

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), and the Defense Health Agency (DHA), acting on behalf of the TRICARE program (collectively, the United States); and Medtronic USA, Inc. (Medtronic) (hereafter collectively referred to as the Parties), through their authorized representatives.

RECITALS

A. Medtronic, a Minnesota corporation, sells medical devices and other products throughout the United States, including in South Dakota.

B. The United States contends that Medtronic caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395lll (Medicare); the Medicaid Program, 42 U.S.C. §§ 1396–1396w-5 (Medicaid); and the TRICARE Program, 10 U.S.C. §§ 1071–1110b (TRICARE).

C. The following conduct is referred to below as the Covered Conduct:

1. The United States contends that it has certain civil claims against Medtronic arising from the following conduct from September 1, 2010 to September 30, 2019, by which Medtronic, principally by and through the actions of certain Medtronic employees responsible for sales in South Dakota, caused the submission of false or fraudulent claims to Medicare, Medicaid, and TRICARE: Seeking to increase sales of its SynchroMed II intrathecal infusion pumps, Medtronic identified neurosurgeon Wilson Asfora, M.D. (Asfora) as a “targeted physician” in Sioux Falls, South Dakota. Medtronic knew that Asfora and his wife owned a local restaurant called the Carnaval Brazilian Grill (Carnaval). Asfora had asked Medtronic to pay for events at Carnaval, and had explained to Medtronic that Carnaval’s business was slow. Contrary to

Medtronic's established written compliance policies, Medtronic agreed to Asfora's request. To curry favor with Asfora and provide him with a financial benefit that he would receive as Carnaval's owner, Medtronic held over 130 events at Carnaval, paying over \$87,000 to Asfora's restaurant. In internal expense reports and in an effort to hide their inappropriate conduct, Medtronic sales personnel falsely stated that the events were held to discuss educational content or business information, when in fact the events were social gatherings, with little or no discussion of Medtronic products. At the events, Medtronic often paid for lavish meals and alcohol, with dinners from multicourse tasting menus and wines paired to each course. The setting for these wine dinners was not appropriate for educational or clinical discussion as attendees typically sat at a family-style table in an open area of Carnaval near the bar, with members of the public seated nearby. Intending the events to be social and to benefit Asfora, Medtronic agreed that Asfora would select and invite the attendees. Asfora invited his social acquaintances, business partners, favored colleagues, and potential and existing referral sources, and Medtronic paid for their meals and drinks. At Asfora's invitation, spouses and significant others attended most of the Carnaval events, and Medtronic allowed them to attend and paid for some of their meals and drinks. Medtronic knowingly and willfully paid kickbacks to Asfora in violation of the Anti-Kickback Statute (AKS), 42 U.S.C. 1320a-7b(b), by making payments to Asfora's restaurant, at his request, to induce Asfora to use Medtronic's SynchroMed II intrathecal infusion pumps. Following its own internal review and the United States' investigation of the conduct described herein, Medtronic terminated the employment of the sales representative involved in the majority of these events and his sales manager and also disciplined twelve other employees aware of the conduct or who attended certain events.

2. The United States contends that it has claims under the Open Payments Program (OPP), 42 U.S.C. § 1320a-7h, and associated regulations, 42 C.F.R. §§ 403.900–.914

(OPP Regulations), against Medtronic arising from the following conduct from April 1, 2014 to April 1, 2020, by which Medtronic failed to report to the Centers for Medicare & Medicaid Services (CMS) the full value of Medtronic's payments or transfers of value to or at the direction of Asfora: As a manufacturer of medical devices for which payment is available under Medicare, Medtronic was required to disclose to CMS certain payments or other transfers of value to a physician like Asfora, pursuant to the OPP and OPP Regulations. As relevant here, Medtronic was required to disclose through reporting on the OPP portal both indirect payments to Asfora that Medtronic made by paying Carnaval, an entity that Medtronic knew Asfora owned, and direct payments to a third party, Carnaval, that Medtronic made at Asfora's request. Although Medtronic sales employees knew of Asfora's ownership of Carnaval and his requests that Medtronic pay for events at Carnaval, the employees withheld that information from Medtronic's compliance department. For 74 events that Medtronic paid for at Carnaval from August 8, 2013 to July 9, 2019, Medtronic underreported to CMS the payments to, or at the direction of, Asfora. For Asfora and the other physician-attendees of the events, Medtronic separately reported to CMS only the value of the food and drinks that each physician personally consumed at Carnaval, rather than reporting the total amount paid to Carnaval for the event as a payment or transfer of value to Asfora.

