UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,	
Plaintiff,	**CIVIL ACTION NO.** 12cv2562 PAM/JSM
ex rel.	
[UNDER SEAL],	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
Plaintiffs-Relators,	
v.	
[UNDER SEAL],	
Defendants.	

COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,	**CIVIL ACTION NO.**
PLAINTIFF,	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
ex rel.	
SAMUEL ADAM COX, III, MEAYNA PHANTHAVONG, and SONIA ADAMS,	**JURY TRIAL DEMANDED**
PLAINTIFFS-RELATORS,	
v.	
MEDTRONIC, INC., MEDTRONIC USA, INC.,	
and MEDTRONIC SOFAMOR DANEK USA, Inc.	
Defendants.	

COMPLAINT

1. The United States of America (United States or the Government), by and through the *qui tam* relators Samuel Adam Cox, III, Sonia Adams, and Meayna Phanthavong (together, Plaintiffs-Relators or Relators), bring this action under the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, against Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc. (collectively, Medtronic or Defendants),

to recover all damages, penalties, and other remedies provided by the False Claims Act for the United States and the Relators, and for their Complaint, allege as follows:

I. NATURE OF THE CASE

2. This is an action for treble damages and civil penalties on behalf of the United States of America arising from false or fraudulent claims, statements, and/or records presented, made, used, or caused to be presented, made, or used by Defendants in violation of the FCA. Medtronic has defrauded and continues to defraud the United States by selling and delivering to federal agencies medical-surgical products manufactured in "non-designated countries" within the meaning of the Trade Agreements Act of 1979 (TAA), 19 U.S.C. §§ 2501-2582, while falsely certifying that the products were made in the United States.

3. Originally enacted during the Civil War, the FCA, as amended in 1986, *see* Pub. L. 99-562, 100 Stat. 3153 (1986), provides that anyone who knowingly submits a false or fraudulent claim to the United States for payment or approval, or a false record material to such a claim, is liable for a civil penalty of at least $5,500 and up to $11,000 per violation, three times the damages sustained by the Government, and litigation costs. *See* 31 U.S.C. § 3729(a)(1), (3).

4. The FCA holds liable, *inter alia*, anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the United States. 31 U.S.C. § 3729(a)(1)(A).

5. The FCA also holds liable, *inter alia*, anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent

claim." *Id.* § 3729(a)(1)(B). (For false claims that were made prior to June 7, 2008, but were not "pending" on that date, the Act holds liable anyone who "knowingly makes, uses, or causes to be made or used, a false statement to get a false or fraudulent claim paid or approved by the Government." *See id.* § 3729 note (1999 amendments); former § 3729(a)(2) (2008). The difference between the "to-get-paid" and the "material-to" standards before and after June 7, 2008 is immaterial to this case.)

6. The FCA allows a person knowing of false or fraudulent claims or records presented to the Government to bring a private (*qui tam*) action on behalf of both the person (relator) and the Government, and to share in any recovery. The *qui tam* complaint is filed under seal (and not served on defendant/s) for 60 days, to enable the Government to (i) investigate without defendants' knowledge and (ii) determine whether to intervene. *See* 31 U.S.C. § 3730(b). The relator is entitled to a share of any money recovered by or on behalf of the United States in the action, plus attorneys' fees, costs and expenses. *See id.* § 3730(d).

7. Based on these provisions, the Plaintiffs-Relators seek treble damages and civil penalties arising from Medtronic's knowing presentation of false claims for payment in which Medtronic certified that certain medical-surgical products that it sold to the United States were manufactured or "substantially transformed" in the United States, and thus were eligible for federal procurement under the Trade Agreements Act—when, in fact, the products were manufactured in China, India, Malaysia, or other "non-designated countries."

8. Plaintiffs-Relators also seek damages and civil penalties arising from Medtronic's knowingly making, using, or causing to be made or used false records or statements in connection with unlawful sales of goods to the Government that did not comply with the TAA.

9. Plaintiffs-Relators, collectively, have direct and independent knowledge that Medtronic has violated the TAA and False Claims Act by offering and selling products to the United States Government that did not originate in countries that were "designated" under the TAA, while at the same time knowingly making false statements and/or records certifying that Medtronic's products were manufactured in the United States or designated countries.

