CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEDTRONIC SOFAMOR DANEK USA, INC.

I. PREAMBLE

Medtronic Sofamor Danek USA, Inc. (MSD) and Medtronic, Inc. (Medtronic) entered into a Settlement Agreement with the United States and this Corporate Integrity Agreement (CIA) is incorporated by reference into the Settlement Agreement. MSD is a wholly owned subsidiary of Medtronic. MSD hereby enters into this CIA with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) and Medtronic hereby enters into certain specified provisions of this CIA to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This CIA shall apply only to U.S. operations of MSD and Medtronic that are subject to U.S. Federal health care program requirements.

Medtronic is the parent corporation of MSD. Medtronic represented to the OIG that, prior to the effective date of this CIA, Medtronic established a voluntary compliance program, which includes a corporate compliance officer, a corporate compliance committee, a Code of Ethics and Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, an ineligible persons screening program, and internal audit and review procedures. Medtronic agrees to continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Medtronic will ensure that during the term of this CIA, it shall comply with certain integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Medtronic and MSD under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date that Medtronic or MSD becomes obligated to make payment to the United States of the Settlement Amount from the Escrow Account established pursuant to the Settlement Agreement between the United States, Medtronic, and MSD, signed on or about the date of signature of this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Medtronic and MSD's final annual report; or (2) any additional materials submitted by Medtronic or MSD pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Arrangements" shall mean every arrangement or transaction entered into by MSD that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between MSD and any actual or potential source of health care business or referrals of health care business to MSD or any actual or potential recipient of health care business or referral from MSD. The term "source" shall include any physician, contractor, vendor, or agent; and the term "health care business or referrals" shall be read to include referring, recommending, or arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

    a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to the provision of services to MSD, including but not limited to, training, education, consulting, research, clinical studies, focus groups, physician advisory boards as well as intellectual property, grants, and charitable contributions.

b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.

2. "Covered Persons" includes:

a. all officers, directors and employees of Medtronic and MSD, including but not limited to, Medtronic's CEO and MSD's President and all members of Medtronic's and MSD's respective management inclusive of senior vice presidents, vice presidents, directors, and managers;

b. all contractors, subcontractors, agents, and other persons who, on behalf of MSD, perform functions related to the sale or marketing of items or services reimbursable by Federal health care programs; and

c. all individuals that sell or market on behalf of Medtronic items or services for which reimbursement may be made by the Federal health care programs.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

3. "Relevant Covered Persons" includes persons involved in the development, approval, management, implementation, use, or review of any of MSD's Arrangements.

III. CORPORATE INTEGRITY OBLIGATIONS

A. Compliance Officers and Committees.

1. *Compliance Officers.*

a. Medtronic represented to the OIG that, prior to the Effective

Date of this CIA, Medtronic appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. To the extent not already accomplished, within 120 days after the Effective Date, the Medtronic Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA. To the extent not already accomplished, within 120 days after the Effective Date, the Medtronic Compliance Officer shall be a member of Medtronic's senior management. The Medtronic Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to Medtronic's Compliance Committee and Chief Executive Officer and shall have direct access to Medtronic's Board of Directors. The Medtronic Compliance Officer shall report directly to Medtronic's Chief Executive Officer regarding compliance matters. The Medtronic Compliance Officer shall not be or be subordinate to Medtronic's General Counsel or Chief Financial Officer. The Medtronic Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Medtronic as well as for any reporting obligations imposed upon Medtronic under this CIA. The Compliance Officer function outlined in this Section III.A.1 shall continue during the Term of this CIA.

b. MSD represented to the OIG that, prior to the Effective Date of this CIA, MSD appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. To the extent not already accomplished, within 120 days after the Effective Date, the MSD Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA. To the extent not already accomplished, within 120

days after the Effective Date, the MSD Compliance Officer shall be a member of MSD's senior management. The MSD Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to MSD's Compliance Committee and President and shall have direct access to Medtronic's and MSD's Boards of Directors. The MSD Compliance Officer shall report directly to MSD's President regarding compliance matters. The MSD Compliance Officer shall not be or be subordinate to Medtronic or MSD's General Counsel or Chief Financial Officer. The MSD Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by MSD as well as for any reporting obligations created under this CIA. The Compliance Officer function outlined in this Section III.A.1 shall continue during the Term of this CIA.

