UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff. v. MEDTRONIC, INC., a corporation, and S. OMAR ISHRAK and THOMAS M. TEFFT, individuals, Defendants.	Case No. _____ CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against Medtronic, Inc. ("Medtronic"), a corporation, and S. Omar Ishrak and Thomas M. Tefft, individuals (collectively, "Defendants"), and Defendants, having appeared and having consented to entry of this Decree without contest, without admitting or denying the allegations in the Complaint, and disclaiming any liability in connection therewith and before any testimony has been taken, and the United States having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED AS FOLLOWS:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et. seq.*

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), namely SynchroMed Implantable Infusion Pump Systems, that are adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, and storage are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820.

4. The Complaint also alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing the SynchroMed Implantable Infusion Pump systems to become adulterated within the meaning of 21 U.S.C. § 351(h) while such devices are held for sale after shipment in interstate commerce.

DEFINITIONS

5. For the purposes of this Decree, the following definitions apply:

A. "SynchroMed device" shall mean all implantable infusion pumps and their accessories that are designed, manufactured, processed, packed, labeled, held, stored, installed, and distributed at or from any Medtronic Neuromodulation facility.

B. "Medtronic Neuromodulation" shall mean the Medtronic Neuromodulation Business Unit of Medtronic, Inc., which is responsible for designing,

manufacturing, processing, packing, labeling, holding, storing, and distributing, among other devices, the SynchroMed devices.

C. "Medtronic Neuromodulation facilities" shall mean Medtronic Neuromodulation's headquarters, located at 7000 Central Ave. NE, Minneapolis, MN, and the manufacturing facility located at 53rd Avenue NE, Columbia Heights, MN.

D. A SynchroMed device is "medically necessary" if (i) it is used to treat one or more of the following conditions for which the benefits of using the SynchroMed device outweigh the risks: (a) severe spasticity; (b) chronic intractable pain; (c) severe chronic pain; and/or (d) primary or metastatic cancer; and (ii) the physician, after reviewing the notification letter attached hereto as Exhibit A, signs a form approved by FDA, attached hereto as Exhibit B, certifying that s/he is aware of FDA's findings and deems the SynchroMed device necessary to treat his/her patient under the conditions referred to in this paragraph (hereafter, "Certificate of Medical Necessity").

E. Days shall refer to calendar days unless otherwise stated.

INJUNCTIVE PROVISIONS

6. Upon entry of this Decree, except as described in paragraph 9, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities) who have received actual notice of the contents of this Decree by personal service or otherwise are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, labeling, holding, storing, and distributing, importing into or exporting from the United States of America, at or from any

Medtronic Neuromodulation facilities, any model of, or components or accessories for, its SynchroMed devices, unless and until:

A. Defendants' methods, facilities, and controls used to design, manufacture, process, pack, label, hold, store, and distribute SynchroMed devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System ("QS") regulation set forth in 21 C.F.R. Part 820.

B. Defendants select and retain at Medtronic's expense, within thirty (30) days of the entry of this Decree, an independent person or persons (the "Expert"), to conduct inspections of Defendants' operations and to review Defendants' procedures and methods for designing, manufacturing, processing, packing, labeling, holding, storing, and distributing SynchroMed devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree. The Expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement between the Expert and Medtronic or Medtronic Neuromodulation) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) days of retaining such Expert.

C. The Expert shall perform comprehensive inspections of Medtronic Neuromodulation facilities that design, manufacture, process, pack, label, hold, store, or distribute the SynchroMed devices or any component thereof and certify in writing simultaneously to Defendants and FDA: (i) that he or she has inspected Defendants' facilities, processes, and controls; (ii) whether Defendants have corrected all findings and

violations set forth in FDA's Inspectional Observations ("Forms FDA 483") and Warning Letters issued to Medtronic Neuromodulation facilities from all FDA inspections since January 2011; and (iii) based upon these comprehensive inspections, whether Defendants' operations are operated in conformity with the Act, its implementing regulations, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following as they relate to SynchroMed devices:

(i) Defendants' compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Part 820;

(ii) Defendants' procedures for their Corrective and Preventive Action ("CAPA") system, including, but not limited to, analyzing quality data to identify, correct, and prevent existing and potential causes of nonconforming product and other quality problems;

