ONE HUNDRED TENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5051
FACSIMILE (202) 225–4784
MINORITY (202) 225–5074
TTY (202) 225–6852

http://oversight.house.gov

February 28, 2007

James Tobin
President and Chief Executive Officer
Boston Scientific Corporate Headquarters
One Boston Scientific Place
Natick, MA 01760-1537

Dear Mr. Tobin:

Concerns about the safety and off label use of drug-eluting cardiac stents were raised by a recent FDA panel.[1] As part of the Committee's ongoing oversight of the medical device industry's research and marketing practices, I am writing to request information about these concerns and drug-eluting cardiac stents.

The Committee requests that Boston Scientific provide the following information relating to Taxus stents:

1. A listing of all trials, studies, or reports initiated, supported, or sponsored by Boston Scientific relating to Taxus stents, including any conducted outside the United States. This list should include those trials, studies, or reports for any premarket approval application (PMA), including any supplemental applications. For each such trial, study or report, provide the following information:
    a. The name of the authors and physicians that participated;
    b. The number of participants;
    c. The date it was initiated, completed, or terminated. If terminated, explain the reasons behind the termination.
    d. A summary of the methodology, findings, and conclusions;
    e. Whether the marketing department provided funding or other support for this study;

[1] FDA, *Circulatory System Devices Panel Meeting* (Dec. 7-8, 2006); *The Case Against Stents: New Studies Hint at Overuse,* Wall Street Journal (Jan. 23, 2007).

f. Whether any compensation or benefit, monetary or otherwise (including support or assistance in creating manuscripts), was provided to any author, physician, or participant;

g. For those studies published or presented at major medical meetings, a copy of all publications and abstracts; and

h. If not published or presented, an explanation for why the study was not published or presented;

2. All documents relating to the development of the printed label that accompanied Taxus stents. This should include all communications with FDA and those within your company;

3. All documents relating to Taxus stents provided to the December 2006 FDA advisory committee;

4. The following documents related to Taxus stents from March 2003 to the present time:

   a. All presentations, training sessions, or materials given to employees or agents who marketed or otherwise promoted Taxus stents, including speakers and consultants;

   b. All pamphlets, literature, and other information to be shown or given to physicians by sales representatives. Please also provide all related communications;

   c. Any other communications provided to healthcare providers regarding the safety and efficacy of Taxus stents, including direct presentations to physicians such as conference calls. Please also provide all related communications;

   d. All documents related to adverse event data from the Swedish Coronary Angiography and Angioplasty Registry;

   e. All internal or external presentations or reports based on the marketing plan for taxus stents, and all communications related to these presentations or reports;

   f. All internal or external presentations or reports relating to continuing medical education, and all communications related to these presentations or reports;

   g. All internal or external presentations or reports relating to off-label use, and all communications related to these presentations or reports;

   h. All documents related to the presence of sales representatives in the cardiac catheterization suites;

   i. All documents relating to funding support provided for nonprofit professional medical organizations or consumer/patient organizations such as the

Cardiovascular Research Foundation, the Transcatheter Cardiovascular Therapuetics or the Society of Cardiovascular Angiography; and

j. All marketing department correspondence with nonprofit professional medical organizations or consumer/patient organizations such as the Cardiovascular Research Foundation, the Transcatheter Cardiovascular Therapuetics, or the Society of Cardiovascular Angiography.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. An attachment to this letter provides additional information on how to respond to the Committee's request.

I request that you provide these documents by March 21, 2007. If you have any questions regarding this request, please contact Stephen Cha with the Committee staff at (202) 225-5056.

Sincerely,

Henry A. Waxman
Chairman

Enclosure