

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26

IN THE CIRCUIT COURT OF THE STATE OF OREGON  
FOR THE COUNTY OF MULTNOMAH

STATE OF OREGON, ex rel. ELLEN F.  
ROSENBLUM, Attorney General for the state  
of Oregon,  
Plaintiff,  
v.  
MEDTRONIC SOFAMOR DANEK, INC.  
and  
MEDTRONIC SOFAMOR DANEK USA,  
INC.,  
Defendants.

Case No.  
STIPULATED GENERAL JUDGMENT  
**ORS 20.140 - State fees deferred at filing**

Plaintiff, State of Oregon acting by and through Attorney General Ellen F. Rosenblum,  
has filed a Complaint for a permanent injunction and other relief in this matter pursuant to ORS  
646.605 et seq. alleging that Defendants Medtronic Sofamor Danek, Inc. and Medtronic Sofamor  
Danek USA, Inc. committed violations of the aforementioned Act. Plaintiff and Defendants, by  
their counsel, has agreed to the entry of this Stipulated General Judgment (“Judgment”) by the  
Court without trial or adjudication of any issue of fact or law, and without finding or admission  
of wrongdoing or liability of any kind.

1 NOW THEREFORE, upon Judgment of the parties hereto, **IT IS HEREBY ORDERED,**  
2 **ADJUDGED AND DECREED AS FOLLOWS:**

3  
4

**PARTIES**

5 1. The Oregon Attorney General is the plaintiff in this case. The Attorney General is  
6 charged with, among other things, the responsibility of enforcing the Oregon Unfair Trade  
7 Practices Act, ORS 646.605, *et seq.*

8 2. Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (“Medtronic”)  
9 are corporations with their principal executive office located at 20 Lower Hatch Street, Dublin 2,  
10 Ireland and operational headquarters at 710 Medtronic Parkway, Minneapolis, MN 55432-5604.  
11 At all times relevant hereto, Medtronic engaged in trade affecting consumers, within the meaning  
12 of the Oregon Unfair Trade Practices Act ORS 605.646, *et seq.*, in the State of Oregon,  
13 including, but not limited to Multnomah County.

14

**I. FINDINGS**

15 A. This Court has jurisdiction over the subject matter of this lawsuit and over the Parties.

16 B. The terms of this Consent Judgment (the “Consent”) shall be governed by the laws of the  
17 State of Oregon.

18 C. Entry of this Consent is in the public interest and reflects a negotiated agreement among  
19 the Parties.

20 D. The Parties have agreed to resolve the issues resulting from the Covered Conduct by  
21 entering into this Consent.<sup>1</sup>

22 E. Medtronic is willing to enter into this Consent regarding the Covered Conduct in order to  
23 resolve the Signatory Attorney General’s concerns under the State Consumer Protection Laws as  
24

25 \_\_\_\_\_  
26 <sup>1</sup> This Consent is entered into pursuant to and subject to the State Consumer Protection law cited  
in footnote 2.

1 to the matters addressed in this Consent and thereby avoid significant expense, inconvenience,  
2 and uncertainty.

3 F. Medtronic is entering into this Consent solely for the purpose of settlement, and nothing  
4 contained herein may be taken as or construed to be an admission or concession of any violation  
5 of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing,  
6 all of which Medtronic expressly denies. Medtronic does not admit any violation of the State  
7 Consumer Protection Laws set forth in footnote 2, and does not admit any wrongdoing that was  
8 or could have been alleged by any Signatory Attorney General. No part of this Consent,  
9 including its statements and commitments, shall constitute evidence of any liability, fault, or  
10 wrongdoing by Medtronic. This document and its contents are not intended for use by any third  
11 party for any purpose, including submission to any court for any purpose.  
12

13 G. This Consent shall not be construed or used as a waiver or limitation of any defense  
14 otherwise available to Medtronic in any action, or of Medtronic's right to defend itself from, or  
15 make any arguments in, any private individual, regulatory, governmental, or class claims or suits  
16 relating to the subject matter or terms of this Consent. This Consent is made without trial or  
17 adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the  
18 foregoing, a State may file an action to enforce the terms of this Consent.  
19

20 H. It is the intent of the Parties that this Consent not be admissible in other cases or binding  
21 on Medtronic in any respect other than in connection with the enforcement of this Consent.  
22

23 I. No part of this Consent shall create a private cause of action or confer any right to any  
24 third party for violation of any federal or state statute except that a State may file an action to  
25 enforce the terms of this Consent.  
26

## II. DEFINITIONS

The following definitions shall be used in construing this Consent:

A. "Covered Conduct" shall mean Medtronic's Promotional practices and dissemination of information regarding Infuse in the United States through the Effective Date of the Consent.

