

March 7, 2008

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The Honorable Charles E. Grassley Ranking Member, Committee on Finance United States Senate 215 Dirksen Senate Office Building Washington, D.C. 20510-6200

## Dear Senator Grassley:

Boston Scientific appreciates the opportunity to respond to your February 26, 2008, letter. Since its founding in 1979, Boston Scientific has pioneered the development of less-invasive medical technologies to advance quality patient care. We are currently comprised of nine business units developing treatments and solutions for a wide array of conditions, including cardiac and vascular diseases, digestive and genitourinary diseases, and pain management.

Many of the technologies that we have developed, such as cerebrovascular coiling of aneurysms (replacing surgical clipping via craniotomy), rotational atherectomy to open nearly totally occluded arteries (replacing open-heart surgery), implantable cardioverter defibrillators (breakthrough technology in the prevention of sudden cardiac death), drugeluting stents, etc., have ultimately become the standard of care for clinicians worldwide. These leading technologies were not developed solely within the four walls of Boston Scientific, but rather were the result of broad, productive collaboration with those who use these products – physicians and other health care providers. We are very proud of our heritage of innovation that has been built on these relationships, innovation that has delivered a broad array of devices that help improve and save lives.

Boston Scientific supports the goal of greater transparency regarding relationships between physicians and the medical device industry. As we address transparency, we believe that it is important to bear in mind the importance – indeed, the essential nature – of collaboration between health care providers and the device industry. This collaboration, the degree of which is unique to the medical device industry, is critical in the research, development and training on innovative medical technology.

As such, we hope you agree that a disclosure program need not imply that all physician relationships are inappropriate. To infer otherwise:

• Would be a disservice to physicians who take very seriously their legitimate role in bringing new technologies to patients;

- Could serve as a disincentive for physicians to participate in the development of, improvement of, and training on the use of medical devices with the ultimate adverse impact on patients;
- Would harm the public interest by chilling the innovation that results from physician and industry collaboration.

Patients, and more broadly the public interest, benefit tremendously from collaboration of this type. Physicians, by nature of their close work with patients and their understanding of patient experiences, are in a unique position to provide informed, patient-centric input to companies on how to improve product design and how to address unmet patient needs.

Physicians also play a fundamental role in conducting scientifically-driven clinical trials, without which new life-saving technologies could not be tested or brought to market. Further, favorable patient outcomes depend on physicians being skilled in the use of devices. As such, physicians play an essential role in education and training on the safe and effective use of our products. Indeed, for some of our products, the FDA requires that we conduct physician training before a physician can implant our devices.

The government has recognized the important public interest furthered by the appropriate collaboration between physicians and medical device companies. At the recent hearing of the Senate Special Committee on Aging, a representative from the U.S. Department of Health and Human Services, Office of Inspector General, testified:

Relationships between physicians and the health care industry, including pharmaceutical and device manufacturers and suppliers, can advance medical science and benefit patients. In the development of new technologies and products, the interaction between device manufacturers and health care professionals can be especially valuable because physicians play an essential role in the development, testing, and extensive training involved in producing effective and safe medical devices, such as heart valves, pacemakers, and medical lasers. Physicians also provide ideas and feedback, conduct research and clinical trials, and share their knowledge through participation in medical education programs. Device companies can legitimately compensate physicians for their actual time and intellectual contributions to product innovations and training in the appropriate use of devices.

Boston Scientific also believes that transparency should apply to <u>all</u> entities involved in the manufacture and sale of medical devices, regardless of size – including companies with less than \$100 million in annual sales. As you may be aware, the majority of medical device companies – perhaps as many as seventy-five percent – fall below the \$100 million sales threshold. In addition, to avoid potentially over-lapping and conflicting state requirements, we believe it is critically important that any federal legislation clearly pre-empts state law.

Recognizing this critical need for appropriate collaborative relationships, while mindful of the potential questions collaboration may raise, Boston Scientific is highly attentive to compliance with the legal and ethical requirements governing our financial relationships with health care providers. We have actively participated in the development of the AdvaMed Code for medical technology companies and are committed to ensuring that our policies align with all laws and support the highest ethical practices.

To that end, we have internal processes that govern the review and approval of payments to healthcare providers. These include the use of established criteria to help ensure that we consistently evaluate financial transactions such as educational grants and other charitable contributions in a way that does not inappropriately link them to any past, present or future business considerations. Like Eli Lilly, whose efforts your letter commends, we too are proud of our commitment to fund quality research and educational programs that advance technology and patient care.

As a large and global company, Boston Scientific has a financial reporting system that is designed to comply with all applicable legal and financial reporting standards. The proposed Physician Payments Sunshine Act would impose data tracking and disclosure obligations that are broader and more complex than the current financial system was designed to accommodate, and, as such, additional enhancements would require a fairly significant investment by the company. Nonetheless, conscious of the public benefit driven by transparency, in mid-2007 we commenced a project to develop the systems necessary for disclosure of payments to physicians, institutions, patient organizations and medical societies. We have a project leader, executive sponsors, and a project team actively working on design requirements, specifications and deliverables.

This is a large undertaking and certain types of data will be more readily accessible than others. We are committed to developing the systems necessary to meet the fair and reasonable standards of transparency that the public expects, and will apply the resources required to implement these systems. To ensure that we are able to meet all the reporting requirements accurately and timely, we would ask that the introduction of such legislation take into account an appropriate development timeline.

Boston Scientific has demonstrated its commitment to appropriate customer relationships and transparency in a number of other areas. As one of the leading medical technology companies in the world, Boston Scientific is committed to setting high standards in everything we do - from the way we collaborate with health care professionals, to the manner in which we report on product performance.

- This commitment to high standards is reflected in our role as a long time supporter of AdvaMed's Code of Ethics. We are proud to be a founding member of the team that created the AdvaMed Code and one of the first AdvaMed member companies to sign the Code of Ethics Licensing Agreement.
- The Boston Scientific Code of Conduct and Compliance Programs are key components of our commitment to conducting business with integrity in everything we do, and in the spirit of transparency are displayed on

<u>www.bostonscientific.com</u>. Continued honest and ethical business conduct earns us the trust of customers, patients, suppliers, investors, regulators, and fellow employees.

- Boston Scientific is committed to providing physicians and patients with timely, meaningful, and accurate product performance information. We have demonstrated leadership in this area for our Cardiac Rhythm Management products through our industry-leading Product Performance Report, which is also readily available on the Boston Scientific website. The Report meets or surpasses all Heart Rhythm Society expectations for product performance reporting.
- Finally, the Boston Scientific website also includes information on grants distributed by the Boston Scientific Foundation. This information is available through the "Making a Difference in the Community" link on our homepage.

We are proud of the work we have undertaken so far to provide greater transparency to our customers and patients, but recognize there is more to accomplish and have proactively taken steps to achieve the types of disclosures contemplated by your proposed legislation. We appreciate the opportunity to respond and to share our views and plans on this topic.

Yours truly

James R. Tobin

President and Chief Executive Officer

**Boston Scientific**