D. This Settlement Agreement is neither an admission of liability by Medtronic nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Medtronic shall pay to the United States the sums specified in this Paragraph (collectively, the Settlement Amount), under the terms and conditions specified herein.

a. With respect to the conduct described in Paragraph C(1) above, Medtronic shall pay to the United States the sum of Eight Million One Hundred Thousand Dollars (\$8,100,000.00), of which Four Million Two Hundred Thousand Dollars (\$4,200,000.00) is restitution, plus interest at the rate of 0.75% per annum, calculated daily, from September 27, 2020 and continuing until and including the day of payment, no later than ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

b. With respect to the conduct described in Paragraph C(2) above, Medtronic shall pay to the United States the sum of One Million One Hundred Thousand Dollars (\$1,100,000.00), plus interest at the rate of 0.75% per annum, calculated daily, from September 27, 2020 and continuing until and including the day of payment, no later than ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. a. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Medtronic's full payment pursuant to Paragraph 1(a) above, the United States releases Medtronic together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (collectively, the Medtronic Entities) from any civil or administrative monetary claim the United States has for the Covered Conduct in Paragraph C(1) above pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies

Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake, unjust enrichment, and fraud. This Agreement does not release any claims of any State.

b. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Medtronic's full payment pursuant to Paragraph 1(b) above, the United States releases the Medtronic Entities from any civil or administrative monetary claim the United States has for the Covered Conduct in Paragraph C(2) above pursuant to the OPP or OPP Regulations.

3. Notwithstanding the releases given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and

- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Medtronic waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. Medtronic fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Medtronic has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE carrier or payer, or any state payer, related to the Covered Conduct; and Medtronic agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

7. Medtronic agrees to the following:

- a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll-1 and 1396-1396w-5; and the regulations and official program

directives promulgated thereunder) incurred by or on behalf of Medtronic, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Medtronic's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Medtronic makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Medtronic, and Medtronic shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Medtronic or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Medtronic further agrees that within ninety (90) days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or

contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Medtronic or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Medtronic agrees that the United States, at a minimum, shall be entitled to recoup from Medtronic any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Medtronic or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Medtronic or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Medtronic's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Medtronic agrees to cooperate fully, actively, and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Such cooperation shall include, but not be limited to, the following:

a. Upon request by the United States with reasonable notice, producing to the United States and not at the expense of the United States, complete and unredacted copies of all

requested non-privileged documents, records, and other evidence in Medtronic's possession, custody, or control relating to Asfora or Carnaval, including, but not limited to, reports, summaries of interviews, and records concerning any investigation that Medtronic has undertaken, or that has been performed by another on Medtronic's behalf, of any actions or arrangements by or involving Asfora or Carnaval that may implicate or involve the AKS and/or FCA;

b. Upon request by the United States with reasonable notice, making current Medtronic employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, at a mutually agreed-upon location;

c. Upon request by the United States with reasonable notice, using best efforts to (i) assist in locating former Medtronic employees identified by attorneys and/or investigative agents of the United States, and (ii) make any such former Medtronic employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, at a mutually agreed-upon location;

d. Upon request by the United States with reasonable notice, making current Medtronic employees available, and using best efforts to make former Medtronic employees available, to testify, consistent with the rights and privileges of such individuals, fully, truthfully, and under oath, without falsely implicating any person or withholding any information, at depositions, at trial, and at any other legal proceedings.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Medtronic agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of South Dakota. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Medtronic's successors, transferees, heirs, and assigns.

18. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE PAGES FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 10/29/2020

BY:

Harin C. Song

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DATED: 10/28/2020

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DATED: 10/27/2020

BY:

Lisa M. Re

LISA M. RE
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United States Department of Health and Human Services

DATED: 10/28/2020

BY:

WHEELER.BRYA

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N.T.1150385950

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

MEDTRONIC USA, INC.



DATED: 10/26/20

BY:

MATTHEW L. STENNES
VP, Chief Litigation & Investigations Counsel
Medtronic USA, Inc.

DATED: 10/26/2020

BY:



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