B. "Effective Date" shall mean the date on which a copy of this Consent, duly executed by Medtronic and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

C. "FDA" shall mean the United States Food and Drug Administration.

D. "Infuse" shall mean any product sold by Medtronic in the United States that contains recombinant human bone morphogenetic protein-2 ("rhBMP-2").

E. "Medtronic" shall mean Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc., including all of its assigns, subsidiaries, predecessors, and successors doing business in the United States.

F. "Multistate Group" shall mean the Attorneys General and their staff representing California, Illinois, Massachusetts, Oregon, and Washington.

G. "Parties" shall mean Medtronic and the Signatory Attorney General.

H. "Promotional," "Promoting," or "Promote" shall mean a Medtronic representation about Infuse used for the purpose of selling Infuse.

I. "Signatory Attorney General" shall mean the Attorney General of Oregon, or his/her authorized designee, who has agreed to this Consent.

1 J. "State Consumer Protection Laws" shall mean the consumer protection laws under  
2 which the Signatory Attorneys General have conducted their investigation.<sup>2</sup>

3 K. A "Medtronic-Sponsored" clinical trial or a clinical trial "Sponsored by Medtronic"  
4 shall mean a trial that was substantially funded by Medtronic or was initiated, managed and  
5 overseen by Medtronic's Clinical Department.

6 **III. COMPLIANCE PROVISIONS**

7 Consistent with applicable constitutional, statutory, and regulatory law, and/or court-interpreted  
8 precedent (including any future changes in such law and/or court-interpreted precedent):

9 A. Medtronic shall register and report the results of all "applicable device clinical trials" relating to  
10 Infuse to ClinicalTrials.gov in accordance with the provisions of the Food and Drug Administration  
11 Amendments Act of 2007, Title VIII and implementing regulations at 42 C.F.R. Part 11.

12 B. When using information about clinical trials relating to Infuse, including published medical  
13 journal articles reporting on such trials, for Promotional purposes<sup>3</sup>, Medtronic shall use such information  
14 in a manner that is:  
15

- 16 1. truthful, non-misleading, accurate, and includes fair balance;
- 17 2. consistent with approved labeling;
- 18 3. appropriately substantiated by objective evidence and does not contain overreaching  
19 messaging; and
- 20 4. otherwise in compliance with applicable FDA regulations.

21 C. When Medtronic's Office of Medical Affairs ("OMA") disseminates published medical journal  
22 articles reporting on clinical trials relating to Infuse, OMA shall only disseminate published articles that:  
23

24  
25 <sup>2</sup> *Oregon Unlawful Trade Practices Act*, Or. Rev. Stat. § 646.605 et seq.

26 <sup>3</sup> For purposes of III.B.2-4, "Promotional purposes" does not include communications with third party payors.

1           1.       are truthful, scientifically and medically valid, and when considered together with any  
2                    supplemental materials disseminated with those articles, not misleading; and

3           2.       for articles reporting on Medtronic-Sponsored clinical trials relating to Infuse, disclose  
4                    that those trials were Sponsored by Medtronic, including Medtronic's role in supporting  
5                    or funding those trials.

6 D.       For medical journal articles reporting on Medtronic-Sponsored trials relating to Infuse for which  
7 Medtronic has approved the release of Medtronic clinical trial data, Medtronic shall contractually require  
8 the authors of these articles to:

9           1.       comply with the publishing journal's standards for identifying the article's authors; or,  
10                   should the publishing journal not have authorship standards, to name as "authors" of the  
11                   article only those individuals who (i) made substantial contributions to the conception  
12                   and design of the trial or to the acquisition or analysis of data, and (ii) had final approval  
13                   of the version to be published;

14          2.       acknowledge, consistent with the publishing journal's methodology for doing so, that the  
15                   trial on which the article is reporting was Sponsored by Medtronic; and

16          3.       comply with the publishing journal's standards for disclosure of any authors' potential  
17                   conflict of interest; or, should the publishing journal have no conflict of interest  
18                   disclosure standards, to comply with the disclosure standards required by International  
19                   Committee of Medical Journal Editors (ICMJE) journals.

20  
21 E.       Medtronic shall not make, or cause to be made, any written or oral statement regarding Infuse that  
22 is false, misleading or deceptive.

23 F.       Medtronic shall submit to the FDA all information required pursuant to 21 C.F.R. Part 54  
24 regarding its financial relationships with investigators for clinical trials of Infuse Sponsored by  
25 Medtronic.