II. PARTIES

A. Plaintiff and Plaintiffs-Relators

10. Plaintiff **United States of America**, through its Department of Veterans Affairs (VA); the VA's Office of Acquisition and Logistics; and that Office's subcomponent, the VA National Acquisition Center, administers the Federal Supply Schedule (FSS) Program for Government procurement of health-care commodities, including medical-surgical instruments, equipment, and supplies. The General Services Administration (GSA), an agency of Plaintiff United States, has primary authority for the FSS Program under 41 U.S.C. § 259(b)(3)(A), but has delegated authority to the VA to administer the procurement of medical-surgical instruments, equipment, and supplies through the FSS Program. *See* 48 C.F.R. (FAR) § 8.402(a).

11. The VA and the Department of Defense (DoD), agencies of Plaintiff United States, also procure medical-surgical instruments, equipment, and supplies directly under non-FSS contracts, including both definitized contacts and longer-term, indefinite-delivery contracts.

12. Plaintiff-Relator and Original Source **Samuel Adam Cox, III** resides in Memphis, Tennessee, and worked as an information-technology consultant and executive in the medical device industry in 2007 and 2008. Plaintiff-Relator Cox began investigating country-of-origin violations by medical-surgical-supply companies with operations in and near Memphis after blowing the whistle on such violations by his former employer, Smith & Nephew Inc. *See United States ex rel. Cox v. Smith & Nephew Inc.*, 749 F. Supp. 2d 773 (W.D. Tenn. 2010). Mr. Cox conducted an independent investigation into Medtronic's wrongdoing and acquired documents and other evidence supporting the allegations in this Complaint. Consequently, Plaintiff-Relator and Original Source Cox has direct and independent knowledge of the false claims and certifications that Medtronic, as alleged herein, submitted to the Government.

13. Plaintiff-Relator and Original Source **Sonia Adams** resides in Olive Branch, Mississippi, and was employed by Medtronic, Inc.'s Operations Division from August 2008 to May 2011. During that time, Plaintiff-Relator Adams worked in human resources at the Medtronic distribution facility on Swinnea Road in Memphis, Tennessee (the "Memphis Distribution Center"). As part of her job, Ms. Adams walked the distribution floor at the facility and spoke to employees about their jobs and their concerns. Ms. Adams was advised by several Medtronic colleagues that that the company

was manufacturing products in China (in particular) and disguising their country of origin. Ms. Adams conducted an independent investigation into Medtronic's wrongdoing and acquired documents and other evidence supporting the allegations in this Complaint. Consequently, Plaintiff-Relator and Original Source Adams has direct and independent knowledge of the false claims and certifications that Medtronic, as alleged herein, submitted to the Government.

14. Plaintiff-Relator and Original Source **Meayna Phanthavong** resides in Memphis, Tennessee, and has worked as a shipping and receiving clerk in Medtronic, Inc.'s Domestic Department at the Memphis Distribution Center from April 2007 to the present. Ms. Phanthavong independently acquired documents supporting the allegations in this Complaint. Consequently, Plaintiff-Relator and Original Source Phanthavong has direct and independent knowledge relating to the false claims and certifications that Medtronic, as alleged herein, submitted to the Government.

B. Defendants

15. Defendant **Medtronic, Inc.** is a *Fortune* 500 company headquartered in Minneapolis, Minnesota. It sells drugs and medical instruments, supplies, and devices to government and private customers. The company employs over 38,000 people at more than 250 manufacturing facilities, sales offices, research centers, education centers, and administration facilities supporting sales in 120 countries. Medtronic reported net sales for fiscal year 2011 of approximately $16 billion. The company's stock trades publicly under the symbol "MDT."

16. Defendant **Medtronic USA, Inc.** is a wholly owned subsidiary of Medtronic, Inc. that is also headquartered, on information and belief, in Minneapolis. Among other things, Medtronic USA, Inc. bids on and performs U.S. Government contracts.

17. Defendant **Medtronic Sofamor Danek USA**, Inc. is a wholly owned subsidiary of Medtronic, Inc. that is headquartered in Memphis, Tennessee. It is one of the world's largest manufacturers of spinal implants and biologic bone-grafting products to treat degenerative diseases, deformities, and spine and cranium trauma. Among other things, Medtronic Sofamor Danek USA, Inc. bids on and performs U.S. Government contracts.

18. Since at least July 2006, Defendants have sold medical-surgical items to the United States through the VA Federal Supply Schedule Program and other contracting vehicles. In so doing, Defendants have agreed to comply, and have certified their compliance, with the TAA's bar on selling the Government products originating in "non-designated countries" under Schedule Contracts and other contracts subject to the TAA.

19. Defendants have violated their Government contracts, the TAA, the TAA's implementing regulations, and the False Claims Act by fraudulently selling federal agencies products manufactured in China, India, Malaysia, and possibly other "non-designated countries," despite certifying that the products were manufactured in the United States.

