## UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

| COMMISSIONERS:       | Edith Ramirez, Chairwoman Julie Brill Maureen K. Ohlhausen Joshua D. Wright Terrell McSweeny |               |
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| In the Matter of     | )  |               |
| MEDTRONIC, INC.,     | )  |               |
| a corporation;       | )  |               |
| and                  | )  | Docket C-4503 |
| COVIDIEN PLC,        | )  |               |
| a public limited con | npany. )   |               |
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# DECISION AND ORDER [Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the acquisition by Respondent Medtronic, Inc. ("Medtronic") of the voting securities of Respondent Covidien plc ("Covidien"), collectively ("Respondents"), and Respondents having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of 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; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now

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in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

- 1. Respondent Medtronic, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its headquarters address located at 710 Medtronic Parkway, Minneapolis, MN 55432-5604.
- 2. Respondent Covidien plc is a public limited company, organized, existing, and doing business under and by virtue of the laws of Ireland, with its headquarters address located at 20 on Hatch, Lower Hatch Street, Dublin 2, Ireland.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

#### **ORDER**

I.

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. "Medtronic" means Medtronic, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Medtronic, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Medtronic shall include Covidien and Medtronic plc.
- B. "Covidien" means Covidien plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Covidien, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Covidien shall not include Medtronic.
- C. "New Medtronic" means it [(r)3(e)4(pr)3c(e)4(-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(,s)-11r)3(i(r-2(a)4)((rab4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-1(s)2(a)4)(e)4(ft)-6(i4(s)-6

- H. "Acquisition Date" means the date on which the Acquisition is consummated.
- I. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of the Drug-Coated Balloons. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- J. "Assets To Be Divested" means the Drug-Coated Balloon Business, the PTA License, the PTA Materials, and the Background IP License.
- K. "Background IP" means all patents

- 1. Information relating to any Respondent's general business strategies or practices that does not discuss with particularity the Drug-Coated Balloon Business;
- 2. Information that is contained in documents, records or books of any Respondent that are provided to the Commission-Approved Acquirer by a Respondent that is unrelated to the Drug-Coated Balloon Business acquired by the Commission-Approved Acquirer or that is exclusively related to the Retained Business;

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| 9. | All commitments and orders for the purchase of goods that have not been shipped, to |
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- 2. Copyrights, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; in each case, other than patents or patent applications (which are addressed in Item 1, above).
- II. "PTA License" means a royalty-free, fully paid-up, perpetual, irrevocable, worldwide, non-exclusive license to the Commission-Approved Acquirer under any PTA Intellectual Property and PTA Product Manufacturing Technology to operate the Drug-Coated Balloon Business, including (i) to make, have made, use, offer to sell, sell, import, and export any Drug-Coated Balloons, and (ii) the research, Development, and manufacture of PTA Products for the incorporation of such PTA Products into Drug-Coated Balloons.
- JJ. "PTA Materials" means copies of the following items (or relevant excerpts thereof) owned by and in possession of Covidien as of the Closing Date (except to the extent related to any Retained Product):
  - 1. All PTA Product S Tc ei(t)-2(uastif(o)P)-41 Tw -38.38 n of CovidiwMC /LBody <</MCID -1(e13

- conformance, and labeling and all other information related to the manufacturing process, and supplier lists.
- MM. "PTA Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information, to the extent each of the foregoing are primarily related to the research, Development, or manufacture of PTA Products.
- NN. "Remedial Agreement(s)" means the following:
  - 1. The Divestiture Agreement; and
  - 2. Any agreement between a Respondent and a Commission-Approved Acquirer (or between a Divestiture Trustee and a Commission-Approved Acquirer that has received the prior approval of the Commission) to accomplish the requirements of this Order, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Assets To Be Divested, that have been approved by the

RR. "Transition Services Agreement" means an a

Coated Balloons by the Commission-Approved Acquirer. Respondents' obligations shall be satisfied as follows:

- 1. Prior to the Closing Date, Respondents shall provide all required notices to Third Parties and Government Entities in connection with agreements where no consent from such Third Parties and Government Entities is required to assign the rights granted to Covidien, including complying with any required notice requirements as to time prior to the transfer;
- 2. Prior to the Closing Date, Respondents shall secure all consents or waivers to assign to the Commission-Approved Acquirer all the agreements listed on Non-Public Appendix E; and
- 3. Within fifteen (15) days after the Closing Date, Respondents shall secure all the consents or waivers to assign to the Commission-Approved Acquirer at least 90 percent of the agreements listed in Non-Public Appendix F.

