ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER
TO AID PUBLIC COMMENT
In the Matter of Johnson & Johnson
File No. 051 0050

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Johnson & Johnson ("J&J"). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from J&J's acquisition of Guidant Corporation ("Guidant"). Under the terms of the proposed Consent Agreement, J&J is required to (a) grant to a third party a fully paid-up, non-exclusive, irrevocable license, enabling that third party to make and sell drug-eluting stents ("DESs") with the Rapid Exchange ("RX") delivery system, (b) divest to a third party J&J's endoscopic vessel harvesting ("EVH") product line, and (c) terminate its agreement to distribute the proximal anastomotic assist device ("AAD") of Novare Surgical System, Inc. ("Novare").

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 from the proposed Consent Agreement or make it final.

Pursuant to an Agreement and Plan of Merger dated December 15, 2004, J&J proposes to acquire Guidant in exchange for cash and voting securities in a transaction valued at approximately $25.4 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 EVH devices and proximal AADs. The proposed Consent Agreement would remedy the alleged violations by replacing the competition that would be lost in these markets as a result of the acquisition.

J&J is a comprehensive and broadly-based manufacturer of products related to all aspects of human health care. In 2004, J&J generated global sales of $47.3 billion and U.S. sales of $27.7 billion. J&J is divided into three business segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics. The products impacted by the proposed transaction, DESs, EVH devices, and proximal AADs, fall within J&J's Medical Devices and Diagnostics segment.

Guidant manufactures products in three broad business units: cardiac rhythm management, vascular intervention, and cardiac surgery. In 2004, Guidant's sales were $3.8 billion globally and $2.53 billion in the United States. Guidant's DES program is part of its vascular intervention business unit, and the company's EVH device and proximal AAD are part of the cardiac surgery 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 system 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, the RX delivery system employs a shorter guidewire that can be handled by a single operator. RX delivery systems currently are highly preferred by physicians in the United States and are increasing in popularity. Boston Scientific Corporation and Guidant own the intellectual property rights to the RX delivery system in the United States. The companies have cross-licensed each other, and J&J has access to the RX delivery system through an agreement with Guidant. Both DESs currently on the market, J&J's Cypher® and Boston Scientific's Taxus®, are available on the 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 of 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. and Abbott Laboratories, likely to enter the U.S. market by the end of 2007. Guidant is the only anticipated entrant with rights to the intellectual property necessary to market a DES with the 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 even reach the stage of seeking FDA approval. The regulatory process itself can also be time-consuming as 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 to three 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 with the ability to offer a DES on an RX delivery system. As a third RX entrant into the DES market, Guidant likely would increase competition and reduce 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 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. (The relevant Boston Scientific RX patents begin to expire this year).

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the market for DESs. Pursuant to the proposed Consent Agreement, the combined J&J/Guidant is required to license Guidant's intellectual property surrounding the RX delivery system at no minimum price to an up-front buyer with a DES program in development no later than ten (10) days after the acquisition is consummated. Through the course of the investigation, Commission staff gathered a great deal of information about each of the companies developing DES products. In particular, staff investigated potential divestiture candidates and concluded that Abbott was among the companies well-positioned to replicate the competitive impact Guidant was likely to have absent the proposed acquisition. 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. Abbott, therefore, is poised to become a strong competitor in the DES market when it enters in the second half of 2007, 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 entrant into the DES market with an RX delivery system.

The Commission's merger remedies are intended to maintain or to restore the competitive *status quo*. The Commission does not, as a matter of course, seek to "improve" on pre-transaction competition. Based on the evidence gathered in the investigation, the Commission has determined that the license to Abbott should replicate the competitive conditions in DESs

that existed prior to the proposed transaction between J&J and Guidant. As a result, a Commission order requiring licenses to additional parties is not necessary.

Given the uncertainty inherent in a development program, the RX license contemplated by the proposed Consent Agreement is transferable, so that if Abbott's DES program is not successful, it will have the incentive and ability to transfer the RX license to another firm developing a DES, ensuring that a successful third DES firm is able to enter the market with an RX delivery system in the relevant timeframe. The proposed Consent Agreement also requires the parties to enter into a covenant not to sue Abbott in relation to certain intellectual property rights regarding stent design, stent coating and the use of certain drugs on a stent.

Endoscopic Vessel Harvesting Devices

EVH devices are used in coronary artery bypass graft ("CABG") surgery to remove a patient's leg vein, arm artery, or other blood vessel that is then used as a conduit to bypass one or more blocked coronary arteries. EVH devices allow for a minimally-invasive procedure requiring only one to three small incisions. EVH has several clinical benefits over the other methods of vessel harvesting (the open method and bridging) both of which are much more invasive, leave large, unsightly scars and carry a greater risk of infection. Surgeons and physician's assistants would not switch to these other methods of vessel harvesting even if the price of using EVH devices increased by five to ten percent.

As with DESs, the United States is the relevant geographic market in which to analyze the effects of the proposed acquisition on the EVH device market. EVH devices are also medical devices subject to regulation by the FDA. Receiving FDA approval to market an EVH device in the United States can be a lengthy process, but is necessary in order to sell the devices in the Unites States. EVH devices sold outside of the United States but not approved by the FDA for sale in the United States therefore do not provide viable competitive alternatives for U.S. consumers.

