



What Was He Thinking? And How Come Everyone Missed His Thought Processes?

By Marianne M. Jennings, J.D.

A West Point graduate, an orthopedic surgeon, and a lawyer with his degree from Georgetown, Dr. Timothy Kuklo served his country well, including a stint at Walter Reed until 2006. His departure from the military was also the stuff of movie heroes. He was leaving to take a faculty position at Washington University in St. Louis even as the data and results from his work with Medtronic's Infuse (a bone-graft product) on soldier patients was published in the *Journal of Bone and Joint Surgery*.

Within a year of his 2006 departure, however, the story would fray at the seams and, just over two years later, the rich tapestry of his life would unravel into twisted threads. Another surgeon at Walter Reed began looking at the Kuklo study and found two troubling things: (1) The signatures of Dr. Kuklo's co-authors were forged; and (2) The study cited higher numbers of patients and injuries than Walter Reed could account for. Col. Norvell Coots, the commander at Walter Reed, described the study as involving a "ghost population." Colonel Coots indicated that the study included patients that the hospital had no record of ever treating, "So this really was all falsified information."¹

But, as sordid as the tale seems at this point, the other shoes must drop. There were nigh on to a closet-full of shoes in this case, many of them of hiking-boot size. Dr. Kuklo was paid nearly \$800,000 in consulting fees by Medtronic, the maker of Infuse, the subject matter of the now-withdrawn study, which was, in turn, the very substance of the now-

revoked article. However, the agonizingly slow trickle of how's, when's, and what's of those consulting fees is also a case study.

Bad news concealed
does not improve
with time.

When the Kuklo article was withdrawn by the *Journal*, Medtronic explained that it had some connection with Dr. Kuklo—it had funded the research through foundations. But, as the tale went public and Congress got involved, the questions and resulting hearings brought more details. Under questioning from Senator Charles Grassley, a senator who continues to explore consulting arrangements of all sizes and types for all physicians, Medtronic next disclosed that it had hired Dr. Kuklo as a consultant when he left the Army in 2006. Later, Medtronic would disclose to the *Wall Street Journal* that it had paid Dr. Kuklo while he was still at Walter Reed for speeches he had given to explain Infuse at meetings for other docs. However, Dr. Kuklo did not file the required VA consulting forms for docs who accept such compensation.

The non-disclosure habit carried over to Dr. Kuklo's faculty position. He did not disclose his payments from Medtronic until one year after joining the faculty, a year that included continuing research that was funded by Medtronic. In fact, the medical school discovered that Dr. Kuklo signed a consulting agreement

with Medtronic and then, three days later, signed and filed the required disclosure form with Wash U on faculty consulting. However, Dr. Kuklo's signed form indicated that he had no consulting arrangements to disclose. One year later, when he filed his annual consulting form with Washington University, he did disclose \$500,000 in consulting fees from Medtronic. The medical school followed its rules and gave Dr. Kuklo the option of dropping the fees from Medtronic to below \$10,000 or halting the research. Dr. Kuklo opted for the latter, and, as a result, a second study on Infuse, funded by Medtronic, was never completed.

But the shoes kept coming. Documents filed with Senator Grassley's office in 2009 by Washington University indicate that Dr. Kuklo accepted his faculty position with Wash U while he was still on active duty in the Army. The Army has now raised questions as to whether Dr. Kuklo made the appropriate inquiries and filed the necessary forms for accepting a teaching position during a period of active duty. Needless to say, the Justice Department has its own separate inquiry under way.

When we read of cases such as this one, self-righteousness controls our initial reaction, "What was he thinking?" or "He's a rogue," followed by, "That would never happen under my watch." Never say never, and don't pass up the opportunity to learn from the missteps of others. Some of the previous columns on ethics could have helped in this situation. Herewith a quick review of the principles discussed before that apply in the Kuklo matter.

¹ Duff Wilson and Barry Meier, "Doctor's Study of Injured G.I.'s Made False Claims, Army Says," *New York Times*, May 13, 2009, p. A1.

