

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement is entered into between 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") (collectively the "United States"), on the one hand, and Medtronic, Inc. ("Medtronic") and Medtronic Sofamor Danek USA, Inc. ("MSD"), on the other hand, through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Medtronic and MSD have been named as defendants in two *qui tam* actions, United States ex rel. [UNDER SEAL] v. Medtronic, Inc., et al., Civil Action No. 02-2709 (W. D. Tenn.), and United States ex rel. Poteet v. Medtronic, Inc., et al., Civil Action No. 03-2979 (W. D. Tenn.) (the "Qui Tam Lawsuits"), both of which allege that Medtronic and MSD violated the False Claims Act, 31 U.S.C. 3729, *et seq.*, by paying illegal kickbacks to certain physicians which resulted in the submission of false or fraudulent claims to federal health care programs.

B. The United States contends that between January 1, 1998 and April 30, 2003, MSD made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for physicians' attendance and expenses at medical education events, think tanks, VIP/MVP events, and meetings at resort locations; (2) services and payments for services to physicians through MSD's Healthcare Economic Services and eBusiness Departments (formerly called the Physician

Provider Services or “PPS” Department); and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with the physicians and entities listed as defendants in the Qui Tam Lawsuits (“the Covered Conduct”). Notwithstanding clause (3) of the preceding sentence and with respect only to that clause, the Covered Conduct does not include any payments or remuneration that MSD provided to individuals who were associated with the entities named as defendants in the Qui Tam Lawsuits, but were not named individually as defendants in the Qui Tam Lawsuits.

C. Based on its investigation, the United States contends that certain of the payments, services, and remuneration discussed above were improper, resulted in the submission of false or fraudulent claims, and give rise to certain legal claims, as described in paragraph 4 below. Medtronic and MSD deny that they engaged in any wrongdoing, and specifically deny that any of the payments, services or remuneration were illegal or improper or resulted in any false or fraudulent claims. Inclusion of or reference to a particular physician or entity in the Covered Conduct does not necessarily constitute a finding by the United States that any payments, services or remuneration provided to that particular doctor or entity was illegal or improper in any way.

D. To avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties reach a full and final settlement as set forth below. This Agreement is neither an admission of liability by Medtronic or MSD nor a concession by the United States that its claims are not well founded.

E. Medtronic and MSD have entered into a Corporate Integrity Agreement (“CIA”) with the Department of Health and Human Services Office of Inspector General (“OIG-HHS”),

attached hereto as Attachment 1, which is incorporated into this Agreement by reference.

F. Medtronic and MSD are in negotiations with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which Medtronic and MSD agree to a settlement concerning the Covered Conduct (the "Participating States").

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Medtronic agrees to pay to the United States and the Participating States, collectively, \$40 million ("the Settlement Amount"). Within fourteen days after this Agreement has been executed, Medtronic shall deposit the Settlement Amount into an interest-bearing Escrow Account that will be established by Medtronic on terms acceptable to the Government. Not more than forty-five (45) days after the entry of Orders dismissing each of the Qui Tam Lawsuits, and the entry of decisions affirming those dismissals in any and all appeals taken from the Orders of dismissal, all funds in the Escrow Account, other than the \$2,900,000 allocated to the Participating States and any interest that has accrued in the Escrow Account on that portion of the Settlement Amount, will be transferred to the United States pursuant to written instructions to be provided by the United States Attorney for the Western District of Tennessee.

2. If the courts refuse to issue Orders of Dismissal in the Qui Tam Lawsuits or if an appellate court reverses either Order, this agreement shall be null and void at the option of either

the United States or Medtronic and MSD upon notice to all Parties through counsel in writing within five business days of the Court's denial of a motion to dismiss either *qui tam* or of an appellate court's reversal of an Order of Dismissal in either suit. If this agreement is rescinded, all funds in the Escrow Account shall be returned to Medtronic. In that event, Medtronic and MSD will not plead, argue or otherwise raise any defense under theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions or proceedings which are brought by the United States (including by means of intervening in the Qui Tam Lawsuits) within 90 calendar days of notification to all parties of that rescission, except to the extent that such defenses were available on September 11, 2002.