Medtronic and MSD shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officers, or any actions or changes that would affect the Compliance Officers' ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committees.*

a. Medtronic represented to the OIG that, prior to the Effective Date of this CIA, Medtronic appointed a Compliance Committee. The Compliance Committee includes and shall continue to include the Compliance Officer and members of senior management responsible for finance, clinical, human resources, legal, sales, and operations. The Compliance Committee shall support the Compliance Officer in fulfilling his or her responsibilities (e.g., assist in the analysis of Medtronic's risk areas and oversee monitoring of internal and external audits and investigations). The Compliance Committee function outlined in this Section III.A.2 shall continue during the Term of this CIA.

b. MSD represented to the OIG that, prior to the Effective Date of this

CIA, MSD appointed a Compliance Committee. The Compliance Committee includes and shall continue to include the Compliance Officer and members of senior management responsible for finance, clinical, human resources, legal, sales, and operations. The Compliance Committee shall support the Compliance Officer in fulfilling his or her responsibilities (e.g., assist in the analysis of MSD's risk areas and oversee monitoring of internal and external audits and investigations). The Compliance Committee function outlined in this Section III.A.2 shall continue during the Term of this CIA.

Medtronic and MSD shall report to OIG, in writing, any changes in the composition of the Compliance Committees, or any actions or changes that would affect the Compliance Committees' ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Medtronic represented to the OIG that, prior to the Effective Date of this CIA, Medtronic developed a Code of Conduct ("the Code of Conduct"), which is applicable to MSD. Medtronic and MSD shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Medtronic's commitment to full compliance with all federal, state and local laws and regulations (which includes Federal health care program requirements);

b. Medtronic's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Medtronic's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

c. the requirement that all Covered Persons shall be expected to report to their Compliance Officer, or other appropriate individuals designated by

Medtronic or MSD, suspected violations of any Federal health care program requirements or of Medtronic's and MSD's own Policies and Procedures;

d. the possible consequences to Medtronic, MSD, and Medtronic's and MSD's Covered Persons of failure to comply with all Federal health care program requirements and with Medtronic and its subsidiaries' Policies and Procedures and the failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and Medtronic's and MSD's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 15 days after the Effective Date, Medtronic and MSD shall distribute the Code of Conduct to each Covered Person and each Covered Person will certify, in writing or electronically, that he or she has received, read, understood and shall abide by Medtronic's Code of Conduct. Medtronic and MSD may distribute the Code of Conduct and the required certification to each Covered Person either electronically or in hard-copy form. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Medtronic shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 60 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures*. Within 120 days after the Effective Date, Medtronic and MSD shall implement written Policies and Procedures regarding the operation of Medtronic's and MSD's compliance programs and their compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures required under this Section, and this CIA;

c. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may violate the Anti-Kickback Statute, and the applicability of the Anti-Kickback Statute to Arrangements as that term is defined in Section II.C.1; and

d. for MSD only, the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute), including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Medtronic and MSD's intranet or other internal web sites available to all employees. If either Medtronic or MSD uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner, and it must adopt tracking procedures designed to track the distribution and reasonably ensure that all appropriate individuals received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least once per Medtronic and MSD's fiscal year (and more frequently, if appropriate), Medtronic and MSD shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Medtronic and MSD shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain Medtronic's and MSD's:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training per Medtronic's and MSD's fiscal year.

2. *Anti-Kickback Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Anti-Kickback Training, in addition to the General Training required above. The Anti-Kickback Training shall include a discussion of:

a. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;

b. Medtronic's and MSD's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

c. the personal obligation of each individual involved in the development, approval, management, implementation, use, or review of MSD's Arrangements to know the applicable legal requirements

and Medtronic's and MSD's policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute; and

e. examples of violations of the Anti-Kickback Statute.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An MSD employee who has completed the Anti-Kickback Training shall review a new Relevant Covered Person's work until such time as the new Relevant Covered Person completes his or her Anti-Kickback Training.

After receiving the initial Anti-Kickback Training described in this Section, each Relevant Covered Person shall receive at least two hours of Anti-Kickback Training per fiscal year of MSD.

