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Spine Surgeon Didn't Disclose Medtronic Pay in Testimony

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In May 2006, University of Minnesota spine surgeon David Polly urged a Senate committee to fund research into the severe arm, leg and spine injuries suffered by soldiers in Iraq and elsewhere.

Dr. Polly told the committee he was testifying on behalf of the American Academy of Orthopaedic Surgeons and referenced his prior work caring for soldiers as a surgeon at the Walter Reed Army Medical Center.

What Dr. Polly didn't disclose during his testimony was that his trip to Washington was paid for by [Medtronic Inc.](#), the big medical-device maker whose bone growth product, called Infuse, has been used to treat soldiers, according to company records.

Dr. Polly and colleagues in Minnesota subsequently received a \$466,644 Department of Defense grant for a two-year study beginning in February 2007 to evaluate Infuse in cases where an injury is also infected, according to the university.

Dr. Polly was paid \$1.14 million by Medtronic for consulting services from 2004 to 2007.

Details of Dr. Polly's consultant billing were provided by Medtronic to Sen. Charles Grassley, an Iowa Republican who has been scrutinizing the relationship between academics and industry.

A lawyer for Dr. Polly said the surgeon plays many roles, including researcher and consultant, and "works very hard to ensure that he properly tracks and allocates the time spent among these roles and will review any concerns in this area. In every instance, he has conducted himself honorably in advocating for injured veterans."

Dr. Polly's billing records provide an unusually detailed look at Medtronic's efforts to enlist doctors to promote its spinal products, especially the Infuse product, which is the subject of a Food and Drug Administration safety warning, issued in July 2008, related to life-threatening complications associated with its use in the cervical spine.

As concerns about safety and the company's payments to doctors have spread, sales of Infuse -- once a hot product -- have begun to fall. In Medtronic's fiscal fourth quarter, reported in May, Infuse sales were down 3% to \$215 million, compared with the year-earlier period.

Medtronic said it was not aware that Dr. Polly hadn't disclosed his ties to the company when testifying and "expected that he would have done so." The company said it has "decided to investigate Dr. Polly's consulting relationship and activities to our company." More broadly, Medtronic said it has, over the past several weeks, undertaken a "comprehensive review" of company procedures aimed at making sure physicians disclose their work for the company and expects to issue new standards in that regard.

A University of Minnesota spokesman said the school was reviewing the information gathered by Sen. Grassley.

Medtronic's relationships with doctors have drawn increased government scrutiny in recent months. The Justice Department is investigating the work of Timothy Kuklo, an Army surgeon and Medtronic consultant who has been accused by the Army of fabricating the results of a study that reported advantages in healing the legs of injured soldiers when Infuse was used.

Dr. Kuklo, who is on leave from his position at Washington University in St. Louis, was paid nearly \$800,000 over the past three years for his work consulting for Medtronic, according to the company.

Dr. Kuklo has declined to comment.

A university committee cleared Dr. Polly to work on the government-funded research of Medtronic's Infuse, saying that his "consulting duties for Medtronic appear sufficiently separate from the research he is performing."

Just after the university approved his work on the government-funded research, Dr. Polly billed Medtronic for time spent writing up the results from another Infuse study and met with Medtronic executives on Infuse-related topics, according to his billing records.

In total, Dr. Polly billed Medtronic for more than \$50,000 in lobbying-related costs. He made trips to Washington in 2005 and 2006 and called on several members of Congress, according to the records.

According to billing records, Dr. Polly's billing rate was \$4,750 for an eight-hour day in 2007, and he billed as many as 13,000 minutes a quarter -- or 216 hours over three months. In some months, he conducted at least some Medtronic business on nearly every day.

His consulting log indicates that on one occasion he spent one minute to wake up a Medtronic executive, although he listed "no charge" for that service. He did bill Medtronic for the 30 minutes he spent in the car with that executive after waking him up.

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