United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

December 17, 2010

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
Washington, DC 20307

Dear Major General Hawley-Bowland:

As senior members of the United States Senate and the Chairman and Ranking Member of the Committee on Finance (Committee), we have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the United States Department of Defense.

Thank you for your response to Senator Grassley dated September 16, 2009, regarding a study published in the *Journal of Bone and Joint Surgery* authored by Dr. Timothy Kuklo. Last year, the *New York Times* reported that Dr. Kuklo published a study that made false claims and overstated the benefits of Infuse, a bone growth product made by Medtronic, Inc. (Medtronic).[1] That study concerned the treatment of American soldiers who were injured in Iraq. According to the *New York Times*, Dr. Kuklo did not obtain the Army's required permission to conduct the study.

We are writing to follow up on another study that was conducted by Dr. Kuklo, Dr. David Polly and Dr. Michael Rosner in 2002 when they were surgeons at Walter Reed Army Medical Center (Walter Reed).[2] Walter Reed informed the Committee that Dr. Kuklo also did not obtain the appropriate authorizations from its Department of Clinical Investigations to conduct their medical records review and publish the study.

Specifically, Drs. Kuklo, Polly and Rosner performed spinal fusion surgeries in 35 patients at Walter Reed and published the outcomes of those surgeries. The surgeries involved the insertion of Hydrosorb, a bioabsorbable implant, packed with Infuse between the vertebrae—an off-label use of medical devices that had been cleared by the Food and Drug Administration (FDA) for different indications.

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[1] Duff Wilson and Barry Meier, "Army Disputes Doctor's Claims in Injury Study," *The New York Times*, May 13, 2009.
[2] Timothy R. Kuklo, Michael K. Rosner, and David W. Polly, "Computerized tomography evaluation of a resorbable implant after transforaminal lumbar interbody fusion," *Neurosurg. Focus*, Vol. 16, Mar. 2004.

According to the FDA, at the time the patients in the study were treated, Hydrosorb was cleared for indications such as the support of weak bony tissue in trauma and general orthopaedic use. However, it was not cleared for use in a load-bearing capacity such as in the spine. Furthermore, it was not approved for the spinal fusion indication described in the March 2004 article by Drs. Kuklo, Polly and Rosner. FDA informed the Committee that the "intervertebral fusion devices (cages) for a spinal fusion indication were, and continue to be, class III Premarket Approval (PMA) devices that require FDA approval before marketing."

In November 2009, the *Minneapolis Star Tribune* reported that Dr. Charles Rosen, professor of orthopaedic surgery at the University of California-Irvine and President of the Association for Medical Ethics, sent a letter to the Army raising concerns about Drs. Polly, Kuklo and Rosner's use of Hydrosorb in spinal fusion surgeries on American soldiers.[3] He also questioned whether or not the research was authorized by an institutional review board (IRB).

In response to questions from Committee staff, Walter Reed informed the Committee that the published study was "unauthorized" research. Specifically, Walter Reed stated that the "article appears to be written as a retrospective review of surgeries…Even a retrospective study require prior authorization from DCI before a protocol can be initiated to review medical records for data for a publication." Further, Walter Reed stated that "DCI does not have any record of any protocol having been filed nor any clearance having been requested for this publication."

In light of what Walter Reed and FDA have told the Committee regarding the Hydrosorb study, we would appreciate your responses to the following questions and requests for information by no later than January 14, 2011:

1) According to Walter Reed, as of September 2010, the Army and other agencies are continuing to investigate the matter involving the study published by Drs. Kuklo. Polly and Rosner. Please keep us apprised of any developments and findings in these investigations, including any findings regarding the outcomes of the surgeries, such as any adverse events reported to Walter Reed since the publication of the study.

2) According to an email from Dr. Kuklo to two Medtronic employees dated January 12, 2004, it appears that the Hydrosorb study conducted by Drs. Kuklo, Polly and Rosner was supported by a restricted educational grant from Medtronic. *See* attached. Is that correct? If so, what was Medtronic's role and extent of communication with Dr. Kuklo and/or Dr. Polly regarding the Hydrosorb study?

[3] Janet Moore, "Surgeon questions study led by U doc with Medtronic tie," *Minneapolis Star-Tribune*, Nov. 29, 2009.

3) With respect to the Hydrosorb study, Walter Reed said the patients were consented for surgery but not participation in research. Physicians are legally permitted to use drugs and medical devices off-label. It is our understanding, however, that Hydrosorb was specifically not intended for load-bearing indications, such as in the spine. What disclosures, if any, were made to the patients regarding this off-label use?

4) What policies and protocols are in place at Walter Reed to ensure that patients are adequately informed of risks associated with procedures that may involve the off-label use of a medical device and/or a use that may be counter to what is approved in the product labeling?

5) Walter Reed noted that federal regulations govern human subjects research conducted at its facility. What policies and protocols are in place to ensure that the physicians who are assigned to Walter Reed comply with these regulations and obtain the appropriate IRB review and approval for research they conduct at Walter Reed?

Thank you in advance for your assistance. If you have any questions, please do not hesitate to contact Chris Law (Senator Baucus) at (202) 224-4515 or Kathryn Ott (Senator Grassley) at (202) 224-3744. All documents responsive to this request should be sent electronically in PDF format to Kathryn_Ott@grassley.senate.gov.

Sincerely,

Max Baucus
Chairman

Charles E. Grassley
Ranking Member

Attachment

From: Kuklo, Timothy R LTC (P) WRAMC-Wash DC [redacted]

Sent: Monday, January 12, 2004 10:01:48 AM

To: [redacted]

Subject: Hydrosorb paper

Attachments: Hydrosorb 1-12-04.doc; Images.ppt

Gentlemen,
I am forwarding you the final version of the Hyrdosorb paper. This is the first completed project from the restricted educational grant you so generously provided. We will continue to push forward, completing all of our proposed projects in a timely manner.
Again, your confidence in our work is greatly appreciated.
Sincerely,
Tim
<<Hydrosorb 1-12-04.doc>> <<Images.ppt>>

Timothy R. Kuklo, MD, JD
Lieutenant Colonel (Promotable), Medical Corps
Program Director, Orthopaedic Surgery
Director, Pediatric and Adult Spine Surgery
Associate Professor of Surgery, USUHS
[redacted]