

June 6, 2009

## **Discredited Research Study Stuns an Ex-Army Doctor's Colleagues**

By **BARRY MEIER** and **DUFF WILSON**

Dr. Romney C. Andersen, a Walter Reed Army Medical Center surgeon, was surprised last summer when his neighbor, a fellow doctor, congratulated him on a new medical journal study bearing his name.

“What study?” Dr. Andersen asked.

Soon, he was not the only person asking questions. Army officials, alerted by Dr. Andersen, began an investigation. They uncovered an apparent case of falsified research by a doctor who had befriended Dr. Andersen when they both worked at Walter Reed, treating American soldiers severely injured in Iraq.

The full report of that Army investigation, recently obtained by The New York Times, provides an unusually detailed anatomy of a suspected case of medical research fraud — one all the more disturbing because it occurred at the nation's premier military research hospital.

Within the last week, the Justice Department opened an inquiry into the episode, said two people with knowledge of it, who spoke only on condition of anonymity.

The disputed journal article was written by a former Army orthopedic surgeon, Dr. Timothy R. Kuklo, who is now a medical professor at Washington University in St. Louis. Dr. Kuklo, the investigation found, forged the signatures of Dr. Andersen and other Army doctors on his study and never showed it to them before it was published.

The British journal that published Dr. Kuklo's study retracted it in March and has banned him from its pages. His future at Washington University will very likely be determined by an inquiry the medical school is said to be conducting. University officials declined to comment for this article.

The Walter Reed episode also shows how medical journals may fail to conduct adequate

due diligence on the studies they publish — information that other doctors rely on for guidance. As happened in the Kuklo case, for example, they often deal only with a study's principal author, rather than all the credited contributors. In his study, Dr. Kuklo, who has not responded to repeated interview requests, reported that a bone-growth product sold by Medtronic, called Infuse, performed “strikingly” better than the traditional bone-grafting technique used to heal soldiers' shattered shin bones. Other Walter Reed doctors told an Army investigator that claim was overblown.

Medtronic financed some of Dr. Kuklo's research and travel while he was at Walter Reed and hired him as a consultant in August 2006 when he took his current academic post. But Dr. Kuklo did not disclose his Medtronic relationship in the journal article, which was published in August 2008.

Medtronic has declined to provide the financial details of its relationship with Dr. Kuklo, although the company said Friday that it planned to provide some of that information next week to Senator Charles E. Grassley, Republican of Iowa, who is investigating the matter.

Medtronic has said that it had no involvement in the disputed Infuse study, despite its business ties to Dr. Kuklo. The report was published in Britain last August in *The Journal of Bone and Joint Surgery*.

Colleagues and friends of Dr. Kuklo say they are shocked by the accusations against him and predict he will eventually be cleared of any wrongdoing.

“I think that Tim is a brilliant researcher and surgeon,” said Lt. Col. Richard C. Rooney, a spine surgeon at William Beaumont Army Medical Center in El Paso, Tex., who knows Dr. Kuklo and his work. “I don't believe the accusations. I don't care if the head of Walter Reed made them.”

For his part, Dr. Kuklo did not formally respond to Army investigators. But Col. J. Edwin Atwood, an Army cardiologist who led the Army's inquiry, wrote in his report that even if Dr. Kuklo had participated, it might have had little influence on his findings.

“What has transpired here,” he wrote, “is the ultimate tragedy and catastrophe in academic medicine.”

Treating War's Injured

With the invasion of Iraq in 2003, the orthopedics department of Walter Reed, a sprawling facility in Washington, became an extension of the front lines. The injured included soldiers with gaping holes in their lower legs caused by explosive devices like homemade bombs filled with ball-bearings and nails. Hundreds of them would receive amputations.

Dr. Kuklo, a native of Canton, Ohio, who had come to Walter Reed as a medical resident in the 1990s, was one of the specialists who treated the wounded.

Back then, his colleagues viewed Dr. Kuklo, a West Point graduate who is married with two children, as likable, hard-working and ambitious. Dr. Andersen also once considered him a friend, and credits Dr. Kuklo with helping him to decide to become an orthopedist. "He was a good mentor," said Dr. Andersen, who is currently serving in a combat hospital in Baghdad.

Infuse, the subject of Dr. Kuklo's study, is a bioengineered bone-growth protein that the Food and Drug Administration approved in 2002. Walter Reed surgeons used it both in certain spinal surgeries and to treat severe leg injuries.

Dr. Kuklo, a spine specialist, also had other research interests that dovetailed with Medtronic's; while at the military hospital, he led five studies financed by the company, Army officials say.

His controversial study had its roots in a short five-paragraph paper, or abstract, that Dr. Kuklo presented at a 2005 meeting of a medical group, the Orthopaedic Trauma Association. In it, he reported that Infuse had healed fractured shins in 28 of 32 soldiers treated, or 88 percent, adding that "further research on this exciting technology is warranted."

