

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER
TO AID PUBLIC COMMENT**

*In the Matter of Boston Scientific Corporation and Guidant Corporation
File No. 061 0046*

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Boston Scientific Corporation (“Boston Scientific”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from Boston Scientific’s acquisition of Guidant Corporation (“Guidant”). Under the terms of the proposed Consent Agreement, Boston Scientific and Guidant are required: (a) to divest all assets (including intellectual property) related to Guidant’s vascular business to a third party, enabling that third party to make and sell drug eluting stents (“DESs”) with the Rapid Exchange (“RX”) delivery system; Percutaneous Transluminal Coronary Angioplasty (“PTCA”) balloon catheters; and coronary guidewires, and (b) to reform Boston Scientific’s contractual rights with Cameron Health, Inc. (“Cameron”) to limit Boston Scientific’s control over certain Cameron actions and the sharing of non-public information about Cameron’s Implantable Cardioverter Defibrillator (“ICD”) product.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw the proposed Consent Agreement or make it final.

Pursuant to an Agreement and Plan of Merger dated January 25, 2006, Boston Scientific proposes to acquire Guidant in exchange for cash and voting securities in a transaction valued at approximately \$27 billion. The Commission’s complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an imminent competitor from the U.S. market for DESs and by lessening competition in the U.S. markets for PTCA balloon catheters and coronary guidewires. The proposed Consent Agreement would remedy the alleged violations by requiring a divestiture that will replace the competition that otherwise would be lost in these markets as a result of the acquisition.

Boston Scientific is a worldwide developer, manufacturer, and marketer of medical devices used in a broad range of interventional medical specialties such as interventional cardiology, peripheral intervention, and vascular surgery. In 2005, Boston Scientific reported worldwide sales of approximately \$6.3 billion, with U.S. sales of \$3.8 billion.

Guidant manufactures products in three broad business units: cardiac rhythm management (“CRM”), vascular intervention, and cardiac surgery. In 2005, Guidant’s sales were \$3.6 billion globally, with U.S. sales of \$2.3 billion. Guidant’s DES program, PTCA balloon catheters, and coronary guidewires are part of the vascular intervention business unit, while its

ICD products are a part of the CRM business unit.

Drug -Eluting Stents

A DES is a medical device typically consisting of a thin, metallic stent coated with an antiproliferative drug and a polymer, mounted on a delivery system. Interventional cardiologists use DESs to treat coronary artery disease, a condition caused by the build-up of plaque deposits within one or more coronary arteries, leading to reduced blood flow. DESs work by propping open the clogged artery or arteries and eluting a drug, which helps prevent the renarrowing of the artery, called restenosis. DESs are the most effective minimally-invasive method for treating coronary artery disease, and other products and procedures are not economic substitutes for DESs.

DESs are sold mounted on a delivery system used to deploy the DES to the blocked area of the coronary artery. The two most common types of delivery systems in the United States are over-the-wire and Rapid Exchange (“RX”). Over-the-wire delivery systems employ a long guidewire and require two operators to implant the DES. In contrast, RX delivery systems employ a shorter guidewire that can be handled by a single operator. RX delivery systems currently are strongly preferred by physicians in the United States and continue to increase in popularity. Boston Scientific and Guidant own the intellectual property rights to the RX delivery system in the United States. The companies have cross-licensed each other, and Johnson & Johnson (“J&J”) has access to the RX delivery system through an agreement with Guidant. Both DESs currently on the market, Boston Scientific’s Taxus® and J&J’s Cypher®, are available on an RX delivery system.

The relevant geographic market in which to analyze the effects of the proposed acquisition on the DES market is the United States. DESs are medical devices that are regulated by the United States Food and Drug Administration (“FDA”). Performing the necessary clinical testing and navigating the approval process for the FDA can be burdensome and time-consuming. As such, DESs sold outside the United States but not approved for sale in the United States do not provide viable competitive alternatives for U.S. consumers.