1. This stuff just wants out there²

It is remarkable how long Dr. Kuklo was able to keep going with all of the consulting, data, conflicts issues swirling. But, out it all did come. Still, there are some additional “it just wants out there” lessons from this particular situation. Bad news concealed does not improve with time. Unlike fine wine, the hard truth does not get better with time. For Medtronic, Washington University, and others involved because of Dr. Kuklo’s missteps, there are some public relations lessons. Get the bad news out there, take your pain. Hold back on hard truths and you battle not only the bad news, but also a second issue of credibility as the bad news continues to trickle. For example, because of the trickle Medtronic slowly turns into a target. Dr. Kuklo is the one who owes all an explanation, and he has remained silent for months since the issues began to emerge. But Medtronic’s slow trickle gives Dr. Kuklo a pass and the company a mess.

Each announcement has confirmed stronger ties with the doctor than those disclosed previously. First, came the outrage over the medical journal’s accusation of falsified research and Medtronic release of, “We have ended our relationship.”³ The implication was, of course, that Medtronic would have no part of such shenanigans. Then came the disclosure that Medtronic had been paying the doctor, but only after he left the Army.⁴ Then...

Well, the next release revealed payments by Medtronic to the doctor whilst Army service was in progress.⁵ But that release was coupled with the reassurance that consulting arrangements with physicians are critical for them and us, i.e., everybody does this sort of thing. Then came yet another disclosure that the payments to Dr. Kuklo ran for a bit longer than originally thought. Then, \$800,000 later...

Let it rip when it comes to bad news. The trickle hurts credibility. If you don’t

know, sit tight until you do and explain the reason for the delay. Other companies can learn from Medtronic’s suffering. The trickle can be miserable. Four stories vs. one? Take the latter.

Fire the star, or at least make the star follow the rules⁶

There is little question that Dr. Kuklo was a star who was granted the deference we have for those who are conducting research and enjoying the accolades that come from advances in medical science. Those at Walter Reed have indicated that they granted Dr. Kuklo leaves to travel and speak about Infuse. They assumed, in their words, that he was “speaking forthrightly.”⁷

“Icons should be treated as toddlers by a swimming pool.”

The disclosure and consulting forms required for those in healthcare have been around for some time. Being ever vigilant in their completion, filing and auditing is the piece we need. Trust, but verify. If a physician has no consulting arrangements, you may have a red flag. If a physician is traveling a great deal and has no consulting forms, you have two red flags. If a physician has no consulting forms, a great deal of travel, and the trappings of wealth, the time for confrontation with three red flags has come.

The faint signals⁸

And along the rock star lines is the fact that icons should be treated as toddlers by a swimming pool: Never take your eyes off them or their behavior. Human nature finds the rich and powerful fancying themselves immune from the drudgery of rules, processes, paperwork and requirements. Because they have been successful, they cannot understand

why the mundane should be imposed upon them. The flat organization, when it comes to ethics and compliance, is necessary. Absolute, unqualified, egalitarian application of all the rules to all the folks.

The codes, the training and the annual review are the cover for an organization. If you want to avoid the constant chase of the tiger by the tail, the ear to the ground for those subtle signals is the key. Some faint signals related specifically to the Kuklo situation would include the amazingly favorable results for the Medtronic product. Another would include a simple audit that spot-checks data with patients. In the case of Walter Reed, just a check on the number of

patients in the study vs. the number of patients treated would have been a signal that something was percolating. These subtle observations, not always part of an Excel spread sheet and certainly not yet ready for a dashboard measure, can make the difference in preventing the damage that ongoing ethical missteps cause.

4. A conflict is a conflict is a conflict... Redux 2⁹

Two previous columns have covered the issue of conflicts, one that addressed specifically the ongoing work of Senator Grassley with regard to physician consulting arrangements. Ironically, Senator Grassley’s work was increasing as the Kuklo case was taking place. When there are legislative rumblings and activities in the areas in which we work, we have the perfect time to discuss, question and review. In short, the introspection should be ongoing and should intensify when others are raising concerns, asking questions, and,

² Marianne M. Jennings, “This Stuff Just Wants Out There,” *New Perspectives* 27(3): 11, 27 (2008).

³ Barry Meier and Duff Wilson, “Medtronic Breaks With a Doctor Accused of Faking a Product Study,” *New York Times*, May 21, 2009, p. B3.

⁴ David Armstrong and Thomas M. Burton, “Medtronic Paid the Surgeon Accused of Falsifying the Study Nearly \$800,000,” *Wall Street Journal*, June 18, 2009, p. B1.