3. *Certification.* Each individual who is required to attend training pursuant to this Section III.C shall, upon completion of the training, certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officers (or designees) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training required by this Section III.C shall be knowledgeable about the subject area.

5. *Update of Training.* At least once per their fiscal year, Medtronic and MSD shall review the training programs developed to satisfy the requirements of this Section III.C, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the Arrangements Review, and any other relevant information.

6. *Training Methods.* Medtronic and MSD may provide the training required under this CIA through videotape, DVD, appropriate computer-based training approaches, or other comparable methods not involving in-person training. If Medtronic

and MSD choose to provide training pursuant to any such method, they shall also make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

7. *Independent Distributors.* Where a Covered Person or Relevant Covered Person is an independent distributor, the General Training obligations under this CIA shall be met so long as the training is provided to a member of management of the independent distributor. MSD shall request, and with respect to all new Arrangements, require the independent distributor to take reasonable steps to apprise its employees and other personnel regarding the content of the training. In addition, MSD shall require such entities to do the following:

a. agree to abide by the Code of Conduct or adopt its own Code of Conduct addressing substantially all of the requirements of Section III.B.1;

b. distribute the following materials to its employees and subcontractors working on MSD matters: (1) Medtronic's or its own Code of Conduct; (2) copies of relevant MSD policies and procedures relating to the work of the independent distributor; and (3) information about MSD's Disclosure Program (including the hotline number);

c. provide either directly or through MSD, Anti-Kickback Training (as described in Section III.C.2) to its employees and subcontractors to the extent they are involved with the development, approval, management, implementation, use, or review of any of MSD's Arrangements;

d. certify to MSD that all employees and subcontractors working on MSD matters have: (1) been screened to exclude Ineligible Persons in accordance with the requirements of Section III.G of the CIA; (2) received a copy of Medtronic's Code of Conduct or its own Code of Conduct, information about MSD's Disclosure Program (including the hotline number); and (3) to the extent applicable, received Anti-Kickback training.

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures*. Within 120 days after the Effective Date, MSD shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement, including Contractual Arrangements and Non-Contractual Arrangements, does not violate the Anti-Kickback Statute (taking into account the regulations, directives, and guidance related to this statute) (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, that shall contain the information specified in Appendix A (Arrangements Database);

b. tracking remuneration to and from MSD to all other parties to Arrangements;

c. tracking service and activity logs to ensure that parties to the Arrangement(s) are performing the services required under the applicable Arrangement(s) (if applicable);

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s);

e. establishing and implementing a written review and prior approval process for all Contractual Arrangements, including but not limited to, a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all existing and new or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;

f. establishing and implementing a written review and approval process for all Non-Contractual Arrangements, including but not

limited to, an annual legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute;

g. requiring the MSD Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to MSD's Compliance Committee; and

h. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events pursuant to Section III.I (Reporting).

2. *New or Renewed Arrangements.* With the exception of Non-Contractual Arrangements, prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, MSD shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by MSD and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with MSD's Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, MSD shall provide each party to the Arrangement with a copy of the Code of Conduct and Anti-Kickback Statute Policies and Procedures; and

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access*. MSD shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, MSD shall engage an individual or entity (or entities), such as an auditing, law or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist MSD in assessing its compliance with the obligations pursuant to Section III.D of this Agreement (Arrangements Review).

The IRO shall assess, along with Medtronic and MSD, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between Medtronic or MSD and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix B to this Agreement, which is incorporated by reference.

b. *Frequency of Arrangements Review.* The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Arrangements Review.

c. *Retention of Records.* The IRO and MSD shall retain and make available to OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports (those exchanged between the IRO and MSD) related to the reviews.

d. *Responsibilities and Liabilities*. Nothing in this Section III.E affects MSD's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

2. *Arrangements Review*. The IRO shall perform a review to assess whether MSD is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 75 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether MSD has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether MSD has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the activity logs are properly completed and reviewed ; (e) verifying (if applicable) that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored; (f) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (f) verifying that effective responses are being implemented when potential violations of the Anti-Kickback Statute are discovered; and (g) verifying that MSD has met the requirements of Section III.D.2.

3. *Arrangements Review Report*. The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to: (a) whether MSD has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether MSD has complied with the

Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include observations, findings and recommendations, if any, on possible improvements to MSD's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute.