3. In the event that Medtronic and MSD do not reach a final settlement agreement or agreements with the Participating States, Medtronic and MSD shall be entitled to withdraw some or all of the \$2,900,000 allocated to the Participating States, plus any interest that has accrued in the Escrow Account on that portion of the Settlement Amount, from the Escrow Account.

4. Subject to the exceptions in Paragraph 6 below, in consideration of the obligations of Medtronic and MSD set forth in this Agreement, conditioned upon timely payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies and departments) agrees to release Medtronic, MSD and all current employees thereof from any civil or administrative monetary claim or cause of action the United States has or may have against Medtronic or MSD under the False Claims Act, 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 under the common law or equitable theories of payment by mistake, unjust

enrichment, conversion, fraud, breach of contract, and recoupment, for the Covered Conduct. In addition, the United States agrees to petition the district court to dismiss both of the Qui Tam Lawsuits with prejudice to the relators.

5. Subject to the exceptions in Paragraph 6 below, in consideration of the obligations of Medtronic and MSD set forth in this Agreement and in the attached CIA, conditioned upon timely payment in full of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Medtronic or MSD under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct, except as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Medtronic and MSD from the Medicare, Medicaid and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Medtronic and MSD) are any and all of the following:

a. Any claims of any kind whatsoever 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 exclusion from Federal health care programs pursuant to 42 U.S.C. § 1320a-7(a);
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- f. Any claims against individuals or entities other than Medtronic, MSD or the current employees thereof; and
- g. Any claims based upon such obligations as are created by this Agreement.

7. Medtronic and MSD release the United States and its agencies, officers, agents, employees, and contractors and their employees, from any and all claims, causes of action, adjustments, and set-offs of any kind arising out of or pertaining to the Covered Conduct, including the investigation of the Covered Conduct.

8. Medtronic and MSD waive and will not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on the Double Jeopardy or Excessive Fines Clause of the Constitution or the holding or principles set forth in *United States v. Halper*, 490 U.S. 435 (1989), and *Austin v. United States*, 509 U.S. 602 (1993), and agrees that the Settlement Amount is not punitive in nature or effect for purposes of such criminal prosecution or administrative action. Nothing in this

Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. Medtronic and MSD agree to the following:

a. Unallowable Costs Defined: That 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. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Medtronic, MSD, or their current and former parent corporations, subsidiaries, division, affiliates, brother and sister corporations, predecessors, successors and assigns, along with their current and former employees, officers and directors, in connection with the following are unallowable costs on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, Veterans Affairs Program (“VA”), and FEHBP (Federal Employee Health Benefits Program):

(1) the matters covered by this Agreement,

(2) the Government’s audit(s), civil and criminal investigation(s), and litigation of the matters covered by this Agreement,

(3) Medtronic’s and MSD’s investigation, defense, and corrective actions undertaken in response to the Government’s audit(s), civil and criminal investigation(s), and litigation in connection with the matters covered by this Agreement (including attorneys’ fees),

(4) the negotiation and performance of the Settlement Agreement,

(5) the payments made pursuant or ancillary to this Settlement Agreement,

including any costs and attorneys' fees, and any payments Medtronic or MSD may make to relators, including costs and attorneys' fees, and

(6) the negotiation of, and obligations undertaken pursuant to the Corporate Integrity Agreement to:

(i) Retain independent review organizations to perform annual reviews as described in Section III. of the CIA; and

(ii) prepare and submit reports to the OIG-HHS.

However, nothing in this Paragraph 7(a)(6) that may apply to the obligations undertaken pursuant to the Corporate Integrity Agreement affects the status of costs that are not allowable based on any other authority applicable to Medtronic or MSD. (All costs described or set forth in this Paragraph 7(a) are hereafter, "unallowable costs").

b. Future Treatment of Unallowable Costs: These unallowable costs shall be separately determined and accounted for in non-reimbursable cost centers by Medtronic and MSD, and Medtronic and MSD will 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, MSD, or any of their current and former parent corporations, subsidiaries, divisions, affiliates, brother and sister corporations, predecessors, successors and assigns, along with their current and former employees, officers and directors, to the Medicare, Medicaid, TRICARE, VA or FEHBP programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Medtronic and MSD further agree that within 90 days of the Effective Date of this Agreement, they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA 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, MSD, or any of their current and former parent corporations, subsidiaries, divisions, affiliates, brother and sister corporations, predecessors, successors and assigns, along with their current and former employees, officers and directors, 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 and MSD agree that the United States, at a minimum, will be entitled to recoup from Medtronic and MSD 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. If Medtronic or MSD fails to identify such costs in past filed cost reports in conformity with this Paragraph, the United States may seek an appropriate penalty or other sanction in addition to the recouped amount.