(iii) Defendants' procedures for their design control system, including, but not limited to, establishing and implementing adequate design and development plans, inputs, outputs, design reviews, verification, validation, risk analyses, design change controls, and a design history file for each type of device;

(iv) Defendants' procedures for their nonconforming product, including, but not limited to, the identification, documentation, evaluation, segregation, and disposition, including rework, of nonconforming product; and

(v) Defendants' design verification and design validation documents for the SynchroMed device to ensure that the approved product specifications are being met. In circumstances where the Defendants have identified a design defect that causes the SynchroMed device to not perform according to the approved product

specifications, the Expert shall review the design defect analysis documentation. The design defect analysis documentation should include a description of the design defect, the potential risk to patients associated with the defect, a timeline of actions taken during the defect investigation, proposed corrective actions, design changes being considered, developed, and /or tested, and actions that have been taken or will be taken to potentially correct the design defect. The Expert shall also review design changes made to the SynchroMed device in the previous five (5) years to verify that the changes previously implemented are effective and do not adversely affect the device.

D. Within forty-five (45) days of receiving the Expert's inspection report under paragraph 6.C, Defendants shall submit a written report ("work plan") to FDA detailing the specific actions Defendants have taken and/or will take to address the Expert's observations and to bring the methods, facilities, processes, and controls used to design, manufacture, process, pack, label, hold, store, and distribute the SynchroMed device into compliance with the requirements of this Decree, the Act, and the QS regulation. The specific actions in the work plan shall be set forth in numbered steps and, where appropriate, the numbered steps may include subordinate lettered steps. The work plan shall include a timetable with a specific date for completing each numbered step and may include, where appropriate, interim dates for completing subordinate lettered steps. The work plan, including its proposed specific actions and timetable, shall be subject to FDA approval, and Defendants shall ensure the implementation of the numbered steps in the work plan in accordance with the timetable approved by FDA. FDA shall approve or disapprove in writing the proposed work plan within sixty (60) days.

E. Defendants may begin implementing the work plan as soon as they receive written FDA approval. Under no circumstances may FDA's silence be construed as approval. As the actions detailed in the work plan are completed, Defendants shall notify the Expert in writing, who shall promptly inspect and verify whether those actions have been completed in a manner that complies with the requirements of this Decree, the Act, and the QS regulation to the Expert's satisfaction and in accordance with the work plan timetable.

F. If the Expert determines that an action has not been completed to his or her satisfaction, the Expert shall promptly notify Defendants in writing. Beginning thirty (30) days after implementation of the work plan, and quarterly thereafter, the Expert shall submit to FDA a table that summarizes the Expert's findings regarding whether the actions have been completed to the Expert's satisfaction and in accordance with the numbered steps in the work plan timetable. FDA may, at its discretion and without prior notice, periodically inspect Medtronic Neuromodulation facilities and undertake such additional examinations, reviews, and analyses as FDA deems appropriate to verify whether the actions reported to the Expert as completed have in fact been adequately completed on time. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA shall notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable approved by FDA.

G. When the Expert determines that all of the actions identified in the work plan have been completed to his or her satisfaction, the Expert shall provide Defendants and FDA with a written certification that all of the actions have been completed and that, based on the inspections conducted under paragraph 6.C and on the

satisfactory completion of the actions in the work plan identified under paragraph 6.D, Defendants' methods, facilities, processes, and controls used to design, manufacture, process, pack, label, hold, store, and distribute the SynchroMed devices, are and, if properly maintained and implemented by Defendants, will continuously remain in conformity with the requirements of this Decree, the Act, and the QS regulation. The Expert's certification shall include a full and complete detailed report of the results of his or her inspection.

H. Within thirty (30) business days of FDA's receiving the Expert's certification under paragraph 6.G, duly authorized FDA representatives may inspect, as FDA deems necessary and without prior notice, the Medtronic Neuromodulation facilities, including buildings, equipment, personnel, finished and unfinished materials, containers, and labeling, and all records relating to the methods used in, and the facilities and controls used for, the manufacture, design, processing, packing, labeling, holding, storage, and distribution of SynchroMed devices, to determine whether the requirements of paragraphs 6.A-G of this Decree have been met, and whether Defendants are otherwise operating in conformity with this Decree, the Act, and the QS regulation.