4. *Validation Review.* In the event OIG has reason to believe that: (a) MSD's Arrangements Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Arrangements Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review complied with the requirements of the Agreement and/or the findings or Arrangements Review results are inaccurate (Validation Review). MSD shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of MSD's final Annual Report must be initiated no later than one year after MSD's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify MSD of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, MSD may request a meeting with OIG to: (a) discuss the results of any Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. MSD agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review issues with MSD prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to MSD a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Arrangements Review that it has concluded that it is, in fact, independent and/or objective.

F. Disclosure Program.

Medtronic and MSD represented to the OIG that, prior to the Effective Date of this CIA, they established a Disclosure Program that includes a toll-free compliance telephone line to enable individuals to disclose, to Medtronic's and/or MSD's Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Medtronic's and MSD's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. To the extent not already accomplished, Medtronic and MSD shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). Medtronic and MSD shall continue the Disclosure Program during the Term of the CIA as set forth in this Section III.F.

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy and include a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Upon receipt of a Disclosure, the relevant Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The relevant Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every Disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any Disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice and (2) provides an opportunity for taking corrective action, Medtronic or MSD shall conduct an internal review of the allegations set forth in that Disclosure and ensure that proper follow-up is conducted.

MSD's Compliance Officer (or designee) shall maintain a confidential Disclosure log, which includes a record and summary of each Disclosure received (whether anonymous or not) by MSD, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews (the "MSD Disclosure Log"). Medronic's Compliance Officer (or designee) also shall maintain either separately or in conjunction with MSD, a confidential Disclosure log, which includes a record and

summary of each Disclosure received (whether anonymous or not) by Medtronic, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The Disclosure log(s) shall be available to OIG, upon request. When Medtronic and MSD provide access to the confidential Disclosure log(s) to the OIG as specified in this Section, they shall provide the logs to the OIG upon request and as soon as practicable, but not later than 10 business days from the date of the OIG request.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).

c. "Screened Persons" include all current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), all current and prospective officers, directors, employees, contractors,

and agents of MSD and all Covered Persons who perform functions related to the delivery sale, or marketing of items or services reimbursable by Federal health care programs.

2. *Screening Requirements.* Medtronic and MSD shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Medtronic and MSD shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. Medtronic and MSD shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter. Medtronic shall screen institutional shareholders if Medtronic has notice that an institutional shareholder (1) has acquired an ownership interest of 5% or more as of the date of screening and (2) acquired that ownership interest through public trading.

c. Medtronic and MSD shall implement a policy requiring all Screened Persons (except prospective and current owners who (1) have an ownership interest of 5% or more; and (2) acquired the ownership interest through public trading) to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Medtronic and MSD to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Medtronic or MSD has actual notice that a Screened Person has become an Ineligible Person, Medtronic or MSD shall remove such person from responsibility for, or involvement with, Medtronic's and MSD's business operations related to the Federal health care programs and shall remove such person from

any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Medtronic or MSD has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, Medtronic or MSD shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at Medtronic or MSD, Medtronic or MSD shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Medtronic or MSD, conducted or brought by a U.S. Federal, state, or local governmental entity or agents involving an allegation that Medtronic or MSD has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Medtronic and MSD shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

To the extent not already accomplished, within 120 days after the Effective Date, Medtronic shall implement an internal policy requiring all Medtronic employees immediately to report to senior management at Medtronic or MSD any ongoing investigation or legal proceeding, conducted or brought by a U.S. Federal, state, or local governmental entity or agents.

I. Reporting.

1. *Reportable Events.*

a. Definition of Reportable Event. For purposes of this CIA, a "Reportable Event" means anything that involves a matter brought to the attention of senior management at Medtronic's corporate headquarters, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If Medtronic or MSD determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Medtronic or MSD shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

The report to OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of Medtronic's or MSD's actions taken to correct the Reportable Event; and

iii. any further steps Medtronic or MSD plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS

In the event that, after the Effective Date, Medtronic or MSD sells, closes, purchases, or establishes a new business unit related to the delivery, sale, marketing, or furnishing of items or services that may be reimbursed by Federal health care programs, Medtronic or MSD shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of sale, closure, purchase, or establishment. This notification shall include the address of the new business unit, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new Medtronic business unit shall be subject to all of Medtronic's requirements under this CIA. Each new MSD business unit shall be subject to all of MSD's requirements under this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Medtronic and MSD shall submit a joint written report to OIG summarizing the status of their implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the names, addresses, phone numbers, and position descriptions of the Compliance Officers required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officers may have;

2. the names and positions of the members of the Compliance Committees required by Section III.A;

3. a copy of the applicable Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a description of the Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a description of the Disclosure Program required by Section III.F;

11. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Medtronic or MSD and the IRO; and (d) the proposed start and completion dates of the Arrangements Review;

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Medtronic and MSD;

13. a description of the process by which Medtronic and MSD fulfill the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a list of all of Medtronic's and MSD's locations (including locations and mailing addresses); the corresponding name(s) under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s);

16. a description of Medtronic's and MSD's corporate structures, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Medtronic and MSD shall submit to OIG annually a joint report with respect to the status of, and findings regarding, Medtronic's and MSD's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officers and any change in the membership of the Compliance Committees described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a description of any changes to the Arrangements Database required by Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.e;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);

9. MSD's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

10. a summary and description of any and all current and prior engagements and agreements between Medtronic or MSD and the IRO, if different from what was submitted as part of the Implementation Report;

11. a certification from the IRO regarding its professional independence and/or objectivity with respect to Medtronic and MSD;

12. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action

relating to all such Reportable Events;

13. a summary of the disclosures in the MSD Disclosure log (if the MSD and Medtronic Disclosure logs are maintained jointly) or the Medtronic and MSD Disclosure logs (if the MSD and Medtronic Disclosure logs are maintained separately) required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute;

14. any changes to the process by which Medtronic or MSD fulfills the requirements of Section III.G regarding Ineligible Persons;

15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Medtronic or MSD in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a description of all changes to the most recently provided list of Medtronic's and MSD's locations (including addresses) as required by Section V.A.15; the corresponding name(s) under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and

18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. The Implementation Report and Annual Reports shall include a certification by Medtronic's Compliance Officer that:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, Medtronic is in compliance with all of its requirements of this CIA; and

b. he or she has reviewed the Report as it relates to Medtronic and has made reasonable inquiry regarding its content and believes that the information in the Report relating to Medtronic is accurate and truthful.

2. The Implementation Report and Annual Reports shall include a certification by MSD's Compliance Officer that:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, MSD is in compliance with all of its requirements of this CIA;

b. to the best of his or her knowledge, MSD has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.D of the CIA;

c. to the best of his or her knowledge, MSD has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA; and

d. he or she has reviewed the Report as it relates to MSD and has made reasonable inquiry regarding its content and believes that the information in the Report relating to MSD is accurate and truthful.

D. Designation of Information. Medtronic and MSD shall clearly identify any portions of their submissions that they believe are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Medtronic and MSD shall refrain from identifying any information as exempt from

disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Medtronic:

Kathy DiGiorno
Compliance Officer
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, Minnesota 55432
Telephone: 763.505.5000
Facsimile: 763.505.1000

MSD:

Machelle Shields
Compliance Officer
Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: 901.396.3133
Facsimile: 901.344.1576

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Medtronic's or MSD's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Medtronic's or MSD's locations for the purpose of verifying and evaluating: (a) Medtronic's or MSD's compliance with the terms of this CIA; and (b) Medtronic's or MSD's compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by Medtronic and MSD to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Medtronic's or MSD's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Medtronic and MSD shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Medtronic's and MSD's employees may elect to be interviewed with or without a representative of Medtronic or MSD present. Medtronic's and MSD's employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for Medtronic or MSD and/or his or her personal counsel at any interview by the OIG. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and Medtronic and MSD shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA. Neither Medtronic nor MSD shall discourage employees from submitting to interviews requested by the OIG.