III. JURISDICTION AND VENUE

20. The Court has federal-question jurisdiction over the subject matter of this action under 28 U.S.C. § 1331. It also has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732, which confers jurisdiction over actions brought under 31 U.S.C. §§ 3729 and 3730.

21. There has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. *See* 31 U.S.C. § 3730(e)(4). Assuming there were such a disclosure, the Plaintiff-Relators are "original sources" under the FCA. *Id.*

22. The Court has personal jurisdiction over Medtronic, Inc. and Medtronic USA, Inc. under 31 U.S.C. § 3732(a), because Defendants Medtronic, Inc. and Medtronic USA, Inc. are incorporated, headquartered, and do business in the District of Minnesota, and Medtronic Sofamor Danek USA, Inc. does business in this District.

23. Venue is proper in this District under 31 U.S.C. §3732(a) because Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc. can be found and do business in this District.

IV. STATUTORY, REGULATORY, AND CONTRACTUAL BACKGROUND

A. The Trade Agreements Act and Implementing Regulations

24. The Buy American Act limits U.S. Government procurements, over a certain dollar value, of "manufactured articles, materials, and supplies" to those that "have been manufactured in the United States substantially all from articles, materials, or supplies mined, produced, or manufactured in the United States . . . ." 41 U.S.C. § 8302.

25. The Trade Agreements Act authorizes the President to waive, in certain instances, domestic preferences, including the Buy American Act, in federal procurements, and to treat goods from countries with which the United States has trade agreements the same as domestic goods. *See* 19 U.S.C. § 2511. "The President has delegated this waiver authority to the U.S. Trade Representative." FAR § 25.402(a)(1).

26. The TAA applies to federal procurements valued in excess of threshold amounts (revised about every two years). Currently, the TAA applies to acquisitions of supplies or services valued at more than about $203,000, but thresholds vary by acquisition type, purchasing agency, and a product's country of origin. *See* FAR §§ 25.402, 25.403(b).

27. If the value of a Government contract exceeds the TAA threshold, with limited exceptions, *see id.* § 25.401, the procuring agency may procure only end products that are (i) mined, produced, or manufactured in the U.S. or a designated country, or are (ii) "substantially transformed" in the U.S. or a designated country. *See* 19 U.S.C. §§ 2511-2512; FAR §§ 25.402, 25.502(b)(2), 52.225-5 (Nov. 2006).

28. "Substantial transformation" means that a product is made into a "new and different article of commerce" with a name, character, or use distinct from that of the article or articles from which it was transformed. An article is not substantially transformed by minor manufacturing or combining processes that leave its identity intact. The assembly process must be complex and meaningful. *See* 19 U.S.C. § 2518(4)(B); FAR § 25.001(c).

29. The categories of "designated countries" under the TAA are: (1) World Trade Organization member and Government Procurement Agreement signatory, (2) North American Free Trade Agreement country, (3) Caribbean Basin Country, (4) Least Developed Country, and, (5) for Department of Defense purchases, the 21 countries with which the U.S. has a reciprocal procurement memorandum of understanding. *See* 19 U.S.C. § 2511(b); 41 U.S.C. § 8304(a); FAR §§ 25.003, 25.402.

B. Contract Requirements and Certifications

30. Federal Supply Schedule Contracts are long-term, multiple-awardee, indefinite-quantity Government contracts principally administered by the GSA. *See* 41 U.S.C. § 259(b)(3)(A). A vendor that is awarded an FSS Contract must publish an "Authorized Federal Supply Schedule Pricelist" for every product or service it offers under the contract (or "schedule"). Federal agencies can then order products or services from the contractor, up to maximum amounts, at the agreed prices, and under the agreed terms and conditions, for the duration of the FSS Contract. *See* FAR Subpart 8.4.

31. The GSA has determined that the TAA applies to every Schedule Contract, because the anticipated dollar value of every Schedule Contract automatically exceeds the TAA threshold. *See* GSA Basic Schedule Ordering Guideline 25 (http://www.gsa.gov / portal/content/200369 #taa); *see also* VA, Office of Acquisition and Logistics—Federal Supply Schedule (FSS) Contracting (http://www.va.gov/oal/ business/fss/taa.asp).

32. Thus, absent narrow exceptions, none of which apply to the contracts alleged in this Complaint, *see* FAR § 25.401, only products made or substantially

transformed in the United States or in designated countries can be offered or sold under FSS Contracts.

