

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

January 12, 2009

Via Electronic Transmission

Kevin P. Reilly
President
University of Wisconsin
1720 Van Hise Hall
1220 Linden Drive
Madison, WI 53706

Dear Mr. Reilly:

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. Actions taken by key opinion leaders often have profound impact upon the decisions made by taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

In a letter dated March 12, 2008, the University of Wisconsin at Madison (University or Wisconsin) responded to my letter inquiring about the reports of outside income filed with the University between 2000 to 2007 by Dr. Thomas Zdeblick, Professor and Chairman, Department of Orthopedics & Rehabilitation. This response contained a chart that detailed Dr. Zdeblick's outside income. This chart did not contain detailed dollar amounts and only showed if Dr. Zdeblick exceeded certain thresholds such as \$20,000.

As part of my oversight duties, I also asked that Medtronic, a major medical device manufacturer, report any payments that the company made to Dr. Zdeblick. While Wisconsin only required Dr. Zdeblick to report if he exceeded \$20,000, the reports from Medtronic give specific numbers and show that Dr. Zdeblick was sometimes paid millions every year.

For instance, in 2007, Dr. Zdeblick reported receiving greater than \$20,000 from Medtronic in consulting and royalties. Medtronic reported to me that the actual payments for consulting were \$31,500 and the payments for royalties were \$2.64 million. As I'm sure you can understand, this amount greatly exceeds \$20,000 and I am concerned that Wisconsin's reporting requirements do not go far enough to fully capture a physician's potential conflict of interest. To help you understand the differences between what the University and Medtronic reported to me, I have attached a chart.

Further, my staff came across an article in which Dr. Zdeblick wrote about the relationship between physicians and industry.^[1] In one section, Dr. Zdeblick wrote:

The individual decision to perform surgery on a patient, and which implant to place in that patient, should not personally profit the surgeon. This means that the surgeon should not receive any royalty for that implant, should have no increase in his or her consulting fee based on the placement of that implant, and should not have substantial ($\geq 5\%$) ownership interest in the implant company.

Dr. Zdeblick also wrote:

Under an appropriate conflict-of-interest plan, any investigator who has substantial financial ties to an industrial sponsor must disclose those ties to individual patients.

According to documents given to me by Medtronic, Dr. Zdeblick receives millions of dollars in royalty payments every year from Medtronic for several of their devices. For instance in 2007, Medtronic paid Dr. Zdeblick royalties for the artificial disc Maverick (\$144,158), the Z Plate System (\$76,518), the Premier Anterior Cervical Plate System (\$654,065), the Novus LT Cage (\$1,402,964), the Vantage Anterior Fixation System (\$237,652), and the Prestige Disc (\$92,979).

Because of Dr. Zdeblick's statement that a surgeon treating a patient "should not receive any royalty for that implant," I am wondering if Dr. Zdeblick has implanted any of these devices into patients at your hospital. If he has implanted any of these Medtronic products, I am wondering if Dr. Zdeblick has "disclos[ed] those ties to individual patients."

Accordingly, please respond to the following questions. For each question, please respond by first repeating the enumerated question followed by the appropriate answer.

1. Since January 2006, has Dr. Zdeblick implanted any of the following devices into patients? If the answer is yes, please explain on how many occasions Dr. Zdeblick implanted the specific device.
 - a. the artificial disc Maverick;
 - b. the Z Plate System;
 - c. the Premier Anterior Cervical Plate System;
 - d. the Novus LT Cage;
 - e. the Vantage Anterior Fixation System; and
 - f. the Prestige Disc.

^[1] "Symposium on Relationships with Industry: Critical for New Technology or an Unnecessary Evil?" *The Journal of Bone and Joint Surgery, Incorporated*, Presentation at the Annual Meeting of the American Orthopaedic Association, Huntington Beach, California, June 24, 2005.

2. If Dr. Zdeblick implanted any of the above named devices, please explain if Dr. Zdeblick disclosed his ties with Medtronic to the patient. For each incident, please provide the disclosure form that was given to the patient.

I look forward to hearing from you by no later than January 26, 2009. Any additional 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 or Christopher Armstrong at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on Finance

cc: Raynard Kington
Acting Director
National Institutes of Health

Attachment

**Selected Disclosures by Dr. Zdeblick (University of Wisconsin)
and Related Information Reported by Device Manufacturers**

Year	Company	Disclosure Filed with University	Amount Company Reported
2003	Medtronic	>\$40,000	\$4,553,000
2004	Medtronic	≥\$20,000	\$4,641,000
2005	Medtronic	≥\$20,000	\$3,894,000
2006	Medtronic	≥\$20,000	\$3,627,000
2007	Medtronic	≥\$20,000	\$2,641,000
	Anulux	≥\$45,000	n/a

Note: When a Physician named a company in a disclosure but did not provide an amount, the text reads “no amount reported.” When a Physician did not list the company in the disclosure, the column reads “not reported.” The Committee contacted several companies for payment information and the notation “n/a” (not available) reflects that a company was not contacted.