understand exactly how this situation came to pass. Further, I request an explanation of how much money NHLBI paid Dr. Konstam for salary and moving expenses, where those funds came from, and whether Dr. Konstam has received any compensation from other institutions and/or companies during the time he was employed by NHLBI. I also request copies of Dr. Konstam's financial disclosure filings, as well as any materials relating to any contract that may exist between Dr. Konstam and the NIH.

I thank you again for your continued cooperation and would appreciate receiving this information no later than October 7, 2008.

Sincerely,

Charles E. Grassley
United States Senator
Ranking Member

^[6] Joseph S. Ross et. al. "Guest Authorship and Ghostwriting in Publications Related to Rofecoxib," *Journal of the American Medical Association*, April 16, 2008.

^[7] Alice Dembner, "Journal: Drug firm paid MDs for bylines," *Boston Globe*, April 16, 2008.

^[8] Sue Hughes, "FDA advisory committee recommends cardiovascular safety studies for diabetes drugs," *Heartwire*, July 3, 2008.