33. To implement this TAA requirement, Schedule Contractors are required to certify that, unless the Government specifically agrees to an exception, all products for sale under an FSS contract will comply with the TAA, *i.e.*, will be made or substantially transformed in the United States or a designated country. FSS Contracts contain the Trade Agreements Act Clause, FAR § 52.225-5 (Jan. 2005), which sets forth the requirements of the TAA, and FSS Contractors execute the Trade Agreements Certificate when bidding on an FSS Contract:

> (a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision[,] is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements." (b) The offeror shall list as other end products those supplies that are not U.S.-made or designated country end products. [Product list follows if necessary.]

FAR § 52.225-6 (Jan. 2005).

34. The Federal Acquisition Regulations also require Government contracting officers to include a substantially identical Trade Agreements Certificate in any other definite- or indefinite-quantity contract the dollar value of which exceeds the applicable TAA threshold. *See* FAR §§ 25.403(b), 25.1101(c); *see generally id.* § 16.504 (authorizing awards of indefinite-quantity contracts).

35. The Trade Agreements Certificate is a material term of all Government contracts in which it appears, and the contractor's compliance with the Certificate is a condition of payment for goods delivered under those contracts. *See, e.g., Wyse Tech.,*

Inc., Comp. Gen. No. B-297454, at 6 (2006) (ruling that agency should not have awarded contract to vendor that "did not offer to comply with the TAA in its proposal or otherwise").

36. The GSA has delegated authority to the VA to administer FSS Contracts for Government procurement of health-care commodities, including medical equipment and supplies (Base Solicitation No. RFP-797-FSS-99-0025), patient mobility devices (Base Solicitation No. RFP-797-652F-05-000), and X-ray equipment and supplies (Base Solicitation No. RFP-797-655A-03-0001), among others. *See* FAR § 8.402(a); VA, Doing Business with VA (http://www. va.gov/osdbu/library/dbwvaFss.asp) (listing nine active VA Schedules).

37. As a policy matter, the VA does not grant exceptions, under subpart (b) of the Trade Agreements Certificate, FAR § 52.225-6(b) (Jan. 2005), to allow FSS Contractors to sell medical-surgical products manufactured in non-designated countries under FSS Contracts. *See* VA, Federal Supply Schedule, Frequently Asked Questions 7, 8 (http://www.fss.va.gov/fss/faqs/ general.asp#q001) ("It is your responsibility to verify that all of your offered products are from the US or a designated country. . . . **ONLY** US-made or designated country end products may be offered [under] the VA FSS Program.").

V. MEDTRONIC'S FALSE CLAIMS AND FALSE CERTIFICATIONS OF COMPLIANCE WITH THE TRADE AGREEMENTS ACT

38. Medtronic has been and is intentionally and knowingly selling noncompliant products to the United States in violation of the Trade Agreements Act and related authorities.

39. In approximately the past six years, the VA's National Acquisition Center has awarded Medtronic, Inc. or Medtronic USA, Inc. the following 10 indefinite-delivery contracts, among others, for medical-surgical instruments, equipment, and supplies:

Contract No.	Award Date	Effective Dates
V797-P-0138	11/18/08	12/01/08 to 11/30/12
V797-P-0139	11/18/08	12/01/08 to 11/30/12
V797-P-0218	08/23/11	10/01/11 to 09/30/12
V797-P-2010D	02/29/12	03/01/12 to /02/28/17
V797-N-12-D-0006	03/29/12	04/13/12 to 04/12/13
V797-P-5823X	currently unknown	currently unknown (incl. 2007-08)
V618-P-4623A	currently unknown	currently unknown (incl. July 2006)
V249-P-0875	currently unknown	currently unknown (incl. 2008)
VA263-P-0205	currently unknown	currently unknown (incl. 2008-2009)
VA255-P-0551	currently unknown	currently unknown (incl. 2010-11)

40. The first six contracts listed in the table immediately above (Nos. V797-P-0138, V797-P-0139, V797-P-0218, V797-P-2010D, V797-N-12-D-0006, and V797-P-5823X) are or were FSS Contracts. Therefore, those six contracts are or were subject to the TAA, and they contain or contained the Trade Agreements Certificate quoted in paragraph 33 above.

41. As of September 2012, Defendants (Medtronic, Inc. and Medtronic USA, Inc.) had approximately 1,211 products listed for sale to federal agencies via the VA's searchable Med-Surg Non-Pharmaceutical Catalog under the first five Schedule

Contracts listed in the table following paragraph 39 above (Nos. V797-P-0138, V797-P-0139, V797-P-0218, V797-P-2010D, and V797-N-12-D-0006). (On information and belief, the sixth contract listed in the table following paragraph 39 above, No. V797-P-5823X, has expired.)