I. If FDA determines that Defendants are not operating in conformity with the requirements of this Decree, the Act, and the QS regulation with regard to the SynchroMed devices, FDA will notify Defendants of the deficiencies it observed and will take any other action FDA deems appropriate (*e.g.*, issuing an order pursuant to paragraph 11). Within thirty (30) days of receiving this notification from FDA, Defendants shall submit to FDA a plan describing the actions Defendants propose to take and a timetable for correcting the deficiencies. The timetable and plan shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the

FDA approved timetable and plan, and shall cause the Expert to reinspect the conditions relevant to the deficiencies noted by FDA and either:

(i) certify that the deficiencies have been corrected to ensure that Defendants' methods, facilities, processes, and controls used for manufacturing, processing, packing, labeling, holding, storing, and distributing the SynchroMed devices are in conformity with the requirements of this Decree, the Act, and the QS regulation; or

(ii) notify Defendants and FDA in writing that one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, Defendants shall correct the deficiencies to the Expert's satisfaction, at which point the Expert shall issue the certification simultaneously to Defendants and FDA. Within forty-five (45) business days after FDA receives the certification, FDA may reinspect as it deems necessary, without prior notice.

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 6.A-I. Such notice shall not be dependent upon Defendants' completion of the SynchroMed Pump Remediation Plan described in paragraph 7.

7. No later than twenty (20) days after entry of this Decree, Defendants shall submit to FDA in writing a Pump Remediation Plan to ensure that the SynchroMed devices currently produced in the United States are in compliance with the Act, its implementing regulations, and this Decree ("SynchroMed PRP").

A. The SynchroMed PRP shall include, among other things:

(i) the identification of the root causes or, if not precisely known, the probable root causes, of failures in the SynchroMed devices Defendants are proposing to correct;

(ii) a description of and the supporting documentation for upgrades, modifications, and/or actions necessary to correct the identified failures;

(iii) the testing conducted or to be conducted to verify and validate such upgrades and/or modifications;

(iv) the projected dates on which Defendants will implement and complete the SynchroMed PRP;

(v) the manner in which the upgrades and/or modifications will be made to the SynchroMed devices; and

(vi) a clear statement whether Defendants believe that premarket approval by FDA is required for the proposed upgrades and/or modifications to the SynchroMed devices proposed in the SynchroMed PRP, and the reason for that belief.

B. Defendants shall not initiate the SynchroMed PRP until FDA has first provided Defendants with written acknowledgement to proceed with all or a portion of the SynchroMed PRP. FDA shall respond in writing within thirty (30) days of FDA's receipt of Defendants' SynchroMed PRP and notify Defendants in writing whether the proposed plan is acceptable. If FDA finds some or all of the SynchroMed PRP unacceptable, it shall state in writing the basis for finding specific portions of the proposed SynchroMed PRP unacceptable, and Defendants shall submit a revised SynchroMed PRP in writing within twenty (20) days of receipt of FDA's response. FDA shall respond in writing within twenty (20) days of FDA's receipt of Defendants' revised SynchroMed PRP and notify Defendants

in writing whether the revised plan is acceptable; and, if specific portions of the revised plan are unacceptable, FDA shall state the basis in its written response.

C. Defendants shall commence those portions of the initial and/or revised SynchroMed PRP that were found acceptable by FDA within thirty (30) days of receiving FDA's written authorization of the initial and/or revised SynchroMed PRP. Defendants shall, beginning one month after the date on which implementation of the SynchroMed PRP, in whole or in part, has begun, and continuing until its completion, submit to FDA quarterly written progress reports that describe the status of the SynchroMed PRP. If Defendants have not obtained FDA's authorization for the SynchroMed PRP within six (6) months after the date this Decree is entered, FDA may take any action(s) it deems appropriate to the extent permitted under paragraph 11 of this Decree.

D. PRP documentation, described above in paragraph 7.A, shall be available for Expert and FDA review in accordance with paragraph 6.

8. Upon entry of this Decree, except as permitted in paragraph 9, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce of, SynchroMed devices, or any other Medtronic

devices of a similar design or for a similar use, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(h).

B. Violates 21 U.S.C. § 331(k), by causing the SynchroMed devices, or any other Medtronic devices of a similar design or for a similar use, to become adulterated within the meaning of 21 U.S.C. § 351(h), while such devices are held for sale after shipment in interstate commerce.

