ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of Medtronic, Inc. and Covidien plc, File No. 141 0187

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted from Medtronic, Inc. ("Medtronic") and Covidien plc ("Covidien"), subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") designed to remedy the anticompetitive effects resulting from Medtronic's proposed acquisition of Covidien. Under the terms of the proposed Decision and Order ("Order") contained in the Consent Agreement, the parties are required to divest Covidien's drug-coated balloon catheter business to The Spectranetics Corporation ("Spectranetics").

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make it final.

Pursuant to a Transaction Agreement dated June 15, 2014, Medtronic proposes to merge with Covidien in exchange for cash and stock valued at approximately $42.9 billion (the "Proposed Acquisition"). 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 substantially lessening competition in the U.S. market for drug-coated balloon catheters indicated for the femoropopliteal ("fem-pop") artery. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

THE PARTIES

Headquartered in Minneapolis, Minnesota, Medtronic is a global leader in medical technology that develops, manufactures, and sells device-based medical therapies. Medtronic is developing a drug-coated balloon catheter indicated for the fem-pop artery that is currently in the Food and Drug Administration ("FDA") approval process.

Headquartered in Dublin, Ireland, Covidien develops, manufactures, and sells medical devices and medical supplies. Like Medtronic, Covidien has a drug-coated balloon catheter indicated for the fem-pop artery under development for which it is seeking FDA approval.

THE RELEVANT PRODUCT AND MARKET STRUCTURE

Drug-coated balloon catheters indicated for the fem-pop artery are used to treat peripheral arterial disease in the fem-pop artery, an artery located above the knee. Peripheral arterial disease results from atherosclerosis, the narrowing of blood vessels due to plaque buildup. Percutaneous transluminal angioplasty ("PTA") balloon catheters are catheters with balloons that, once inserted into an artery, are expanded to push plaque against the artery's lumen wall to reopen blood flow. Drug-coated balloon catheters are a type of PTA balloon catheter that releases paclitaxel, a cell-proliferation inhibiting drug, into the artery wall during a medical procedure to prevent restenosis, or re-narrowing, of the artery.

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. Drug-coated balloon catheters are medical devices that are regulated by the FDA. As such, drug-coated balloon catheters 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 drug-coated balloon catheters indicated for the fem-pop artery is highly concentrated with only one current supplier, C.R. Bard, Inc. Medtronic and Covidien are likely to enter as the second and third U.S. suppliers, respectively. While there are other firms with drug-coated balloon catheters in development for sale in the U.S. market, Medtronic and Covidien are the only two anticipated market participants that have advanced to the clinical-trial stage of the FDA approval process for drug-coated balloon catheters indicated for the fem-pop artery.

ENTRY

Entry into the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The development process for a drug-coated balloon catheter is difficult, time-consuming, and expensive. It can take tens of millions of dollars of research and development, significant further funding for clinical trials, and an extensive amount of time to even reach the stage of applying to the FDA for approval. The regulatory approval process itself can also be time-consuming as the FDA reviews the volume of material and data a company submits in support of its application.

EFFECTS OF THE ACQUISITION

The Proposed Acquisition would cause significant competitive harm to consumers in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery. The merger would combine the second and third anticipated entrants into the market, likely prolonging a duopoly in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery. Because Medtronic and Covidien are the only two anticipated entrants that have advanced to the clinical trial stage of the FDA approval process, the consolidation of the two firms would deprive consumers of the benefits of a third competitive entrant into the market for a substantial period of time. As a result, the Proposed Acquisition likely would reduce the substantial additional price

competition that would have resulted from an additional U.S. supplier of drug-coated balloon catheters indicated for the fem-pop artery. Further, the Proposed Acquisition likely would reduce innovation in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery.

THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by Medtronic's proposed acquisition of Covidien by requiring the parties divest to Spectranetics all of the assets and resources needed for it to become an independent, viable, and effective competitor in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery.

Spectranetics possesses the industry and regulatory experience to achieve FDA approval of Covidien's drug-coated balloon catheter and become the third entrant into the U.S. market. Headquartered in Colorado Springs, Colorado, Spectranetics is a leader in peripheral vascular solutions with a portfolio of products that is highly complementary to Covidien's drug-coated balloon catheter. Spectranetics manufactures and markets a range of devices to treat peripheral and coronary arterial disease and is well positioned to restore the benefits of competition that would be lost through the Proposed Acquisition.

Pursuant to the Order, Spectranetics will receive all rights and assets related to Covidien's drug-coated balloon catheter products, including all of the intellectual property used in the drug-coated balloon catheter business. In addition, Spectranetics will take over the manufacturing facility where Covidien currently coats the PTA balloon catheters with paclitaxel. The Order further requires that Covidien provide Spectranetics with a worldwide license to produce the PTA balloon catheters incorporated into the drug-coated balloon catheters. In order to ensure continuity of supply of a critical input, the Order requires that the parties supply Spectranetics with PTA balloon catheters for up to three years while Spectranetics transitions to independent manufacturing. This provision ensures that drug-coated balloon catheters will continue to be available for ongoing clinical trials while Spectranetics works to obtain FDA approval to manufacture the PTA balloon catheters independently.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Spectranetics to assist the company in establishing its manufacturing capabilities and securing all necessary FDA approvals. Further, the Order requires that the parties transfer all confidential business information to Spectranetics, as well as provide access to employees who possess or are able to identify such information. Spectranetics also will have the right to interview and offer employment to employees associated with Covidien's drug-coated balloon catheter business.

The parties must accomplish the divestiture no later than ten days after the consummation of the Proposed Acquisition. If the Commission determines that Spectranetics is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Medtronic and Covidien comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Spectranetics. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

The purpose of this analysis is to facilitate public comment on the 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.