1 G. Medtronic shall in reasonable good-faith comply with all reporting requirements for clinical trials  
2 of Infuse, as required under 21 CFR 812.150(b), as applicable.

3 H. All obligations undertaken by Medtronic pursuant to this Consent shall apply prospectively only,  
4 from the Effective Date forward, and all such obligations will terminate 5 years from the Effective Date  
5 except for those addressed in Paragraph III.E.

6 I. Nothing in this Consent shall require Medtronic to:

- 7 1. take an action that is prohibited by the FDCA or any regulation promulgated  
8 thereunder, or by the FDA; or
- 9 2. fail to take an action that is required by the FDCA or any regulation promulgated  
10 thereunder, or by the FDA. Any written or oral Promotional claim subject to this  
11 Consent which is the same or substantially the same as language required or  
12 agreed to by the FDA or its authorized designees shall not constitute a violation of  
13 this Consent.  
14

#### 15 **IV. PAYMENT**

16 A. No later than 30 days after the Effective Date of this Consent, Medtronic shall pay \$12  
17 million to the states and that amount shall be divided and paid by Medtronic directly to each  
18 Signatory Attorney General of the Multistate Group in an amount to be designated by, and in the  
19 sole discretion of, the Multistate Group.<sup>4</sup> Said \$12 million payment shall be used by the States  
20 as attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to,  
21 consumer protection enforcement funds, including future consumer protection enforcement,  
22 consumer education, litigation or local consumer aid fund or revolving fund, used to defray the  
23

24 \_\_\_\_\_  
25 <sup>4</sup> The State of Oregon's share is \$2,400,000 and shall be deposited into the Protection and  
26 Education Revolving Account established pursuant to ORS 180.095 and shall be used for the  
purposes described therein including educating consumers and prescribers regarding pain  
treatment.

1 costs of the inquiry leading hereto, or for any lawful purpose, at the sole discretion of each  
2 Signatory Attorney General.

3 B. The Parties acknowledge that the payment described herein is not a fine, penalty, or  
4 payment in lieu thereof.

5  
6 **V. RELEASE**

7 A. By its execution of this Consent, the State of Oregon releases and forever discharges  
8 Medtronic and all of its assigns, parents, subsidiaries, predecessors, successors, current and  
9 former officers, directors, shareholders, employees, agents, contractors, and attorneys  
10 (collectively, the "Released Parties") from the following: all civil claims, causes of action,  
11 damages, restitution, disgorgement, fines, costs, attorneys' fees, remedies, and/or penalties that  
12 the Signatory Attorney General has asserted or could have asserted against the Released Parties  
13 under the above-cited consumer protection statutes, or any amendments thereto, or by common  
14 law claims concerning unfair, deceptive, or fraudulent trade practices or, if applicable, state  
15 statutes equivalent to the federal Food, Drug, and Cosmetic Act that the Signatory Attorney  
16 General has the authority to release resulting from the Covered Conduct up to and including the  
17 Effective Date that is the subject of the Consent.

18 B. Notwithstanding any term of this Consent, specifically reserved and excluded from the  
19 release in Paragraph V.A as to any entity or person, including Released Parties, are any and all of  
20 the following:

- 21 1. any criminal liability that any person and/or entity, including Released Parties,  
22 has or may have to the State of Oregon.
- 23 2. any civil or administrative liability that any person and/or entity, including  
24 Released Parties, has or may have to the State of Oregon not expressly covered by  
25  
26



1 the release in Paragraph V.A above, including, but not limited to, any and all of  
2 the following claims:

- 3 a. state or federal antitrust violations;
- 4 b. claims involving “best price,” “average wholesale price,” “wholesale  
5 acquisition cost,” or any reporting practices;
- 6 c. Medicaid claims, including, but not limited to, federal Medicaid drug  
7 rebate statute violations, Medicaid fraud or abuse, and/or kickback  
8 violations related to any State’s Medicaid program;
- 9 d. state false claims violations; and
- 10 e. actions of state program payors of the Oregon arising from the purchase of  
11 Infuse.