EXCLUSIONS

9. Paragraphs 6 and 8 of this Decree shall not apply to the following:

A. Manufacturing, processing, packing, labeling, holding, storing, and distributing SynchroMed devices that are intended for use in medically necessary cases, as defined in paragraph 5.D. Medtronic may provide a medically necessary SynchroMed device only if the following requirements have been and continue to be, or will be, met: (i) the patient's physician has completed the Certificate of Medical Necessity (CMN), referenced in paragraph 5.D and attached hereto as Exhibit B; (ii) Medtronic promptly provides FDA with copies of all CMNs for the first three (3) months following entry of this Decree; (iii) Medtronic maintains and promptly provides to FDA upon request copies of any additional CMNs executed after the first three (3) months; and (iv) Medtronic provides reports of granted CMNs to FDA every three (3) months for a period of one (1) year and not less than every six (6) months for a period of four (4) years thereafter. In circumstances where the SynchroMed pump is required for use in an emergency case and it is impractical or there is insufficient time to obtain a CMN in advance of the procedure, Medtronic may provide the SynchroMed device for such use so long as the patient's physician (i) completes the CMN following the procedure, and (ii) submits the completed CMN to Medtronic as

soon as possible following the procedure. The parties agree that such situations will be infrequent. In those cases in which prior approval is not feasible, Medtronic will supply FDA with a copy of completed CMN within three (3) business days of receiving the CMN from the physician.

B. Manufacturing, processing, packing, labeling, holding, storing, and distributing SynchroMed devices intended for patients seeking a replacement SynchroMed device. Medtronic shall provide a replacement SynchroMed device to a patient only if the following requirements have been and continue to be, or will be, met: (i) the patient's physician has completed the Replacement Pump Certificate ("RPC"), attached hereto as Exhibit C; (ii) Medtronic promptly provides FDA with copies of all RPCs for the first three months following entry of this Decree; (iii) Medtronic maintains and promptly provides to FDA upon request copies of any RPCs executed after the first three (3) months; and (iv) Medtronic provides reports of granted RPCs to FDA every three (3) months for a period of one (1) year and not less than every six (6) months for a period of four (4) years thereafter. In circumstances where a replacement SynchroMed pump is needed for use in an emergency case and it is impractical or there is insufficient time to obtain an RPC in advance of the procedure, the Defendants may distribute the replacement SynchroMed device for such use, provided that the patient's physician (i) completes the RPC following the procedure, and (ii) submits the completed RPC to Medtronic as soon as possible following the procedure. The parties agree that such situations will be infrequent. In each case in which prior approval is not feasible, Medtronic will supply FDA with a copy of the completed RPC within three (3) business days of receiving the RPC from the physician.

C. Manufacturing, processing, packing, labeling, holding, storing, and distributing any component, part, raw material, accessory, refill kit, or sub-assembly, solely for the purpose of providing service or repair to a SynchroMed device implanted prior to the date of the entry of this Decree, or that was provided pursuant to paragraph 9.A, 9.B, or 9.I of this Decree. Medtronic may provide replacement components, parts, raw materials, accessories, refill kits, and sub-assemblies to patients, their physicians, healthcare providers, and facilities for service or repair of SynchroMed devices and components only if the following requirements have been met: (i) Medtronic sends a copy of the notification letter attached hereto as Exhibit A to the physicians, healthcare providers, or facilities to whom Medtronic provides such items; and (ii) Medtronic maintains records, and allows FDA access to such records upon request, of all service and repair components, parts, raw materials, accessories, refill kits and sub-assemblies provided under this paragraph, including copies of the notification letters sent to physicians, healthcare providers, and facilities.

D. Manufacturing, processing, packing, labeling, holding, storing, and distributing limited quantities of SynchroMed devices that are not intended for human use and are intended for use in development, testing, verification, validation, or qualification activities necessary to complete (i) design changes in support of the SynchroMed PRP, (ii) changes to production and process controls, (iii) changes to manufacturing procedures, (iv) corrective and preventive actions, and/or (v) changes to components, parts, or suppliers.

E. Testing, verifying, or validating design changes of SynchroMed devices, including any component or accessory, and subsequently manufacturing and

distributing the SynchroMed devices, components, or accessories, for the sole purpose of implementing a correction or removal as defined in 21 C.F.R § 806.

F. Design work related to remediation of existing safety issues with the SynchroMed devices, or related to safety issues with the SynchroMed devices discovered during the implementation of this Decree.

