

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

May 15, 2009

Via Electronic Transmission

Mark Stephen Wrighton
Chancellor
Washington University in St. Louis
One Brookings Drive
St. Louis, Missouri 63130

Dear Mr. Wrighton:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars appropriated for these programs. The actions taken by thought leaders, like those at Washington University in St. Louis (Washington University/Institution), often have a profound impact upon the decisions made by taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

According to an article published in *The New York Times* on May 13, 2009¹, Dr. Timothy Kuklo published a study that made false claims and overstated the benefits of Infuse, a product made by Medtronic, Inc. (Medtronic). Dr. Kuklo is an associate professor of orthopedic surgery at Washington University in St. Louis (Washington University) and from 2003 until sometime in 2006, he was stationed at Walter Reed Medical Center (WRMC). The article goes on to state that Dr. Kuklo “forged the signatures of four Walter Reed doctors on the article before submitting it last year to a British medical journal, falsely claiming them as co-authors.” The *New York Times* also charges that Dr. Kuklo did not obtain the Army’s required permission to conduct the study, and that WRMC provided the dean of Washington University with a copy of their investigation of Dr. Kuklo.

The study was published in *The Journal of Bone and Joint Surgery* (JBJS) and was retracted at the request of the Army, according to the *New York Times*. Apparently, the article had been rejected previously by another journal and Dr. Kuklo presented the data publicly on several other occasions. The study claimed to be a review of 138 soldiers who were treated at WRMC with lower leg injuries caused by explosions in Iraq, which was far greater than the number for which the hospital could find records.

¹ Wilson, Duff and Meier, Barry “Army Disputes Doctor’s Claims in Injury Study,” *The New York Times*, May 13, 2009.

According to the *New York Times*, Dr. Kuklo has claimed to be a consultant for Medtronic and listed Medtronic as a financial supporter while he was still at WRMC.

Accordingly, I request that your Institution respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with a response. In cooperating with the Committee's review, please note that no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

- 1) Please provide the Committee with a copy of WRMC's investigation of Dr. Kuklo.
- 2) Please provide the Committee with all communications/materials and/or documents and/or reports/investigations regarding Dr. Kuklo and his study published in the *JBJS*, to include any previous submissions to other journals and/or presentations of the same or similar data.
- 3) Please explain what disciplinary action, if any, is being taken against Dr. Kuklo. Please provide pertinent documents and/or communications.
- 4) Please provide a list of all grants received by Dr. Kuklo from the time he began his affiliation/employment with Washington University to the present. For each grant please list the following:
 - a. funding agency/company;
 - b. brief description of the study;
 - c. amount of funding; and
 - d. amount of salary support for Dr. Kuklo.
- 5) For each grant identified above, please state whether or not Dr. Kuklo reported to the designated Washington University official "the existence of [a] conflicting interest." Also, please explain how Washington University ensured "that the interest has been managed, reduced, or eliminated." Provide separate responses for each grant received for the period when Dr. Kuklo began affiliation/employment with Washington University to the present, and provide any supporting documentation for each grant identified.
- 6) For each grant identified above, please provide the amount of money paid directly to Dr. Kuklo for "salary." Please detail this information by grant supporter, grant title, grant topic, year, and salary amount.
- 7) Please provide an update on any reports of research misconduct and/or reviews of the discrepancies in financial and/or conflict of interest disclosures by Dr. Kuklo, including what action, if any, Washington University will consider. The time span of this request covers the time he began his affiliation/employment with Washington University to the present.

- 8) Please report whether a determination can be made as to whether or not Dr. Kuklo violated guidelines governing clinical trials and the need to report conflicts of interest to an IRB. Please respond by naming each clinical trial for which Dr. Kuklo was the principal investigator, along with confirmation that conflicts of interest were reported, if possible. The time span of this request covers January 2007 to the present.
- 9) Please provide any notifications and/or communications to the NIH regarding conflicts of interest and research by Dr. Kuklo. The time span of this request covers the time he began his affiliation/employment with Washington University to the present.
- 10) Please provide copies of the forms detailing Dr. Kuklo's outside income and conflicts of interest from the time he began his employment at Washington University to the present. Because reporting practices vary widely from one institution to another, I would appreciate you also placing Dr. Kuklo's outside income into a chart, detailing compensation from companies. For each payment to Dr. Kuklo from a company, please provide the following information:
 - a. Name of company;
 - b. Date of payment;
 - c. Payment description (CME, honorarium, research support, etc);
 - d. Amount of payment; and
 - e. Annual amount of payment from company.

I look forward to hearing from you by no later than May 29, 2009. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Paul Thacker at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member