- 12
- 13 3. any liability under the State of Oregon’s above-cited consumer protection laws  
14 which any person and/or entity, including Released Parties, has or may have to  
15 individual consumers.
- 16

## 17 VI. DISPUTE RESOLUTION

18 A. For the purposes of resolving disputes with respect to compliance with this Consent,  
19 should any of the Signatory Attorneys General have a reasonable basis to believe that Medtronic  
20 has violated a provision of this Consent subsequent to the Effective Date, then such Signatory  
21 Attorney General shall notify Medtronic in writing, and with particularity, of both (1) the  
22 specific objection-being raised, and (2) the specific provisions of this Consent that the practice  
23 appears to violate, and give Medtronic 30 days to respond to the notification. Nothing shall  
24 prevent the Signatory Attorneys General from agreeing in writing to provide Medtronic with  
25 additional time to respond to such notice beyond the 30 days called for in this Section VI.A.  
26

1 B. Upon receipt of written notice from any of the Signatory Attorneys General, Medtronic  
2 shall provide a good-faith written response to the Signatory Attorney General's notification,  
3 containing either a statement explaining why Medtronic believes it is in compliance with the  
4 Consent or a detailed explanation of how the alleged violation occurred and statement explaining  
5 how and when Medtronic intends to remedy the alleged violation.

6 C. Except as set forth in Sections VI.D and E below, the Signatory Attorney General may  
7 not take any action concerning the alleged violation of this Consent during the 30 day response  
8 period. Nothing shall prevent the Signatory Attorneys General from agreeing in writing to not  
9 take action concerning the alleged violation of this Consent beyond the 30 days called for in this  
10 Section VI.  
11

12 D. Nothing in this Consent shall be interpreted to limit the State's Civil Investigative  
13 Demand (CID) or investigative subpoena authority, to the extent such authority exists under  
14 applicable state law, and Medtronic reserves all of its rights in responding to a CID or  
15 investigative subpoena issued pursuant to such authority.  
16

17 E. The Signatory Attorney General may assert any claim that Medtronic has violated this  
18 Consent in a separate civil action to enforce compliance with this Consent, or may seek any other  
19 relief afforded by law for violations of the Consent, but only after complying with the  
20 requirements of Sections VI.A-C above. However, the Signatory Attorney General may take any  
21 action, including, but not limited to, legal action to enforce compliance with the Consent, without  
22 delay if the Signatory Attorney General believes that, because of the specific practice, a threat to  
23 the health or safety of the public requires immediate action.  
24

## 25 VII. GENERAL PROVISIONS

26 A. Medtronic shall not knowingly cause or encourage third parties, nor knowingly permit

1 third parties acting on its behalf, to engage in practices from which Medtronic is prohibited by  
2 this Consent.

3 B. This Consent does not constitute an approval by any of the Signatory Attorneys General  
4 of Medtronic's business practices, and Medtronic shall make no representation or claim to the  
5 contrary.

6 C. Any failure by any Party to this Consent to insist upon the strict performance by any  
7 other Party of any of the provisions of this Consent shall not be deemed a waiver of any of the  
8 provisions of this Consent, and such Party, notwithstanding such failure, shall have the right  
9 thereafter to insist upon the specific performance of any and all of the provisions of this Consent.  
10

11 D. This Consent represents the full and complete terms of the settlement entered into by the  
12 Parties hereto. In any action undertaken by the Parties, no prior versions of this Consent and no  
13 prior versions of any of its terms that were not entered by the Court in this Consent may be  
14 introduced for any purpose whatsoever.  
15

16 E This Court retains jurisdiction of this Consent and the Parties hereto for the purpose of  
17 enforcing and modifying this Consent and for the purpose of granting such additional relief as  
18 may be necessary and appropriate.

19 F. This Consent may be executed in counterparts, and a facsimile or .pdf signature shall be  
20 deemed to be, and shall have the same force and effect as, an original signature.

21 G. All Notices under this Consent shall be provided to the following via email and  
22 Overnight Mail:

23  
24 For Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc.:

25 Office of the General Counsel  
26 710 Medtronic Parkway  
Minneapolis, MN 55432-5604

1 and

2 James Dowden, Esq.  
3 Ropes & Gray LLP  
4 Prudential Tower  
5 800 Boylston Street  
6 Boston, MA 02199  
7 [james.dowden@ropesgray.com](mailto:james.dowden@ropesgray.com)

6 and

7 James Mountain, Jr., Esq.  
8 1001 SW Fifth Ave.  
9 16<sup>th</sup> Floor  
10 Portland, OR 97204  
11 [james.e.mountain@harrang.com](mailto:james.e.mountain@harrang.com)

11 For Attorney General:

12 David Hart  
13 Assistant Attorney General  
14 100 SW Market Street  
15 Portland, Oregon 97201  
16 [david.hart@doj.state.or.us](mailto:david.hart@doj.state.or.us)

16 **XI. Money Award**

17 A. Judgment Creditor: State of Oregon, ex rel. Ellen F Rosenblum, Oregon Attorney  
18 General

19 (a). Address of Judgment Creditor: 100 SW Market Street, Portland, Oregon 97201.