42. The seventh through tenth contracts listed in the table following paragraph 39 above (Nos. V618-P-4623A, V249-P-0875, VA263-P-0205, and VA255-P-0551) are or were non-FSS, indefinite-quantity contracts that, on information and belief, were valued in excess of the applicable TAA dollar threshold. Relators base their allegations of the contract values (which are determined at contract award) on the fact that, according to USASpending.gov, the Government made total payments under each of these four contracts of at least $308,598 (under Contract No. V249-P-0875) and up to $7,524,150 (under Contract No. VA255-P-0551), during years when the threshold value for application of the TAA was $203,000 or less. Accordingly, on information and belief, the seventh through tenth contracts listed in the table following paragraph 39 above are or were subject to the TAA, based on contract type and value, and contained Trade Agreements Certificates substantially like the one quoted in paragraph 33 above.

43. In addition, in approximately the past six years, the VA and the Department of Defense (DoD) have awarded Defendant Medtronic Sofamor Danek USA, Inc. the following 10 definitized contracts, among others, for medical-surgical instruments, equipment, and supplies:

Contract No.	Awarding Agency	Effective date	Obligation Amount
VA263-P-0133	VA	09/25/07	$1,009,590
SPM2D108C0011	DoD	09/11/08	$262,460
V626-A-89242	VA	09/22/08	$234,101
N6264509P2000	DoD	10/08/08	$650,000
W81XWH09P0400	DoD	05/12/09	$1,373,512
VA553-V-00001	VA	04/26/10	$418,038
VA553-V-00002	VA	04/27/10	$944,257
SPM2D112C0003	DoD	01/11/12	$874,700
VA553-V-00000	VA	04/23/10	$315,263
VA640-A-00450	VA	06/08/10	$432,473

44. On information and belief, the TAA applied to every contract listed in the table following paragraph 43 above. Relators base this allegation on the facts that, according to USASpending,gov, (i) the Government obligated (essentially, budgeted) amounts exceeding the TAA dollar thresholds to each of these contracts, and (ii) none of the potential regulatory *exceptions* to the applicability of the TAA appear to apply; in particular, none of these contracts were awarded on a sole-source basis or otherwise without full and open competition. *See* FAR § 25.401(a), especially (a)(5). Accordingly, on information and belief, all of the contracts listed in the table following paragraph 43 above were subject to the TAA, based on contract type and value, and contained Trade Agreements Certificates substantially like the one quoted in paragraph 33 above.

45. On information and belief, Medtronic executed Trade Agreements Certificates certifying that all of the items for sale under every contract listed in the tables following paragraphs 39 and 43 above were manufactured or substantially transformed in the United States or in designated countries.

46. But in fact, many products that Medtronic sells under its Government contracts are manufactured by a Chinese company, Weigao Orthopaedic Device Co.,

Ltd., located in Weihai City in Shandong Province, China, or by other manufacturers (potentially including Medtronic itself) in China, India, or Malaysia.

47. Medtronic has close ties to Weigao Orthopaedic Device. In 2008, Medtronic and Weigao Orthopaedic Device formed a joint venture (the "Medtronic-Weigao Joint Venture") in China. Medtronic owns 51% of the joint venture; Weigao Orthopaedic Device owns 49%. The Joint Venture develops and markets Medtronic's vertebral and joint products in China.

48. China, India, and Malaysia are not designated countries under the TAA.

49. Medtronic uses uniquely numbered, electronic intercompany purchase orders and stock-transport orders to move specific medical-surgical items from its Chinese, Indian, and Malaysian warehouse facilities to the United States.

50. Many of the medical-surgical products that Medtronic transfers from its Chinese, Indian, and Malaysian facilities to the United States are shipped to Medtronic's U.S. Distribution Center on Swinnea Road in Memphis, Tennessee (Plant 1139, or "Memphis Distribution Center").

51. Medtronic also operates U.S. Distribution Centers in Bartlett, Tennessee (about 18 miles from Memphis); Fort Worth, Texas; Sunnyvale, California (where Medtronic's Kyphon Products Division is headquartered); Torrance, California; and Elizabeth, New Jersey, and possibly at other locations.

52. Medtronic's internal, electronic record of the fulfillment of a particular medical-surgical-customer order in the United States shows (i) the Medtronic facility ("Plant"), if any, where each delivered medical-surgical item was stored in inventory at

the time of the order, and (ii) the facility ("Vendor" or "Supplying Plant") that was responsible for shipping that item to the selected Medtronic Distribution Center in the United States.

