

interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 2014-28605 Filed 12-4-14; 8:45 am]

BILLING CODE 6750-01-P

## 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://ftcpublish.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://ftcpublish.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 Web site, 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 Web site.

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).<sup>1</sup> 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://ftcpublish.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 Web site.

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 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 Web site 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

<sup>1</sup> 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).

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 12-4-14; 8:45 am]

BILLING CODE 6750-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-6056-N]

#### Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2015

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a \$553.00 calendar year (CY) 2015 application fee for institutional providers that are initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid, or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2015 and on or before December 31, 2015.

**DATES:** This notice is effective on January 1, 2015.

**FOR FURTHER INFORMATION:** Frank Whelan, (410) 786-1302 for Medicare enrollment issues. Alvin Anderson, (410) 786-2188 for Medicaid and CHIP enrollment issues.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period titled "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers." This rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and CHIP provider enrollment processes. As provided in section 1866(j)(2)(C)(i) of the Social Security Act (as amended by section 6401 of the Affordable Care Act) and in 42 CFR 424.514, "institutional providers" that are initially enrolling in the Medicare, Medicaid, or CHIP program, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. An "institutional provider" for purposes of Medicare is defined at § 424.502 as "(a)ny provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-

855B (not including physician and non-physician practitioner organizations), CMS-855S, or associated Internet-based PECOS enrollment application." As we explained in the February 2, 2011 final rule (76 FR 5914), in addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only, and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), psychiatric residential treatment facilities, and may include other institutional provider types designated by a state in accordance with their approved state plan.

As indicated in §§ 424.514 and 455.460, the application fee is not required for either of the following:

- A Medicare physician or non-physician practitioner submitting a CMS-855I.
- A prospective or revalidating Medicaid or CHIP provider—
  - ++ Who is an individual physician or non-physician practitioner; or
  - ++ That is enrolled in Title XVIII of the Act or another state's Title XIX or XXI plan and has paid the application fee to a Medicare contractor or another state.

##### II. Provisions of the Notice

###### A. CY 2014 Fee Amount

In the December 2, 2013 **Federal Register** (78 FR 72089), we published a notice announcing a fee amount for the period of January 1, 2014 through December 31, 2014 of \$542.00. This figure was calculated as follows:

- Section 1866(j)(2)(C)(i)(I) of the Act established a \$500 application fee for institutional providers in CY 2010.
- Consistent with section 1866(j)(2)(C)(i)(II) of the Act, § 424.514(d)(2) states that for CY 2011 and subsequent years, the preceding year's fee will be adjusted by the percentage change in the consumer price index (CPI) for all urban consumers (all items; United States city average, CPI-U) for the 12-month period ending on June 30 of the previous year.
  - The CPI-U increase for CY 2011 was 1.0 percent, based on data obtained from the Bureau of Labor Statistics (BLS). This resulted in an application fee amount for CY 2011 of \$505 (or \$500 × 1.01).
  - The CPI-U increase for the period of July 1, 2010 through June 30, 2011 was 3.54 percent, based on BLS data. This resulted in an application fee amount for CY 2012 of \$522.87 (or \$505 × 1.0354). In the aforementioned February 2, 2011 final rule, we stated