The U.S. market for DESs is highly concentrated; currently only two firms, J&J and Boston Scientific, have products on the market. Guidant’s DES program is still in development, but it is anticipated to be one of at least three entrants, along with Medtronic, Inc. (“Medtronic”) and Abbott Laboratories (“Abbott”), likely to enter the U.S. market by the end of 2007 or early 2008. Guidant is the only anticipated entrant with rights to the intellectual property necessary to market a DES with an RX delivery system – the dominant delivery system in the United States.

Developing and receiving FDA approval for a DES is difficult, time-consuming and expensive. It can take hundreds of millions of dollars of research and development, significant funding for clinical trials, and an extensive amount of time to reach even the stage of seeking FDA approval. The regulatory process itself can also be time-consuming because the FDA

reviews the volumes of materials and data a company submits in support of its application for approval. Considering all these factors, entry into the manufacture and sale of DESs is impossible to achieve within two years.

In addition to the regulatory barriers facing firms seeking to enter the DES market, there are substantial intellectual property barriers an entrant must overcome. Firms must invent around or obtain licenses to patents covering nearly every aspect of a DES, including the design of stents, stent delivery systems, and the drugs and polymers used on DESs. Due to the difficulty of entry, firms must commit to entering the market years in advance of any anticipated entry, and timely and sufficient entry in response to a small but significant price increase is impossible.

The proposed acquisition would cause significant competitive harm in the market for DESs by eliminating Guidant as the only potential competitor to Boston Scientific and J&J with the ability to offer a DES on an RX delivery system. Guidant is the only potential entrant with access to the RX patents and freedom to commercialize its DES product in the United States. Evidence shows a third fully competitive firm – one with access to an RX delivery system – is likely to enhance competition in the DES market. Unless remedial action is taken, the acquisition of Guidant by Boston Scientific would deprive customers of the benefits of a third fully competitive entrant in the U.S. DES market.

As a third RX competitor in the DES market, Guidant likely would increase competition and reduce prices for DESs. Market participants expect that the launch of Guidant's DES product would increase substantially competition in the market. Customers and analysts predict that Guidant's product would take substantial market share from both J&J's and Boston Scientific's products upon its launch. Customers – both interventional cardiologists and hospital purchasing agents – and competitors also agree that a third fully competitive entrant would significantly reduce the price of DES products and be likely to give them the full benefit of competition in the DES market. This view is reinforced by evidence showing that competition between Boston Scientific and J&J already has reduced prices for DESs.

Although two other firms, Abbott and Medtronic, are poised to enter the market in the same approximate time frame as Guidant, their lack of access to the RX delivery system makes it unlikely that either company could be a substantial competitive constraint on prices in the DES market in the near term. The proposed acquisition therefore decreases the number of potential DES suppliers with access to the RX delivery system from three to two until at least late 2008, when Guidant's key patents relating to the RX delivery system begin to expire.

PTCA Balloon Catheters and Coronary Guidewires

PTCA balloon catheters and coronary guidewires are also devices used in interventional cardiology procedures, including DES placement. A PTCA balloon catheter is a long, thin flexible tube (the catheter) with a small inflatable balloon at its tip. During an angioplasty procedure, it is inserted into a blocked coronary artery and inflated to widen the artery and

improve blood flow. The PTCA balloon catheter is delivered to the lesion site over a coronary guidewire, an extremely thin wire with a flexible tip.

As with DESs, the relevant geographic market in which to analyze the effects of the proposed acquisition on the PTCA balloon catheter and coronary guidewire markets is the United States. Both are medical devices regulated by the FDA. PTCA balloon catheters and coronary guidewires sold outside the United States but not approved for sale in the United States do not provide viable competitive alternatives for U.S. consumers.

Boston Scientific and Guidant are the only suppliers in the PTCA balloon catheter and coronary guidewire markets with substantial sales in the United States. In the PTCA balloon catheter market, Boston Scientific is the market leader with a market share of approximately 69 percent. Guidant has a 21 percent market share, and J&J and Medtronic combined account for the remaining 10 percent of the market. Guidant is the market leader in the coronary guidewire market with a 46 percent share of the market, while Boston Scientific has a market share of 39 percent. J&J, Medtronic, and Abbott account for the remaining 15 percent of the market.