# C. Respondents shall:

- 1. submit to the Commission-Approved Acquirer, at Respondents' expense, all Confidential Business Information related to the Assets To Be Divested;
- 2. deliver all Confidential Business Information related to the Assets To Be Divested to the Commission-Approved Acquirer:
  - a. in good faith;
  - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
  - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
- 3. pending complete delivery of all such Confidential Business Information to the Commission-Approved Acquirer, provide the Commission-Approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Assets To Be Divested that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order.
- D. Respondents shall not use, directly or indirectly, any Confidential Business Information (other than as necessary to comply with the requirements of this Order, any Remedial Agreement, or any Law) related to the Drug-Coated Balloon Business, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any Person except in connection with the divestiture of the Assets To Be Divested, to the Interim Monitor, if any, and to the Divestiture Trustee, if any, provided however, that:

- 1. This Paragraph II.D. shall not apply to any Confidential Business Information related to the Drug-Coated Balloon Business that Respondents can demonstrate to the Commission that Medtronic obtained other than in connection with the Acquisition;
- 2. This Paragraph II.D. shall not apply to any Confidential Business Information to the extent related to Retained Products, the Retained Business or PTA Products;
- 3. This Paragraph II.D. shall not apply to the use of Confidential Business Information by Respondents in complying with the requirements or obligations of the Laws of the United States or other countries:
- 4. This Paragraph II.D. shall not apply to the use of Confidential Business Information by Respondents to defend against legal claims brought by any Third Party, or investigations or enforcement actions by Government Entities; and
- 5. This Paragraph II.D. shall not apply to the use of Confidential Business Information by Respondents to the extent consented to by the Commission-Approved Acquirer;

provided, however, that Respondents shall require any Covidien employees or agents who as of the Closing Date have access to Confidential Business Information related to the Drug-Coated Balloon Business to enter into, no later than thirty (30) days after the Closing Date, confidentiality agreements with Respondents and the Commission-Approved Acquirer not to disclose such Confidential Business Information except as set forth in this Paragraph II.D.

# E. Respondents shall:

- 1. Enter into an agreement to supply PTA Products to the Commission-Approved Acquirer at no more than Respondents' Actual Cost for a period of one (1) year following the Closing Date; and
- 2. At the Commission-Approved Acquirer's option, renew the supply agreement for PTA Products for up to two (2) additional one-year terms under such terms and conditions as approved by the Commission.

## F. Respondents shall:

- Not later than fifteen (15) days before the Closing Date (a) provide to the Commission-Approved Acquirer a list of all Drug-Coated Balloon Employees; and (b) in compliance with all Laws, allow the Commission-Approved Acquirer to inspect the personnel files and other documentation relating to such Drug-Coated Balloon Employees;
- 2. Not later than fifteen (15) days before the Closing Date provide an opportunity for the Commission-Approved Acquirer: (a) to meet personally, and outside the presence or hearing of any employee or agent of Respondents, with any one or more of the Drug-Coated Balloon Employees; and (b) to make offers of employment to any one or more of the Drug-Coated Balloon Employees;

#### III.

#### IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Remedial Agreement(s).
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of this Order in a manner consistent with the purposes of this Order.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and related requirements of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission.
  - 2. The Interim Monitor shall act in a fidu sd

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impede the Interim Monitor's ability to monitor Respondents' compliance with this Order.

F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents,

| M. | The Interim Monitor appointed pursuant to this Order may be the same Person appointed |
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- Divestiture Trustee, by the court; provided, however, the Commission may extend the divestiture period only two (2) times.
- 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the Assets To Be Divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
- 4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; provided further, however, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
- 5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of the Assets To Be Divested.
- 6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result

from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

- 7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Assets To Be Divested; provided, however, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order.
- 8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning th

E. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VI.

#### IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every thirty (30) days thereafter until Respondents have fully complied with Philas Praphon Ulsantc ppr prof 0 Tw 1(r;ccu)-4(r)-1(r)-1.31

#### VII.

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of a Respondent; (2) acquisition, merger or consolidation of Respondents; or (3) other change in the Respondents that may affect compliance obligations arising out of this Order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

#### VIII.

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all 1(ponde)4(nt)]TJ46(c)4(s)-1(ubj)2 Tw -2, 44(nd)]T10(4.r)6(j)2 T10(4.r)6(j)2 T10(4.r)6(j)2 T1

# Nonpublic Appendices A-F

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