Not long after that presentation, Dr. Kuklo's military career began to wind down. Along with a consulting deal, he struck a separate arrangement with Medtronic in August 2006 that would pay him royalties for any spinal devices he developed. Army officials say they have been unable to find records to indicate that Dr. Kuklo either sought or was given permission to strike the Medtronic deals.

Dr. Kuklo, who moved into a \$2.1 million home near St. Louis, was not the first departing Walter Reed doctor to get a consulting deal from Medtronic. For instance, it had struck an arrangement with Dr. Kuklo's former boss, Dr. David W. Polly Jr., when he left the

military hospital in 2003.

Dr. Polly is now one of Dr. Kuklo's staunchest public defenders. Recently, Dr. Polly blocked a reporter's request that the University of Minnesota, where he now works, release his financial disclosure statement showing how much he made from Medtronic.

### Starting an Inquiry

When Dr. Andersen first learned about the Infuse article last summer, he said he thought that Dr. Kuklo might have made honest mistakes in his study. But after talking with the article's other supposed co-authors and checking Walter Reed records, he became convinced that parts of it had been fabricated. So he called Dr. Kuklo and confronted him.

Dr. Kuklo defended the study, saying that all the data had been drawn either from Walter Reed files or from his personal records that he had left behind at the hospital.

Unconvinced, Dr. Andersen notified Army officials and the editor of the British journal in September about his concerns.

In his 2005 abstract, Dr. Kuklo had reported only Infuse results. But his August 2008 journal article cited other Walter Reed data to compare Infuse with the traditional bone-graft treatment for fractured shins. He declared Infuse the winner by a wide margin.

Dr. Kuklo said he had reached that finding by reviewing the records of two groups of the soldiers with similarly severe leg injuries, who had been treated either with Infuse or a bone graft. But Dr. Andersen suspected that Dr. Kuklo had fabricated the comparison groups, because many soldiers had received both Infuse and a bone graft — not one or the other.

"It was like he was comparing apples and oranges," Dr. Andersen said. "But there weren't any apples or oranges to compare."

The British periodical was not the first place Dr. Kuklo submitted his article. Army investigators were told that he had tried first, without success, to publish it in The New England Journal of Medicine, one of the country's premier medical journals. A spokeswoman for The New England Journal declined to comment.

Dr. Kuklo told Dr. Andersen that he had also sent the study to a leading American orthopedic periodical, *The Journal of Bone and Joint Surgery*, before submitting it to the British journal. (The two similarly named journals operate independently.)

Dr. Andersen contacted the American journal's editor, Dr. James D. Heckman, who confirmed in an e-mail message that Dr. Kuklo had submitted the report in mid-2007. The journal rejected it two months later, sending Dr. Kuklo the comments of an editor and two outside doctors who had reviewed it, Dr. Heckman wrote.

Dr. Andersen, curious about what Dr. Kuklo had actually submitted, asked Dr. Heckman for copies of those reviews. But the editor turned him down, even though Dr. Andersen was supposedly one of the study's authors. In a recent interview, Dr. Heckman said that his journal, like many others, considered such reviews confidential and shared them only with a study's lead author.

"It is all confidential information," Dr. Heckman said, when asked by a reporter for the reviews. "It is protected by the peer-review process."

Last October, Dr. Kuklo received a telephone call from Colonel Atwood at Walter Reed.

After describing his inquiry, Colonel Atwood put a military lawyer on the phone who told Dr. Kuklo that he was suspected of "conduct unbecoming an officer," a formal charge, and read him his legal rights.

### Questioning Signatures

Dr. Kuklo, who then hired a lawyer, did not respond to a series of questions posed by Colonel Atwood, the Army's inquiry shows. In a recent interview, Dr. Polly, the former Walter Reed physician who is now a Medtronic consultant, said Dr. Kuklo was mistaken to sign his co-authors' names. But he added that was not uncommon in the military for one officer, when it was expedient, to sign for another.

Dr. Kuklo, however, did not indicate that he was signing his four co-authors' names on their behalf. He even used a distinctively different handwriting style for each of them, a form he submitted to the British journal shows.

Colonel Atwood concluded that his inquiry had substantiated all the accusations against the physician.

"I view this as potentially having the worst consequences to Walter Reed of any event that has occurred during my six-year tenure," he wrote in his report.

Later this month, Dr. Andersen expects to return to Walter Reed from Baghdad, to take a new position as the hospital's chief orthopedic surgeon. He says that it has been difficult to reconcile the Dr. Kuklo he knew with the false research he says he believes his former mentor published.

"When your impressions of someone are that they would never do something like this, it was difficult for me," Dr. Andersen said. "But the more I looked at the data, the more I said this just can't be close to being true."