

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

May 15, 2009

Via Electronic Transmission

Major General Carla G. Hawley-Bowland
Commanding General
United States Army, North Atlantic Regional Medical Command
Walter Reed Army Medical Center
6900 Georgia Avenue NW

Dear Major General Hawley-Bowland:

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. This includes the responsibility to conduct oversight of the health care industry, including makers of medical devices, which receive hundreds of billions of taxpayer dollars every year for the care of Americans.

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 Medtronic’s chief executive and 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The study was published in *The Journal of Bone and Joint Surgery (JBJS)* and was retracted at the request of the Army, according to the *New York Times*.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. 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.

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

Also, I have learned from the Center for Public Integrity that Medtronic may have, among other things, sponsored travel for both Dr. David Polly and Dr. Timothy Kuklo while they were on staff at WRMC. I would like to understand WRMC's policies in this area in a little more depth.

Accordingly, I request that WRMC respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with an answer. In cooperating with the Committee's review, 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 *JBJJ*, to include any previous submissions to other journals and/or presentations of the same or similar data.
- 3) Please explain WMRC's policies and procedures for WMRC physicians accepting payments and/or compensation and/or other transfer of value from private companies. Please provide copies of such policies and procedures that have been in place from January 1, 2004 to the present.
- 4) Please provide copies of the forms detailing Dr. Timothy Kuklo's and Dr. David Polly's outside income and/or conflicts of interest. The time span of this request covers January 1, 2001 to the present.
- 5) Please provide a list of all grants for research funded for Dr. Kuklo for which he was the primary investigator. For each of Dr. Kuklo's grants, please provide a brief description of the study and the amount of funding. The time span of this request covers Dr. Kuklo's employment at WMRC.
- 6) Please describe WMRC's policies and procedures for accepting outside funding and/or other transfers of value from private companies. Please provide copies of such policies and procedures that have been in place from January 1, 2004 to the present.
- 7) Please provide a list of all grants for research on Infuse for which WRMC received funding and/or other transfers of value from private companies and/or for which any foundation affiliated with WRMC received funding from private companies. For each grant please provide a brief description of the study, and the amount of funding. The time span of this request covers January 1, 2003 to the present.
- 8) Please explain if WMRC has determined whether or not Dr. Kuklo violated guidelines governing clinical trials and the need to report conflicts of interest. 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 Dr. Kuklo's employment at WMRC.

- 9) Please explain WRMC's policies and procedures involving Army physicians who participate in outside employment involving medical research and consulting. Please provide copies of such policies and procedures that have been in place from January 1, 2004 to the present.
- 10) Please explain WRMC's policies and procedures for approving corporate sponsored travel and/or standards of ethical conduct for Army physicians.
- 11) Please provide a list of all corporate sponsored travel by Dr. David Polly and Dr. Timothy Kuklo. The time span of this request covers January 2001 to the present.

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