COMMITTEE ON FINANCE
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BAUCUS-GRASSLEY INVESTIGATION INTO MEDTRONIC REVEALS MANIPULATED STUDIES, CLOSE FINANCIAL TIES WITH RESEARCHERS

Medtronic Employees Wrote and Edited Peer-Reviewed Studies of Company's Bone-Growth Product InFuse without Disclosure

Washington, DC – Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) today released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products. Without public disclosure of their roles, Medtronic employees collaborated with physician authors to edit – and in some cases, write – segments of published studies on its bone-growth product InFuse. The studies as published may have inaccurately represented InFuse's risks and may have placed added weight on side effects of alternative treatments. Medtronic, which describes itself as "the world's largest independent medical technology company," also maintained significant, previously-undisclosed financial ties with physicians who authored studies about InFuse, making $210 million in payments to physicians over a 15-year period.

"Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has," Senator Baucus said. **"Patients everywhere will be better served by a more open, honest system without this kind of collusion."**

"These findings emphasize the value of the Grassley-Kohl Physician Payments Sunshine Act, which will result in public disclosure of industry payments to physicians starting next year. The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and studies they feature," Grassley said. **"These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."**

In 2002, The Food and Drug Administration (FDA) approved InFuse for use stimulating spinal bone growth in patients with a degenerative disease affecting the lower spine. According to Medtronic, InFuse has been used to treat more than 500,000 patients.

The report released today by Senators Baucus and Grassley on behalf of the Finance Committee – which has sole jurisdiction over Medicare and Medicaid – is the product of an investigation they began in June 2011. Medtronic cooperated with the committee's inquiry and produced more than 5,000 documents pertaining to 13 different studies of InFuse for the investigation. The full report on the investigation is available on the Finance Committee's website here. Major findings of the investigation include:

- Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles. Medical journals should ensure any industry role in drafting articles or contributions to authors be fully disclosed.

- Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

- An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with InFuse in a 2005 *Journal of Bone and Joint Surgery* article.

- Medtronic officials inserted language into studies that promoted InFuse as a better technique than an alternative by emphasizing the pain associated with the alternative.

- Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to InFuse being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

Senators Baucus and Grassley have led several major investigations of the health care industry to protect consumers and taxpayer dollars. Earlier this year, they kicked off an ongoing investigation into the connections of several drug manufacturers with medical groups and physicians who have advocated the increased use of narcotic painkillers, or opioids. Last year, they released an investigation detailing tactics used by major for-profit home health companies to game Medicare. Also in 2011, when their investigation found that the drug company Sanofi interfered in the approval of generic alternatives to its blood-thinner drug Lovenox, the senators called on the FDA to help guarantee consumers have access to affordable generic medications. In 2010, Baucus and Grassley released a report detailing the relationship between Abbott labs and a Maryland doctor who allegedly implanted nearly 600 unnecessary cardiac stents into his patients, costing the federal government as much as $3.8 million in Medicare overpayments. The senators also spearheaded a two year inquiry which revealed undisclosed side effects of the diabetes drug Avandia. This resulted in the FDA restricting use of the drug, ensuring that patients and doctors have the information they need to make safe, informed decisions about their medication.

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