VIII. DOCUMENT AND RECORD RETENTION

Medtronic and MSD shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Medtronic or MSD prior to any release by OIG of information submitted by Medtronic and MSD pursuant to their obligations under this CIA and identified upon submission by Medtronic and MSD as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Medtronic and MSD shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

MSD is expected to fully and timely comply with all CIA obligations applicable to MSD. Medtronic is expected to fully and timely comply with all CIA obligations applicable to Medtronic. A breach of this CIA does not constitute a breach of the Settlement Agreement between Medtronic, MSD, and the United States executed contemporaneously herewith. Any breach of the terms of that agreement does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if MSD fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any action that individual States may take against Medtronic or MSD under appropriate authorities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Medtronic, MSD and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day

after the date the obligation became due) for each day Medtronic or MSD fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. Notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MSD fails to establish and implement the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MSD fails to engage an IRO, as required in Section III.E and Appendix B.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Medtronic and MSD fail to submit the joint Implementation Report or the joint Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

5. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MSD fails to submit the annual Arrangements Review Report in accordance with the requirements of Section III.E.

6. A Stipulated Penalty of $1,500 for each day Medtronic or MSD fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Medtronic or MSD fails to grant access.)

7. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Medtronic or MSD as part of their Implementation Report, Annual Reports, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of $1,000 for each day Medtronic or MSD fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Medtronic or MSD, stating the specific grounds for its determination that Medtronic or MSD have failed to comply fully and adequately with the CIA obligation(s) at issue and steps Medtronic or MSD shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Medtronic or MSD receive this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions. Medtronic and MSD may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Medtronic fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Medtronic or MSD receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Medtronic or MSD has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Medtronic or MSD of: (a) Medtronic's or MSD's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Medtronic or MSD shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Medtronic or MSD elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Medtronic or MSD cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Medtronic or MSD has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by Medtronic or MSD to report a Reportable Event, or

take corrective action, as required in Section III.I;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Medtronic constitutes an independent basis for Medtronic's exclusion from participation in the Federal health care programs and a material breach of this CIA by MSD constitutes an independent basis for MSD's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Medtronic or MSD has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Medtronic or MSD of: (a) Medtronic's or MSD's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Medtronic and MSD shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Medtronic or MSD is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Medtronic or MSD has begun to take action to cure the material breach; (ii) Medtronic or MSD is pursuing such action with due diligence; and (iii) Medtronic or MSD has provided

to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Medtronic fails to satisfy the requirements of Section X.D.3, OIG may exclude Medtronic from participation in the Federal health care programs, and if MSD has failed to satisfy the requirements of Section X.D.3, OIG may exclude MSD from participation in the Federal health care programs. OIG shall notify Medtronic or MSD in writing of its determination to exclude Medtronic or MSD (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Medtronic's or MSD's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Medtronic or MSD may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Medtronic or MSD of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Medtronic or MSD shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Medtronic or MSD was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Medtronic or MSD shall

have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Medtronic or MSD to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Medtronic or MSD requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Medtronic or MSD was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Medtronic or MSD has begun to take action to cure the material breach within that period; (ii) Medtronic or MSD has pursued and is pursuing such action with due diligence; and (iii) Medtronic or MSD provided to OIG within that period a reasonable timetable for curing the material breach and Medtronic or MSD has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Medtronic or MSD, only after a DAB decision in favor of OIG. Medtronic's or MSD's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Medtronic or MSD upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Medtronic or MSD may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB

decision. Medtronic or MSD shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Medtronic or MSD, Medtronic or MSD shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Medtronic, MSD and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Medtronic and MSD;

B. This CIA shall become final and binding on the date that Medtronic or MSD becomes obligated to make payment to the United States of the Settlement Amount from the Escrow Account established pursuant to the Settlement Agreement between the United States, Medtronic, and MSD, signed on or about the date of signature of this CIA. Medtronic and MSD shall notify the OIG of the date that Medtronic or MSD becomes obligated to make payment of that Settlement Amount;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. OIG may agree to a suspension of Medtronic's or MSD's obligations under the CIA in the event of Medtronic's or MSD's cessation of the delivery, sale, marketing, or furnishing of items or services reimbursed by any Federal health care programs. If such cessation occurs and Medtronic or MSD is relieved of its CIA obligations by OIG, Medtronic or MSD shall notify OIG at least 30 days in advance of the date on which Medtronic or MSD intends to begin delivering, selling, marketing, or furnishing items or services reimbursed by any Federal health care programs. Upon receipt of such

notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Medtronic and MSD signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF MEDTRONIC, INC.

/Janice M. Symchych/

JANICE M. SYMCHYCH, ESQ.
Vice President and Deputy General Counsel
Medtronic, Inc.