G. Manufacturing, processing, packing, labeling, holding, storing, and distributing SynchroMed devices for development activities and distributing such devices for demonstration and research purposes only, such as use in product demonstrations and research in laboratories, including preclinical animal research, provided that the devices are labeled "NOT FOR HUMAN USE."

H. Manufacturing, processing, packing, labeling, holding, storing, and distributing SynchroMed devices solely for the purpose of permitting clinical trials to be conducted in accordance with 21 C.F.R. Part 312 or 812, or for international clinical trials conducted in accordance with Good Clinical Practices, provided that Defendants comply with all applicable laws and regulations relating to the manufacture and distribution of investigational devices.

I. Manufacturing, processing, packing, labeling, holding, storing, and distributing SynchroMed devices that were ordered or provided for cases that were scheduled prior to entry of this Decree.

J. Importing components and accessories necessary to manufacture and distribute SynchroMed devices, parts, components, and accessories as permitted by paragraphs 9.A–I of this Decree.

ADDITIONAL REQUIREMENTS

10. After Defendants have complied with paragraphs 6.A-I and FDA has notified Defendants in writing pursuant to paragraph 6.J, Defendants shall retain an independent person or persons (the "Auditor") at Medtronic's expense to conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of two (2) years thereafter. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the Auditor and Medtronic or Medtronic Neuromodulation) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in paragraph 6.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Medtronic Neuromodulation is operated and administered in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Findings"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Findings. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) days after the date each audit inspection is completed. If any Audit Report(s) identify any deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the two (2) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in

separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Findings, Defendants shall, within forty-five (45) days of receipt of the Audit Report, correct those Findings, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Finding will take longer than forty-five (45) days, Defendants shall, within fifteen (15) days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. Defendants shall complete all corrections according to the Correction Schedule. Within forty-five (45) days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Finding(s). Within ten business days of the completion of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Findings has been corrected and, if not, which adverse Audit Report Findings remain uncorrected.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection; the analysis of samples; a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this Decree; or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions with

respect to SynchroMed devices. Such actions may include, but are not limited to, the following:

i. Cease designing, manufacturing, processing, packing, labeling, holding, storing, distributing, importing and/or exporting SynchroMed devices produced at the Medtronic Neuromodulation facilities;

ii. Revise, modify, or expand any report(s) prepared pursuant to the Decree;

iii. Submit additional notifications, reports, or any other materials or information to FDA with respect to SynchroMed devices;

iv. Recall and/or provide refunds for, at Medtronic's sole expense, adulterated or misbranded devices or components manufactured, distributed, and/or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

v. Issue a safety alert, public health advisory and/or press release with respect to the SynchroMed devices; and/or

vi. Take any other corrective action(s) with respect to the SynchroMed devices as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this Decree.

12. The following process and procedures shall apply in the event that FDA issues an order under paragraph 11:

A. Unless a different timeframe is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing

either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court stays, sets aside, or modifies FDA's order. Judicial review of FDA's order shall be made pursuant to paragraph 24.

D. The process and procedures set forth in paragraphs 12.A–C shall not apply to any order issued pursuant to paragraph 11 if such order states that, in FDA's judgment, the order raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of the order. Should Defendants seek to challenge any such order, they may petition this Court for relief

while they implement FDA's order. Judicial review of FDA's decision under this paragraph shall be made pursuant to paragraph 24.

13. Any cessation of operations or other action as described in paragraph 11 shall continue until Defendants: (a) receive written notification from FDA that Medtronic Neuromodulation appears to be in compliance with this Decree, the Act, and its implementing regulations or (b) receive written authorization from the Court. After a cessation of operations, and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree. Defendant Medtronic shall pay the costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 11, at the rates specified in paragraph 15.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations at the Medtronic Neuromodulation facilities and, without prior notice, take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of the SynchroMed devices and the design of the SynchroMed devices. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374 and with copies

of any photographs or video recordings, upon the receipt of a written request by Defendants, and at Medtronic's expense. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

15. Defendant Medtronic shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Medtronic at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $88.45 per hour and fraction thereof per representative for inspection work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses. FDA shall submit a bill of costs to Defendant Medtronic. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased in accordance with the modified rates without further order of the Court.