53. Medtronic stores medical-surgical products made in China in inventory at Plants including Medtronic's Hong Kong Distribution Center (coded as 3PL 1145), the Medtronic-Weigao Joint Venture (Distribution Center 1162), and a Medtronic Plant in Shanghai, China (Distribution Center 1168). The Hong Kong Distribution Center is a Supplying Plant that ships Chinese-made medical-surgical products to the Memphis Distribution Center. Medtronic also purchases medical-surgical products directly from Weigao Orthopaedic Device in China for delivery to the Memphis Distribution Center.

54. Medtronic stores medical-surgical products made in India in inventory at a Medtronic Plant in Delhi, India (Distribution Center 1152), and possibly at other Plants. A Medtronic Supplying Plant in Mumbai, India (Distribution Center 1151), ships Indian-made medical-surgical products to the Memphis Distribution Center.

55. Medtronic stores medical-surgical products made in Malaysia in inventory at a Medtronic Plant in Malaysia (Distribution Center 1149), and possibly at other Plants. Medtronic's Hong Kong Distribution Center (3PL 1145) is a Supplying Plant that ships Malaysian-made medical-surgical products to the Memphis Distribution Center.

56. When medical-surgical products made in China, India, Malaysia, or other non-designated countries arrive at Medtronic's Memphis Distribution Center, Medtronic processes the products in a way that disguises their foreign origins.

57. When a medical-surgical product (or a sales unit thereof, *e.g.*, a box) made by a foreign supplier arrives at the Memphis Distribution Center, a Medtronic employee in the Receiving Department logs and preliminarily inspects the product, including checking the description, product number, and quantity against the electronic goods receipt information in Medtronic's SAP (Systems, Applications and Products in Data Processing) system. The product is then routed to another location in the facility for a quality inspection. There, a Medtronic employee in the Quality Inspection Department removes the product's protective wrapping and packaging and inspects the product against Medtronic's specifications and/or drawings. When the product passes quality inspection, a Medtronic employee repackages the product and relabels it as having been manufactured in the United States. One of the types of labels affixed to foreign-made products at the Memphis Distribution Center shows the name and address of Defendant Medtronic Sofamor Danek USA, Inc. followed by, "Manufactured in MEMPHIS, TN, US."

58. The repackaged and relabeled medical-surgical product is then stored, sold, and shipped to customers from the Memphis Distribution Center as if the product were manufactured in the United States, regardless of its true country of origin.

59. Medtronic repackages and relabels medical-surgical products manufactured in non-designated countries intending to hide the products' true countries of origin, and knowing that its actions will hide the countries of origin.

60. By repackaging and relabeling products made in China, India, Malaysia, or other non-designated countries as if they were manufactured in the United States,

Medtronic does not "substantially transform" the products within the meaning of the TAA, 19 U.S.C. § 2518(4)(B).

61. For example, in or about May 2011, Medtronic sold and delivered two units of a medical-surgical product described as "A07A CEMENT MIXER," Medtronic material No. 613994686367, to a VA Medical Center in Tampa, Florida. The product had been manufactured in China or Malaysia, stored in inventory as "finished goods" at Medtronic's Hong Kong Distribution Center, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer.

62. In or about June 2011, Medtronic sold and delivered two units of a medical-surgical product described as "BONE SCREW 76447535 MULT AXIAL 7.5X35 TI," Medtronic material No. 885074134918, to the Walter Reed Army Medical Center on Georgia Avenue, NW, in Washington, DC. The product had been manufactured in China, stored in inventory as "finished goods" at the Medtronic-Weigao Joint Venture in China, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer.

63. In or about June 2011, Medtronic consigned and delivered one unit of the medical-surgical product described as "RING 638RL28 CG FUTURE 10L MEXICO," Medtronic material No. 613994758637, to a VA Medical Center at 10701 East Boulevard in Cleveland, Ohio. The product had been manufactured in Malaysia (notwithstanding the reference to Mexico, a designated country, in its description), stored in inventory as "finished goods" at Medtronic Distribution Center 1149 in Malaysia, transferred to the

Hong Kong Distribution Center, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer. On information and belief, the customer paid for the consigned product after using it.

64. In or about June 2011, Medtronic consigned and delivered one unit of the medical-surgical product "RING 638RL28 CG FUTURE 10L MEXICO," Medtronic material No. 613994758637, to the VA Medical Center on East 23rd Street in New York, New York. The product had been manufactured in Malaysia, stored in inventory as "finished goods" at Medtronic Distribution Center 1149 in Malaysia, transferred to the Hong Kong Distribution Center, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer. On information and belief, the customer paid for the consigned product after using it.