The U.S. market for EVH devices is highly concentrated with J&J and Guidant as the only competitors until very recently, when Terumo Corporation entered. Guidant currently dominates the market with over eighty percent market share. Terumo received FDA approval for its device in January, 2005 and has yet to generate significant sales.

Firms seeking to enter the market for EVH devices face regulatory hurdles and significant intellectual property barriers, both of which make entry into the market for EVH devices in the next two to three years highly unlikely. In addition, while the use of EVH devices in CABG surgery is increasing, the number of overall CABG surgeries appears to be decreasing due to, among other things, the increase in stenting procedures; this steady decline in the number of CABG procedures being performed in the United States makes it less likely that firms would choose to enter the EVH device market in response to a modest increase in the price of the devices.

The proposed acquisition would constitute a virtual merger to monopoly in the market for EVH devices and is likely to lead to increased prices and decreased innovation in the market for those devices. Until recently, Guidant and J&J were the only two firms to offer an EVH device in the United States, and while Terumo recently entered, it is likely that it will take several years before Terumo's device has a significant impact on the market for EVH devices.

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the market for EVH devices by requiring J&J to divest its EVH product line to a Commission-approved buyer at no minimum price. J&J has reached an agreement to divest the EVH business to Datascope. Datascope, a diversified medical device company, has a line of products used in cardiac surgery, including products used in CABG procedures. Pursuant to the Consent Agreement, J&J is required to accomplish the divestiture of its EVH product line no later than fifteen (15) business days after the acquisition is consummated.

The proposed Consent Agreement permits the Commission-approved buyer of the EVH product line assets to enter into a supply agreement with J&J for a period of up to two (2) years. The supply agreement may be necessary because of the need to recreate or move manufacturing and/or packaging equipment and to allow time for the acquirer to receive approval from the FDA to begin manufacturing and/or packaging EVH device kits in its own facility. This supply agreement may also be necessary to allow J&J to supply certain components of the EVH devices until the acquirer is able to procure similar components from third-party vendors.

In addition, the proposed Consent Agreement permits J&J to provide certain transitional services to the Commission-approved buyer of the EVH product line assets. These transitional services may be necessary for a smooth transition of the product line to the acquirer and to ensure continued and uninterrupted service to customers during the transition.

Proximal Anastomotic Assist Devices

Surgeons use proximal AADs in CABG procedures to avoid the need to clamp the aorta when attaching a harvested vessel to it. If a proximal AAD is not used, the surgeon must use a clamp to stop the flow of blood to a segment of the aorta while the harvested vessel is surgically attached. Using a clamp can cause calcified plaque particles to dislodge from the aorta and travel through the blood stream to the brain, risking neurological dysfunction or stroke.

The proper geographic market in which to analyze the effects of the proposed transaction on the market for proximal AADs is the United States. Proximal AADs are medical devices that must be approved by the FDA before being marketed in the United States. As with other medical devices, the clinical testing and regulatory approval process for proximal AADs can be costly and time-consuming, preventing proximal AADs approved outside of the United States but not approved within the United States from serving as a competitive alternative for U.S. consumers.

There are currently three firms in the U.S. market for proximal AADs, making it a highly concentrated market. The evidence indicates that J&J and Guidant's manual proximal AADs are each others' closest competitors. Medtronic also participates in the market with an automatic device that it recently launched in the United States. A fourth firm, St. Jude Medical, removed its automatic device, Symmetry®, from the market last year amidst reports of device failures. J&J's proximal AAD, eNclose®, was developed and is manufactured by Novare; J&J and Novare have a distribution agreement making J&J the sole distributor of eNclose® in the United States.

As with the other medical devices discussed, entry into the market for proximal AADs is difficult, costly, and time-consuming. Additionally, the alleged safety concerns regarding St. Jude's Symmetry device have resulted in greater scrutiny of proximal AADs by the FDA. The increased scrutiny is likely to substantially increase the cost of developing a proximal AAD. In addition, it appears that the publicity surrounding Symmetry's removal from the market has dampened physician enthusiasm for these devices. These developments, along with the declining number of overall U.S. CABG procedures, decrease the likelihood of entry into this market.

The proposed acquisition is likely to cause significant competitive harm in the market for proximal AADs by eliminating competition between J&J and Guidant and reducing the number of competitors in the market from three to two. The evidence has also shown that J&J and Guidant's products are likely each others' closest competitors in the proximal AAD market because they are more similar to each other than to Medtronic's product. The proposed acquisition is therefore likely to enable the combined J&J/Guidant to raise prices for proximal AADs unilaterally.

The proposed acquisition's anticompetitive effects in the market for proximal AADs are remedied by the proposed Consent Agreement's requirement that J&J terminate its distribution agreement with Novare for Novare's proximal AAD, eNclose. It is anticipated that it will take Novare no more than two months to find a new distribution partner for eNclose.

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 J&J'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 EVH 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 required 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.

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.