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FEDERAL TRADE COMMISSION

[File No. 141 0187]

Medtronic, Inc. and Covidien plc; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before December 29, 2014.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/covidienmedtronicconsent online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Medtronic and Covidien - Consent Agreement; File No. 141 0187" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/covidienmedtronicconsent by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Medtronic and Covidien - Consent Agreement; File No. 141 0187" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the

Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Christine E. Tasso, Bureau of Competition, (202-326-2232), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 26, 2014), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 29, 2014. Write "Medtronic and Covidien - Consent Agreement; File No. 141 0187" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or

foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/covidienmedtronicconsent by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "Medtronic and Covidien - Consent Agreement; File No. 141 0187" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR § 4.9(c).

Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 29, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

Analysis of Agreement Containing Consent Order to Aid Public Comment

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.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2014-28609 Filed 12/04/2014 at 8:45 am; Publication Date: 12/05/2014]