Entry into the U.S. markets for PTCA balloon catheters and coronary guidewires is difficult, time-consuming, and expensive. FDA approval, which can take several years to obtain, is required to market both products in the United States. In addition, intellectual property barriers relating to the design of these products exist, and a new entrant would need to successfully navigate through these barriers to enter the PTCA balloon catheter or coronary guidewire market. New entry in these small markets is also unlikely because of the large sales and marketing force necessary to detail these products to physicians compared to the limited size of the likely sales opportunity.

The proposed acquisition is likely to cause competitive harm in the markets for PTCA balloon catheters and coronary guidewires by eliminating competition between Boston Scientific and Guidant and reducing the number of significant competitors in the market. The evidence has also shown that Boston Scientific's and Guidant's products are likely each others' closest competitors in the PTCA balloon catheter and coronary guidewire markets. For example, numerous industry participants consider Boston Scientific and Guidant to be the closest competitors in these markets, a view confirmed by the parties' own documents. Moreover, customers uniformly consider Boston Scientific and Guidant to be their first and second choices for PTCA balloon catheters and coronary guidewires. The proposed acquisition therefore likely would enable the combined Boston Scientific/Guidant to raise prices for PTCA balloon catheters and coronary guidewires unilaterally.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the markets for DESs, PTCA balloon catheters, and coronary guidewires. Pursuant to the proposed Consent Agreement, the combined Boston

Scientific/Guidant is required to divest Guidant's entire vascular business, at no minimum price, to an up-front buyer before Boston Scientific's acquisition of Guidant.

Guidant's vascular business includes, among other things, its DES development program (including the RX delivery system patents) and its PTCA balloon catheter and coronary guidewire products. The parties have selected Abbott as the up-front buyer for the divestiture package. Abbott is a well-known and respected pharmaceutical and diagnostics company that has a number of vascular devices on the market already or in development. It has experience with both drugs and vascular devices, a highly regarded DES design, a strong and growing vascular sales force, and the necessary manufacturing capabilities. As such, Abbott is well-positioned to replicate Guidant's competitiveness in the DES market with the acquisition of the RX intellectual property, and in the PTCA balloon catheter and coronary guidewire markets with the addition of Guidant's product lines in those areas.

Boston Scientific's agreement with Abbott provides Boston Scientific with a license to the Guidant DES program, and Abbott and Boston Scientific will therefore share the Guidant DES program. In addition, Abbott has its own DES product in development upon which it will be able to use the RX delivery system patents. Abbott is poised to become a strong competitor in the DES market when it enters in the second half of 2007 or early 2008, approximately the same time as Guidant's anticipated date of entry. Access to the RX delivery system will allow Abbott to replace Guidant as the third independent competitor in the DES market with an RX delivery system. Because Abbott's DES (after acquiring the RX intellectual property in the divestiture) will resolve the competitive concerns associated with the elimination of the third RX DES, the proposed sharing of the Guidant program between Abbott and Boston Scientific is competitively neutral.

The Consent Agreement contains a number of provisions to help ensure that the divestiture to Abbott is successful. First, in purchasing all of Guidant's vascular business, Abbott will obtain four existing manufacturing facilities and one currently under construction. Although certain Guidant vascular products are manufactured in facilities that are not being transferred, the space dedicated to the Guidant vascular products in those facilities is physically separate, and the manufacturing of those products will be transferred to Abbott-owned facilities in a timely fashion. To minimize the possibility of supply disruptions and to prevent information exchanges between Abbott and Boston Scientific during the transition period, the Consent Agreement requires Abbott and Boston Scientific to enter into interim transitional service and confidentiality agreements.

Finally, Abbott has taken a small equity position (under 5 percent) in Boston Scientific as part of the financing of Boston Scientific's acquisition of Guidant. To limit any long-term entanglements between the parties, the proposed Consent Agreement requires Abbott to relinquish its voting rights (by voting its shares in the same proportion as all other shareholders in shareholder votes) and to divest its equity stake in Boston Scientific within thirty months of closing.

