United States Senate Committee on Finance

Sen. Chuck Grassley · Iowa Ranking Member

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<u>MEMORANDUM</u>

TO: Reporters and Editors FR: Jill Kozeny, 202/224-1308

for U.S. Senator Chuck Grassley of Iowa

RE: Support for the Physician Payments Sunshine Act, S.2029

DA: Wednesday, February 27, 2008

Senator Chuck Grassley, Ranking Member of the Committee on Finance, today commented on statements made yesterday by Medtronic, Inc. and AdvaMed in support of disclosing payments made by pharmaceutical drug, medical device and biotechnology companies to physicians.

In addition, in a hearing of the Senate Special Committee on Aging to be held this morning, Zimmer Holdings Inc. will voice its "strong support" for the Physician Payments Sunshine Act (S.2029). The legislation would require pharmaceutical drug, medical device and biotechnology companies to disclose payments to physicians.

In recent years, the Department of Justice has settled several lawsuits with companies for improperly compensating medical doctors. Last September, Senator Grassley and Senator Herb Kohl, Chairman of the Special Committee on Aging, introduced S.2029 to throw a spotlight on the ways companies compensate doctors. These payments have been found in some cases to alter medical judgment in ways that benefit companies at the expense of patient care.

Here is Senator Grassley's comment:

"These device makers deserve a lot of credit for getting ahead on this important issue and endorsing the objectives of our legislation. It's good to see corporate support for bringing transparency to practices in the pharmaceutical drug, device and biotechnology industry."

The text of the statements from Medtronic, Inc and AdvaMed is below, along with a summary of S.2029.

Tuesday, Feb. 26, 2008

Medtronic Statement Regarding Senate Hearings on Industry and Physician Relationships

MINNEAPOLIS - In advance of hearings on Wednesday, February 27, in the Senate Special Committee on Aging, Medtronic, Inc. (NYSE:MDT), today issued the following statement:

On Wednesday, February 27, the Senate Special Committee on Aging will explore relationships between industry and physicians and consider the proposed "Sunshine Act" (S.2029) introduced earlier this year by Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI).

The Sunshine Act would require industry to publicly disclose via the Internet certain payments made to physicians in return for their time and expertise with product development, research and training. For decades, the innovative power and clinical expertise of physicians have produced technologies that industry has brought to patients around the world, and Medtronic believes these vital collaborations must be protected.

The Sunshine Act is aimed at curbing inappropriate relationships or conflicts of interests between industry and physicians, an effort that Medtronic - one of the world's leading medical technology companies - supports.

Medtronic believes, however, the bill can and should go even further by requiring the same level of disclosure by all companies in the industry, regardless of size and including those companies owned in whole or in part by physicians. Companies with yearly revenues less than \$100 million and physician-owned companies are currently excluded from the bill, and they account for more than 75 percent of the companies in the industry.

Medtronic believes a level playing field for all companies is appropriate and that these entities should operate under the same disclosure requirements, recognizing that transparency can help alleviate any real or perceived conflicts of interest with these types of companies as well.

"We have been pleased to work with the members of the Senate Special Committee on Aging, the Senate Finance Committee, and members of the House of Representatives and Senate on this legislation," said Bill Hawkins, president and CEO of Medtronic. "We will continue to work with the sponsors of this legislation to incorporate all companies in the industry into the bill and bring greater transparency to these important relationships."

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 27, 2007. Actual results may differ materially from anticipated results.

Medtronic, Inc. Rob Clark, 763-505-2635 Government Affairs or Martha Goldberg

AdvaMed Suggests Changing Disclosure Bill 02/26/2008

Saying it supports appropriate disclosure of medical device industry financial relationships with doctors, AdvaMed released recommendations for seven changes to the Physician Payment Sunshine Act (S. 2029). The release came the day before the association was to testify at a Senate Special Committee on Aging 2/27 hearing on the issue.

"Continued innovation in medical technology relies on direct interaction with physicians who have first-hand clinical experience with advanced medical treatments in their practice of patient care," said AdvaMed CEO Stephen Ubl. "Our industry works closely with physicians to invent new medical devices, improve existing technologies, and provide training to physicians to ensure they can use devices safely and effectively. The importance of the relationship between physicians and medical technology innovators cannot be understated. It is a critical component of the engine that drives the next wave of medical advancements. In an effort to underscore the importance of physician/medical innovator collaboration, and to ensure openness with these relationships, AdvaMed would support S. 2029 provided that key changes are made to the bill."

Ubl said the bill could be significantly improved by: expressly preempting state disclosure laws to ensure consistency in application and patient understanding; applying the requirements to all companies that make a significant amount of aggregate payments to physicians, while excluding those that do not; requiring compliance by physician-owned manufacturers, distributors, and group purchasing organizations; displaying disclosure information in a meaningful and easily-understood format that provides the appropriate context for patient education; protecting manufacturers' proprietary information for technologies under development by ensuring that disclosure of consulting arrangements for clinical trials and product development agreements are required only after a product is cleared or approved by FDA; exempting reporting of medical textbooks, anatomical models, or items having a fair market value of less than \$100 that benefit patients, relate to physicians' work, or serve an educational function; and exempting certain items, such as demonstration units and models for physician and patient evaluation.

Meanwhile, Medtronic, which also is to testify at the hearing, said the legislation should go further by requiring the same level of disclosure by all companies in the industry, regardless of size and including those companies owned in whole or in part by physicians. Medtronic said the bill as drafted exempts companies with yearly revenues less than \$100 million and physician-owned companies, but they account for more than 75% of the industry's companies. "Medtronic believes a level playing field for all companies is appropriate and that these entities should operate under the same disclosure requirements, recognizing that transparency can help alleviate any real or perceived conflicts of interest with these types of companies as well," the Medtronic statement said.

Summary of S. 2029, as introduced. Physician Payments Sunshine Act of 2007

- (a) REPORTING: requires drug and device companies to report, on a fiscal-year quarterly basis, any payment or transfer of value to any physician.
 - a. Each electronic disclosure must include:
 - i. Name of physician or entity;
 - ii. Physical address;
 - iii. The facility with which the physician is affiliated, if any;
 - iv. The value of the payment or other transfer of value;
 - v. The date on which the payment or transfer was made;
 - vi. description of the nature of the payment, including compensation, food, entertainment, or gifts, trips or travel, a product or other item at less than market value, educational programs, product rebates, consulting fees or honoraria, or any other benefit as defined by the secretary; and
 - vii. The medical issue or condition addressed, if any.
- (b) SUMMARY: each manufacturer must submit an annual summary report.
- (c) PENALTIES: \$10,000 to \$100,000 for failure to report.
- (d) WEBSITE: the Secretary shall establish procedures to ensure that the

information is made accessible to the public through a website that

is searchable, downloadable, and understandable.

(e) REPORT TO CONGRESS: no later than April 1 of each year beginning in 2009, the

Secretary shall report to congress a summary of the data

reported and enforcement actions taken.