16. Within five (5) business days of the entry of this Decree, Defendants shall post a copy of this Decree in the employee common areas at the Medtronic Neuromodulation facilities and on Medtronic's intranet website in such a manner as to ensure that it will be viewed by employees at the Medtronic Neuromodulation facilities.

Defendants shall ensure that the Decree remains posted in its employee common areas and on its intranet website for as long as the Decree remains in effect.

17. Within ten (10) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), with responsibility for the design, manufacture and/or distribution of the SynchroMed devices at or from the Medtronic Neuromodulation facilities (hereinafter, collectively referred to as "Associated Persons"). For international Associated Persons, Medtronic Neuromodulation shall provide a copy of the Decree by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested) within twenty-five (25) days after the entry of this Decree. Within thirty (30) days after the entry of this Decree, Medtronic shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have been provided a copy of this Decree pursuant to this paragraph and attaching documentation of the manner in which copies of the Decree were provided.

18. In the event that Medtronic Neuromodulation becomes associated, at any time after the entry of this Decree, with any new Associated Person, Medtronic shall within fifteen business days of the commencement of such association: (a) provide a copy of this Decree to each such Associated Person by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested); and (b) on a quarterly basis, notify FDA in writing, in accordance with paragraph 20, when, how, and to whom the Decree was provided.

Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities that have been provided a copy of this Decree pursuant to this paragraph, and documentation of the manner in which copies of the Decree were provided.

19. Defendant Medtronic shall notify the District Director, FDA Minneapolis District Office, in writing at least fifteen (15) days before: (i) any change in ownership, character, or name of the Medtronic Neuromodulation business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation that, in each case, may affect compliance with this Decree; (ii) the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of Medtronic Neuromodulation or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that, in each case, may affect compliance with this Decree. Medtronic shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) days before any sale or assignment. Medtronic shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

20. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to the District Director, Minneapolis District Office, 250 Marquette Ave., Suite 600, Minneapolis, MN 55401. All notifications, correspondence, and communications required to be sent to Defendants by the terms of this Decree shall be addressed to Director of Consent Decree Compliance Task Force, Medtronic Neuromodulation, 7000 Central Avenue NE, Minneapolis, MN 55432.

FINANCIAL PROVISIONS

21. In the event that Defendants fail, as determined by FDA, to comply with any time frame or provision of this Decree, then FDA shall have the sole and unreviewable discretion to order Medtronic to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.00) per violation of this Decree and an additional sum of fifteen thousand dollars ($15,000.00) for each day such violation continues.

22. In the event Defendants fail, as determined by FDA, to satisfactorily complete one or more of the numbered steps, including the completion date for all numbered steps, in the work plan referenced in paragraph 6.D, FDA may order Medtronic to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.00) for each incomplete numbered step, per business day (e.g., if two steps are not timely complied with for two business days, then liquidated damages may be assessed up to $60,000.00), until the numbered step is fully implemented and completed to FDA's satisfaction. The amount of liquidated damages imposed under paragraphs 21 and/or 22 shall not exceed ten (10) million dollars ($10,000,000.00) in any one calendar year.

23. The remedy under paragraphs 21–22 shall be in addition to any other remedies available to the United States under this Decree or the law. Defendants understand and agree that the imposition of liquidated damages under paragraphs 21–22 does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to paragraphs 21–22.

GENERAL PROVISIONS

24. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered under this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by any party.

25. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Medtronic shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

26. The parties may at any time petition each other in writing to modify any deadline provided herein; and if the parties mutually agree in writing to modify a deadline, such modification may be granted and may become effective without leave of the Court.

27. If, and for so long as, an individual defendant ceases to be employed by and to act on behalf of Medtronic or any of its subsidiaries, franchisees, affiliates and/or "doing business as" entities, then that individual shall not be subject to this Decree, except as to such individual's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by and to act on behalf of Medtronic or any of its subsidiaries, franchisees, affiliates, and/or "doing business as" entities.

28. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate. SO ORDERED:

This _____ day of _____, 2015.

The undersigned hereby consent to the entry of the foregoing Decree:

_____
UNITED STATES DISTRICT JUDGE

For the Defendants:

S. OMAR ISHRAK
Individually and on behalf of
Medtronic, Inc., as its Chairman and
CEO

THOMAS M. TEFFT
Individually and on behalf of
Medtronic, Inc., as its Senior Vice
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