Implantable Cardioverter Defibrillators

ICDs are small electronic devices installed inside the chest to prevent sudden death from cardiac arrest due to abnormal heart rhythms. They are designed to counteract fibrillation of the heart muscle and restore normal heart rhythms by applying a brief electric shock. Three firms – Medtronic, Guidant, and St. Jude Medical – account for more than 98 percent of the \$1.8 billion in annual sales in the U.S. ICD market, and have been the only competitively significant providers of ICDs in the United States for over ten years. Although Boston Scientific does not currently sell and is not developing any ICD products, it owns a ten to fifteen percent equity stake in a CRM start-up known as Cameron Healthcare Inc. More importantly, it has an option to acquire Cameron that provides certain information sharing and control rights prior to the exercise of the option. Cameron is developing a novel, “leadless” subcutaneous ICD that is on track to receive FDA approval in approximately two to three years.

As in the DES, PTCA balloon catheter, and coronary guidewire markets, additional entry into the U.S. market for ICDs is difficult, time-consuming, and expensive. FDA approval is required to market ICDs in the United States and a new entrant would need to navigate around the substantial intellectual property barriers that exist in order to make a significant market impact.

Boston Scientific’s option to acquire Cameron provides Boston Scientific with access to non-public information about Cameron and control over certain actions of Cameron that were originally intended to protect Boston Scientific’s investment. After Boston Scientific is combined with Guidant, those previously unobjectionable provisions may adversely affect competition in the ICD market because they allow the combined Boston Scientific/Guidant to receive information from and exercise control over Cameron – a potentially significant future competitor.

To alleviate these competitive concerns, the proposed Consent Agreement imposes limits on Boston Scientific’s access to Cameron information and on Boston Scientific’s ability to exercise any control over Cameron. First, a firewall will be established that will limit the circumstances under which Boston Scientific will receive Cameron information, as well as the individuals at Boston Scientific who may receive such information. Second, with respect to the control provisions, Boston Scientific will relinquish its right to exercise those provisions unilaterally. Pursuant to the proposed consent order, a proxy will be appointed who will independently determine whether Boston Scientific may exercise its contractual control rights. The purpose of the proxy is to ensure that Boston Scientific makes decisions with respect to the control provisions in the same manner as it would have absent the Guidant transaction. In making that determination, the proxy will act as an ordinary, prudent corporation of the scope of Boston Scientific (prior to the acquisition of the Guidant CRM business).

Finally, with respect to the ten to fifteen percent equity stake held by Boston Scientific in Cameron, Boston Scientific has agreed to provisions similar to those governing Abbott’s equity

investment in Boston Scientific, namely that it will vote its shares in the same proportion as all other shareholders in any shareholder vote. Furthermore, Boston Scientific will divest its equity investment in Cameron within eighteen months if it does not acquire control of Cameron prior to the expiration of its option or if it is enjoined from acquiring Cameron.

To ensure that the Commission will have an opportunity to review any attempt by Boston Scientific to exercise its option to acquire Cameron, the proposed Consent Order contains a prior notice provision committing Boston Scientific to an H-S-R framework even if the transaction otherwise would be non-reportable.

Appointment of an Interim Monitor and a Divestiture Trustee

The proposed Consent Agreement contains a provision that allows the Commission to appoint an interim monitor to oversee Boston Scientific's compliance with all of its obligations and performance of its responsibilities pursuant to the Commission's Decision and Order. The interim monitor is required to file periodic reports with the Commission to ensure that the Commission remains informed about the status of the divestitures, about the efforts being made to accomplish the divestitures, and the provision of services and assistance during the transition period for the divestiture.

Finally, the proposed Consent Agreement contains provisions that allow the Commission to appoint a divestiture trustee if any or all of the above remedies are not accomplished within the time frames established by the Consent Agreement. The divestiture trustee may be appointed to accomplish any and all of the remedies required by the proposed Consent Agreement that have not yet been fulfilled upon expiration of the time period allotted for each one.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.