7-14-06
DATE

/Kathleen Erickson DiGiorno/

KATHLEEN ERICKSON DiGIORNO
Compliance Officer
Medtronic, Inc.

7/14/06
DATE

/Ty Cobb/

TY COBB, ESQ.
Hogan & Hartson
Counsel for Medtronic, Inc.

7/14/06
DATE

ON BEHALF OF MEDTRONIC SOFAMOR DANEK USA, INC.

PETER WEHRLY
President
Medtronic Sofamor Danek USA, Inc.

DATE

TODD N. SHELDON, ESQ.
Vice President and Senior Legal Counsel
Medtronic Sofamor Danek USA, Inc.

DATE

ON BEHALF OF MEDTRONIC, INC.

JANICE M. SYMCHYCH, ESQ.
Vice President and Deputy General Counsel
Medtronic, Inc.

DATE

KATHLEEN ERICKSON DiGIORNO
Compliance Officer
Medtronic, Inc.

DATE

TY COBB, ESQ.
Hogan & Hartson
Counsel for Medtronic, Inc.

DATE

ON BEHALF OF MEDTRONIC SOFAMOR DANEK USA, INC.

/Peter Wehrly/

PETER WEHRLY
President
Medtronic Sofamor Danek USA, Inc.

7/18/06
DATE

TODD N. SHELDON, ESQ.
Vice President and Senior Legal Counsel
Medtronic Sofamor Danek USA, Inc.

DATE

ON BEHALF OF MEDTRONIC, INC.

JANICE M. SYMCHYCH, ESQ.
Vice President and Deputy General Counsel
Medtronic, Inc.

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KATHLEEN ERICKSON DiGIORNO
Compliance Officer
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TY COBB, ESQ.
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Counsel for Medtronic, Inc.

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ON BEHALF OF MEDTRONIC SOFAMOR DANEK USA, INC.

PETER WEHRLY
President
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/Todd N. Sheldon/

TODD N. SHELDON, ESQ.
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/Ty Cobb/

TY COBB, ESQ.
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7/17/06
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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MACHELLE SHIELDS
Compliance Officer
Medtronic Sofamor Danek USA, Inc.

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ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Gregory E. Demske/

7/17/06

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

DATE

APPENDIX A

ARRANGEMENTS DATABASE

MSD shall create and maintain an Arrangements Database to track all new and existing Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, in order to ensure that each Arrangement does not violate the Anti-Kickback Statute.

A. The Arrangements Database shall contain certain information to assist MSD in evaluating whether each Contractual Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. Each party involved in the Arrangement;

2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);

3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;

4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;

5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;

6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;

7. Whether each party has fulfilled the requirements of Section III.D.2; and

8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

B. The Arrangements Database shall contain certain information to assist MSD in evaluating whether each Non-Contractual Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. The name of the entity or individual receiving the Non-Contractual remuneration;

2. The type of Non-Contractual remuneration (listing in the aggregate multiple distributions of the same type of Non-Contractual remuneration to each entity or individual);

3. The aggregate value of each type of Non-Contractual remuneration given to each entity or individual during the Reporting Period;

4. Whether the Non-Contractual remuneration given pursuant to the Non-Contractual Arrangement is determined based on the volume or value of referrals between the parties; and

5. Whether the Non-Contractual Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement.

MSD shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify MSD if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, MSD may continue to engage the IRO.

If MSD engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, MSD shall submit the information identified in Section V.A.11 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify MSD if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, MSD may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals qualified to conduct the Arrangements Review; and

2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

3. prepare timely, clear, well-written reports that include all the information required by Section III.E.3 of the CIA.

D. IRO Independence/Objectivity.

The IRO must perform the Arrangements Review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and MSD and/or Medtronic.

E. IRO Removal/Termination.

1. *Provider.* If MSD terminates its IRO during the course of the engagement, MSD must submit a notice explaining its reasons to OIG no later than 30 days after termination. MSD must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require MSD to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring MSD to engage a new IRO, OIG shall notify MSD of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, MSD may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. MSD shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with MSD prior to requiring MSD to terminate the IRO. However, the final determination as to whether or not to require MSD to engage a new IRO shall be made at the sole discretion of OIG.