⁵ Barry Meier, “Medtronic Paid Surgeon While He Was in the Army,” *New York Times*, June 11, 2009, p. B4.

⁶ Marianne M. Jennings, “Firing the Rock Star,” *New Perspectives* 27(4): 24-25 (2008).

⁷ Barry Meier and Duff Wilson, “Medical School Says Former Army Surgeon Had Ties to Medtronic,” *New York Times*, July 15, 2009, p. B3.

⁸ Marianne M. Jennings, “Of Puzzles and Faint Signals,” *New Perspectives* 28(2): 14-16 (2009).

⁹ Marianne M. Jennings, “A Conflict Is a Conflict Is a Conflict . . .,” *New Perspectives* 27(1): 32-33 (2008) and “A Conflict Is a Conflict Is a . . . Redux,” *New Perspectives* 28(1) 14-15 (2009).

especially when they are requesting documents.

How many ways to say it? There is little need for literary command. There are only two ways to manage a conflict of interest: (1) Don't do it (and there are times when laws and regulations prohibit the relationship; or (2) Disclose it. Dr. Kuklo violated the second.

Perhaps the emphasis should be on reminding all of us that we don't get to decide when and how much to disclose. The answer is disclosure. Followed by, when in doubt, disclose. Followed by, if you don't want to disclose something, you probably should.

We are not finished with the relationships between and among physicians and pharmaceutical firms. The Institute of Medicine has called for physicians to stop taking gifts from the pharmas. In a report issued this past April, the IM has some stern language about the impact of the gifts on the mission of medical

schools, particularly as it relates to their research activities. Entitled, "Conflict of Interest in Medical Research, Education, and Practice," the April 28, 2009 report (available at www.iom.edu) also recognizes the futility of the "tiger by the tail approach" and stresses preventing "bias and mistrust rather than trying to remedy damage after it is discovered."

Conclusions and Some Advice

There can be little question that Dr. Kuklo was an outlier. That is, there are few who would take so much risk and flaunt so many rules during the course of their careers. There are individuals in whom we are unable to place the most basic form of trust, i.e., that they would at least follow the basic rules related to mandatory forms. We are prepared for the loophole seekers. We understand those who drift away from compliance and need to be reined in on occasion. But we are all taken aback by the individual who violates so many rules in a way that

seems to verify the classic observation of, "The bigger the lie...the easier it is to believe." However, the Kuklo situation reminds us that we cannot always rely on trust. Fortunately, we have enough common threads in the outlier cases to provide us with a bit of a map to trouble. Follow the faint signals, the precursors, and the telling behaviors and you can catch the outlier before the damage occurs. **NP**

Marianne M. Jennings is a professor of Legal and Ethical Studies at the W. P. Carey School of Business, Arizona State University where she teaches graduate courses in the MBA program. Professor Jennings has authored hundreds of articles in academic, professional and trade journals. Her latest book 'Business Ethics: Case Studies and Readings,' was published in January 2009. Her book, the 'The Seven Signs of Ethical Collapse' (St. Martin's Press), published in 2006, has received several book awards, including recognition from Library Journal. She may be reached at Marianne.Jennings@asu.edu.

Would you like to be able to really dig in to your data and identify process and control issues?

Are you under pressure to identify revenue enhancement opportunities at your hospital?

If you answered yes to these questions, **you are not alone**. Many Healthcare Internal Audit Departments struggle with these challenges. With the current financial strain on hospital budgets, the use of proven **Computer Assisted Audit Techniques (CAAT)** tools should be an important part of your internal audit plan.

CHAN offers CAAT Services in more than 20 audit areas, including:

- Revenue Charge Capture
- RAC Readiness Analysis
- Chargemaster Analysis
- AR Hindsight Review

Partner with CHAN to improve your department's effectiveness. For these services, CHAN performs the data analysis, provides reports that highlight potential exceptions and gives guidance throughout the process.

CHAN also offers web-based Continuous Auditing/Monitoring Tools for Revenue Charge Capture and AR Hindsight Reviews. For more information and a complete list of CHAN CAAT Services, go to www.chanllc.com/CAAT or call us at **314.802.2000**.

CHAN was **the first and remains the only** company in the nation focused exclusively on providing internal audit services to the healthcare industry.