65. In or about July 2011, Medtronic sold and delivered three additional units of "BONE SCREW 76447535 MULT AXIAL 7.5X35 TI," Medtronic material No. 4902944627, to the Walter Reed Army Medical Center in Washington, DC. The product had been manufactured in China, stored in inventory as "finished goods" at Medtronic Distribution Center 1168 in Shanghai, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer.

66. In or about July 2011, Medtronic sold and delivered the medical-surgical product "RING 638RL28 CG FUTURE 10L MEXICO," Medtronic material No.

613994758637, to the VA Medical Center on East 23rd Street in New York City. The product had been manufactured in Malaysia, stored in inventory as "finished goods" at Medtronic Distribution Center 1149 in Malaysia, transferred to the Hong Kong Distribution Center, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer.

67. In or about July 2011, Medtronic sold and shipped a medical-surgical product described as "CATHETER LA6JL 40 6F 100CM," Medtronic material No. 613994818218, to a VA Medical Center on Northeast 13th Street in Oklahoma City, Oklahoma. The product had been manufactured in India, stored in inventory as "finished goods" at Medtronic Distribution Center 1152 in Delhi, transferred to Medtronic Distribution Center 1151 in Mumbai, then shipped from there to the Memphis Distribution Center, where it was repackaged and relabeled as U.S.-made before shipment to the customer.

68. On information and belief, (i) the contract or contracts under which Medtronic sold the items identified in the preceding seven paragraphs to agencies of the United States were subject to the Trade Agreements Act, and were in all likelihood listed in the table following paragraph 39 or 43 above; (ii) the applicable contract or contracts contained a Trade Agreements Certificate; and (iii) the Trade Agreements Certificate or Certificates executed by Medtronic in the applicable contract or contracts did not list any of the products described in paragraphs 61-67 as exceptions to the application of the TAA.

69. By offering, selling, delivering, and billing for the products described in paragraphs 61-67 above to the U.S. Government under contracts subject to the TAA, Medtronic falsely certified and represented that the products had been manufactured or substantially transformed in the United States or a designated country.

70. Had the procuring agencies known the true countries of origin of the products described in paragraphs 61-67 above, the procuring agencies would not have allowed Medtronic to offer or sell those products to the Government, and the procuring agencies would not have ordered, accepted, or paid for those products.

71. Government contracting and medical-supply officials relied, to the detriment of the Government, on Medtronic's false certifications and representations that all products for sale under Medtronic's FSS Contracts were manufactured or substantially transformed in the United States or designated countries.

72. The example transactions in paragraphs 61-67 above are representative of thousands of transactions since at least 2006 in which Medtronic has taken delivery of products manufactured in China, India, and Malaysia at Medtronic Plants in those countries, then made intercompany transfers or stock transfers from Medtronic Supplying Plants in those countries to the Memphis Distribution Center, where Medtronic employees repackaged, relabeled, stored, shipped, and billed for the products as if they were manufactured in the United States.

73. Medtronic could, but has chosen not to, capture and track in its databases the true countries of origin of its medical-surgical products. For example, in 2011, the material information page in Medtronic's internal SAP information system for the AO7A

cement mixer referenced in paragraph 61 above (query: "Display Material 613994686367 (Finished products ZFRT)") contained fields for country of origin and region of origin, but they were left blank.

74. As further examples, the country-of-origin and region-of-origin fields were also blank in the SAP material record pages of three other products that Medtronic sold and shipped to the VA Medical Center in Tampa in 2011:

- "KIT KPE1001 KYPAC EXP 10/2 (Finished products ZFRT)," Medtronic material No. 613994721273;
- "KIT KPE1001 KYPAC W/EOIS (Finished products ZFRT)," also Medtronic material No. 613994721273; and
- "SYRINGE A08A KYPHX (Finished products ZFRT)," Medtronic material No. 613994683374.

75. Although the country-of-origin and region-of-origin fields were blank in the SAP records for each of the four products described in the preceding two paragraphs, those SAP records indicate that each of the four products was assigned a Commodity Code or an Import Code Number ("Comm./imp. code no."), which indicates that each of the four products originated outside the United States.

76. Notwithstanding Medtronic's decision not to populate the country-of-origin fields in its SAP material records, Medtronic's internal transfer records for each medical-surgical product that it has sold and delivered to the U.S. Government since 2006 will identify the Medtronic Plant or Distribution Center where the product was initially stored

after being manufactured, and, if the product was stored overseas, the Supplying Plant or Distribution Center responsible for shipping the product to the United States.