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 MSD on the effect of inclusion of unallowable costs (as defined in this Paragraph) on the cost reports, cost

statement, or information reports of Medtronic or MSD.

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

10. Medtronic and MSD agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Medtronic and MSD will make reasonable efforts to facilitate access to, and encourage the cooperation of, their directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and will furnish to the United States, upon reasonable request, all non-privileged documents and records in its possession, custody, or control relating to the Covered Conduct.

11. This Agreement is intended to be for the benefit of the Parties only, including their current and former parent corporations, subsidiaries, predecessors, successors, and assigns, and by this instrument the Parties do not release any claims against any other person or entity.

12. Medtronic and MSD agree that they waive and will 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 payors based upon the claims defined as the Covered Conduct. Medtronic and MSD represent that they have no direct billing relationship with health care beneficiaries, their insurers or any federal health care program.

13. Except as expressly provided to the contrary in this Agreement, each Party shall

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

14. Medtronic and MSD represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever and they have been advised with respect hereto by counsel prior to entering into this Settlement Agreement.

15. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between the United States and Medtronic or MSD under this Agreement will be the United States District Court for the Western District of Tennessee, except that disputes arising under the attached Corporate Integrity Agreement shall be resolved exclusively under the dispute resolution provisions of that agreement.

16. This Agreement and the Corporate Integrity Agreement among Medtronic, MSD, and OIG-HHS constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only OIG-HHS and Medtronic and MSD must agree in writing to modification of the Corporate Integrity Agreement.

17. The individuals signing this Agreement on behalf of Medtronic and MSD represent and warrant that they are authorized to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

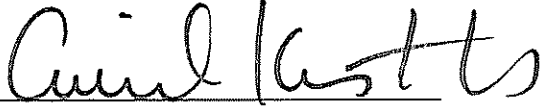
18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

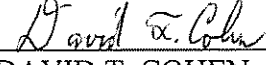
19. All parties consent to the United States' disclosure of this Agreement, and

information about this Agreement, to the public.

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

DATED: July 13, 2006 BY: 
DAVID KUSTOFF
United States Attorney
Western District of Tennessee

DATED: July 18, 2006 BY: 
DAVID T. COHEN
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
Office of Counsel to the Inspector General
United States Department of
Health and Human Services

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BY: _____

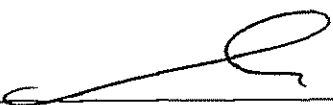
DAVID KUSTOFF
United States Attorney
Western District of Tennessee

DATED: _____

BY: _____

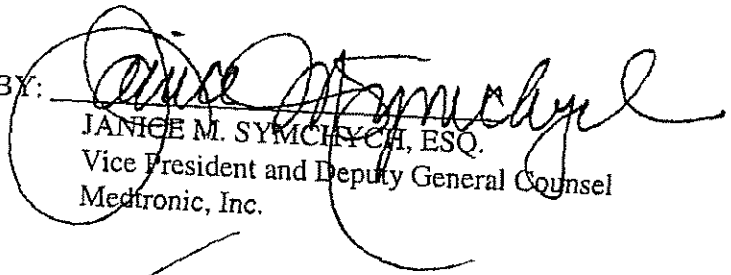
DAVID T. COHEN
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 7/17/06

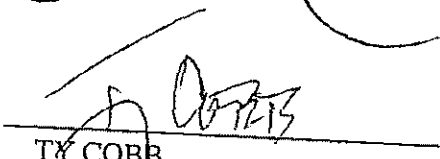
BY:  _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
Office of Counsel to the Inspector General
United States Department of
Health and Human Services

DATED: 7-14-06

BY: 
JANICE M. SYMCZYK, ESQ.
Vice President and Deputy General Counsel
Medtronic, Inc.

DATED: 7/17/06

BY: 
TY COBB
HOGAN & HARTSON
Counsel for Medtronic, Inc. and
Medtronic Sofamor Danek USA, Inc.