20 (b). Judgment Creditor's Attorney: David Hart, OSB #002750, Assistant Attorney  
21 General.

22 (c). Address of Judgment Creditor's Attorney: Oregon Department of Justice, 100 SW  
23 Market Street, Portland, Oregon 97201

24 B. Judgment Debtor: Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA,  
25 Inc.:

26 (a). Address of Judgment Debtor: 710 Medtronic Parkway, Minneapolis, MN 55432-

- 1           5604 USA.
- 2       (b).   Date of Birth: N/A
- 3       (c).   Social Security Number: N/A
- 4       (d).   Driver's License No./State of Issuance: N/A
- 5       (e).   Judgment Debtor's Attorney: James Mountain, Jr.
- 6       (f).   Address of Judgment Debtor's Attorney: 1001 SW Fifth Avenue, 16<sup>th</sup> Floor,
- 7                   Portland, OR 97204-1116
- 8   C.   Other person(s) or public body entitled to a portion of payment: None
- 9   D.   Principal Amount of Judgment: \$2,400,000
- 10   E.   Pre-Judgment Interest: None.
- 11   F.   Post-Judgment Interest: 9% (nine percent) per annum as per ORS 82.010, commencing
- 12           to accrue 30 days from the Effective Date.
- 13   G.   Other Costs, Disbursements, Periodic Payments, Arrearages: None.
- 14   H.   Attorneys' Fees and Associated Costs: None. Parties to bear their own costs and fees.

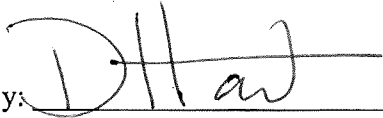
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26

**IT IS SO ORDERED, ADJUDGED AND DECREED.**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Presiding Judge**

1 For the State of Oregon:

2  
3 By:  \_\_\_\_\_

Date: 12/12/17

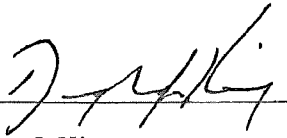
4 David Hart, OSB 002750  
5 Assistant Attorney in Charge  
6 Financial Fraud/Consumer Protection Section  
7 Oregon Department of Justice  
8 100 SW Market Street  
9 Portland, OR 97201  
10 Tel. (971) 673-1880  
11 Fax (971) 673-1884  
12 Email: [david.hart@doj.state.or.us](mailto:david.hart@doj.state.or.us)

9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26

1 For Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc.:

2

3

4 By: 

Date: 12/11/17

5 Douglas J. King  
6 President  
7 Medtronic Sofamor Danek, Inc.  
8 Medtronic Sofamor Danek USA, Inc.  
9 1800 Pyramid Place  
10 Memphis, TN 38132

11

12 By: 

Date: 12/7/17

13 James P. Dowden  
14 Attorney for Medtronic  
15 Ropes & Gray LLP  
16 Prudential Tower  
17 800 Boylston Street  
18 Boston, MA 02199  
19 Tel. (617) 951-7000  
20 Fax (617) 951-7050  
21 Email: [james.dowden@ropesgray.com](mailto:james.dowden@ropesgray.com)

22

23 By: \_\_\_\_\_

Date: \_\_\_\_\_

24 James E. Mountain, Jr.  
25 Attorney for Medtronic  
26 1001 SW Fifth Avenue  
16<sup>th</sup> Floor  
Portland, OR 97204-1116  
Tel. (503) 242-0000  
Fax (503) 241-1458  
Email: [james.e.mountain@harrang.com](mailto:james.e.mountain@harrang.com)

1 For Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc.:

2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26

By: \_\_\_\_\_ Date: \_\_\_\_\_

Douglas J. King  
President  
Medtronic Sofamor Danek, Inc.  
Medtronic Sofamor Danek USA, Inc.  
1800 Pyramid Place  
Memphis, TN 38132

By: \_\_\_\_\_ Date: \_\_\_\_\_

James P. Dowden  
Attorney for Medtronic  
Ropes & Gray LLP  
Prudential Tower  
800 Boylston Street  
Boston, MA 02199  
Tel. (617) 951-7000  
Fax (617) 951-7050  
Email: [james.dowden@ropesgray.com](mailto:james.dowden@ropesgray.com)

By: James E. Mountain Jr. Date: 12/05/2017

James E. Mountain, Jr.  
Attorney for Medtronic  
1001 SW Fifth Avenue  
16<sup>th</sup> Floor  
Portland, OR 97204-1116  
Tel. (503) 242-0000  
Fax (503) 241-1458  
Email: [james.e.mountain@harrang.com](mailto:james.e.mountain@harrang.com)