77. When a medical-surgical product offered and sold by Medtronic in the United States was (i) stored at a Medtronic Plant or Distribution Center in China, India, or Malaysia, and (ii) transferred to the United States from a Medtronic Plant or Distribution Center in one of those countries, this indicates that the product was manufactured in China, India, or Malaysia, notwithstanding how the product was labeled when it reached a customer.

78. Plaintiff United States has been and continues to be injured by Medtronic's false statements and false certifications intended to conceal Medtronic's material violations of the country-of-origin provisions of its Government contracts and the TAA.

VI. CAUSES OF ACTION

COUNT I

Presenting False Claims
(False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

79. Plaintiffs-Relators re-allege and incorporate by reference the allegations in the previous paragraphs of this Complaint.

80. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3732.

81. By virtue of the acts described above, Medtronic knowingly submitted, caused to be submitted and continues to submit and to cause to be submitted false or fraudulent claims for payment and reimbursement by the United States, by knowingly or

recklessly making false statements about the country or countries of origin of products offered for sale to the United States that did not originate in the United States or a designated country as defined in the Trade Agreements Act, 19 U.S.C. §§ 2511-2512.

82. The United States, unaware of the falsity of the statements and/or claims made by Medtronic, and in reliance on their accuracy, paid false claims because Medtronic intentionally or with gross disregard for the truth sold products to the Government that did not originate in the United States or a designated country, while falsely certifying compliance with the TAA.

83. The falsity of the claims for payment presented by Medtronic for products manufactured in non-designated countries was material, as the falsity concealed material violations of Government contracts and the Trade Agreements Act, and frustrated the enforcement and the policy goals of the TAA.

84. Had federal procurement officials known the true origins of Medtronic's non-TAA-compliant products, the Government would not have purchased or paid for those products.

85. Medtronic's knowing presentation of false claims for payment by the United States has violated 31 U.S.C. § 3729(a)(1)(A) and has damaged, and continues to damage, the United States in an amount to be determined at trial.

COUNT II

Using False Records or Statements
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

86. Plaintiffs-Relators reallege and incorporate by reference the allegations in the previous paragraphs of this Complaint.

87. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3732.

88. By virtue of the acts described above, Medtronic knowingly made, used, or caused to be made or used, and continues to make, use, or cause to be made or used, false statements or records that were or are material to false or fraudulent claims for payment by the United States. Medtronic falsely certified that all products it offered for sale to the United States were made or substantially transformed in the United States or in designated countries, and/or Medtronic certified that it provided accurate country-of-origin information, whereas, in fact, Medtronic provided materially false country-of-origin documentation.

89. The false statements or records that Medtronic knowingly made, used, or caused to be made or used, were material, as they concealed violations of the Trade Agreements Act and frustrated the enforcement and the policy goals of the TAA.

90. The United States was unaware of the falsity of the statements or records that Medtronic made, used, or caused to be made or used, and relied on the accuracy of those statements or records.

91. Had Medtronic made, used, or caused to be made or used accurate statements or records regarding the origins of its non-TAA-compliant products, the Government would not have purchased or paid for those products.

92. Medtronic's knowing creation and use of false statements or records in a manner material to false claims under one or more Government contracts has violated 31 U.S.C. § 3729(a)(1)(B) and has damaged, and continues to damage, the United States in an amount to be determined at trial.

VII. PRAYER

WHEREFORE, Plaintiffs-Relators pray for judgment against Medtronic as follows:

A. An order that Medtronic cease and desist from violating the Trade Agreements Act, 19 U.S.C. §§ 2511-2512;

B. Judgment against Medtronic in an amount equal to three times the damages the United States has sustained because of Medtronic's fraud, plus a civil penalty of $11,000 for each violation of the False Claims Act, under 31 US.C. § 3729(a);

C. An award to Plaintiffs-Relators of the maximum share of money recovered from Defendants by, or on behalf of, the United States, under 31 U.S.C. § 3730(d)(1) or (2), depending on whether the Government intervenes in this action;

D. An award to Plaintiffs-Relators (jointly) of "reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs," under 31 U.S.C. § 3730(d)(1), and

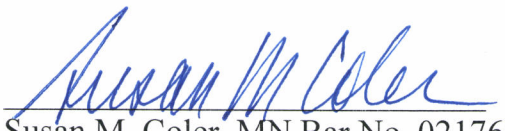
E. Such other relief as the Court deems just and proper.

VIII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs-Relators hereby demand a trial by jury.

Dated: October 5, 2012

Respectfully submitted:



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