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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,

Defendants.

Case No.

COMPLAINT ALLEGING VIOLATIONS OF
THE UNLAWFUL TRADE PRACTICES ACT
ORS 646.605 to ORS 646.656

CLAIM NOT SUBJECT TO MANDATORY
ARBITRATION

**ORS 20.140 - State fees deferred at filing;
standard filing fee (ORS 21.135(2)(g))**

Plaintiff, State of Oregon (“State”), alleges claims for relief based on violations of
Oregon’s Unlawful Trade Practices Act (“UTPA”), ORS 646.605 to 646.656. The State alleges
that at all times material herein:

1.

Ellen F. Rosenblum is the Attorney General for the State of Oregon and sues in her
official capacity pursuant to ORS 646.632.

2.

Defendants Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc.
 (“Defendants” and/or “Medtronic”), are corporations with their principal executive office at 20
Lower Hatch Street, Dublin 2, Ireland and operational headquarters at 710 Medtronic Parkway,
Minneapolis, MN 55432-5604.

3.

At all times relevant hereto, Medtronic engaged in trade affecting consumers, within the
meaning of the Oregon Unfair Trade Practices Act ORS 605.646, *et seq.*, in the State of Oregon,

1 including, but not limited to Multnomah County.

2 **Jurisdiction and Venue**

3 4.

4 The Circuit Court for the State of Oregon has personal jurisdiction over Defendants
5 pursuant to ORCP 4 A. Defendants engaged in substantial activities within the State of Oregon
6 by operating a business that provides services that are primarily for personal, family, and
7 household use. All transactions occurred in the course of Defendants' business.

8 5.

9 Defendants waived the Notice required by ORS 646.632(2) and did not submit to the
10 Attorney General an acceptable Assurance of Voluntary Compliance.

11 6.

12 Defendants' conduct, as described in this Complaint, was willful within the meaning of
13 ORS 646.605(10).

14 **Background**

15 7.

16 Medtronic manufactures, designs, markets, promotes, and sells Infuse and a component
17 of the device known as recombinant bone morphogenetic protein-2 ("rhBMP-2" or "BMP") for
18 use in lumbar spine fusion surgeries, among other uses. BMP is soaked into and binds with an
19 absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge
20 dissolves, the BMP is designed to stimulate the cells to produce new bone.

22 8.

23 BMP is used as an alternative to bone grafting, which involves the transplantation of a
24 piece of bone from the patient's own hip (or bone from a cadaver) to the spine to promote bone
25 growth. The purported goal of Infuse is to achieve the ultimate outcome of bone transplantation
26

1 by stimulating bone growth with the use of BMP without producing the possible adverse side
2 effects of a bone grafting procedure.

3 **Medtronic's Course of Conduct**

4 9.

5
6 In order to expand the market for BMP and dramatically improve profits from its use,
7 Medtronic engaged in a sophisticated and deeply deceptive marketing and publication strategy
8 regarding Infuse.

9 10.

10 More specifically, Medtronic collaborated with physician-authors, many of whom were
11 paid millions in consulting fees by the company, to publish studies in peer-reviewed journals that
12 unfairly and deceptively (i) omitted discussion of adverse results, (ii) downplayed side-effects,
13 (iii) overstated the comparative efficacy of Infuse, and (iv) failed to disclose consultant ties to
14 Medtronic and other conflicts of interest.

15
16 11.

17 Medtronic executives exercised significant control over the authorship of the published
18 articles, including directly editing and authoring portions of them and directing physician authors
19 to misrepresent the purported "superiority" of Infuse.

20
21 12.

22 Medtronic consistently failed to disclose, or disclose fully, its extensive editorial
23 involvement in the authorship of the articles that were published under the bylines of physician-
24 consultants.

25 ///

26 ///

13.

1
2 Moreover, certain of the articles did not disclose that the authors were well-paid
3 consultants of Medtronic.

4 14.

5 These articles were published from 2002 through 2009 in various journals, including The
6 Spine Journal.

7 15.

8 Medtronic knowingly disseminated the deceptive articles into the State.
9

10 16.

11 Medtronic also used the deceptive scientific literature that it produced to train sales
12 representatives to use the exaggerated safety, efficacy and superiority claims about Infuse in
13 discussions with physicians and thus generate sales for Infuse in Oregon.

14 17.

15 Through its carefully planned publication scheme involving purportedly unbiased, trusted
16 scientific publications, Medtronic misrepresented to physicians and patients in Oregon that
17 Infuse was vastly superior to other existing therapies, and that patients who used Infuse
18 experienced little to no adverse events.
19

20 18.

21 In reality, however, Medtronic knew or should have known that Infuse's efficacy was, at
22 best, merely equivalent to other existing therapies, and that Infuse may pose additional safety
23 risks, including inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde
24 ejaculation, urinary retention, bone resorption, implant displacement, sterility, and cancer.

26 ///

19.

1
2 In June 2011, the Spine Journal dedicated an entire issue to repudiating the deceptive
3 articles, concluding that they were misleading and biased.

4 20.

5 In October 2012, a U.S. Senate inquiry revealed that Medtronic failed to disclose the
6 extensive financial ties between the company and the physician-authors who published the
7 studies. Additionally, the inquiry found that Medtronic did not reveal the extent to which it
8 exercised editorial control so as to unfairly and deceptively manipulate the content of the studies.
9

10 **CLAIMS FOR RELIEF**

11 21.

12 The allegations contained in paragraphs 1-20 are incorporated by reference as if they
13 were set out at length herein.

14 22.

15 Medtronic, in the course of promoting and marketing Infuse for off-label uses,
16 misrepresented its approved uses which had the capacity or tendency to deceive or mislead
17 health care providers and patients. Pursuant to ORS 646.608(3), the Attorney General need not
18 prove actual confusion or misunderstanding to prevail in an action under the UTPA.

19 23.

20 Medtronic, in the course of promoting and marketing Infuse, made omissions concerning
21 its approved uses and those omissions deceived or tended to deceive consumers. Pursuant to
22 ORS 646.608(2), such failures to disclose facts are representations, actionable under the UTPA.

23 24.

24 Medtronic, in the course of promoting and marketing Infuse, represented that Infuse had
25 approvals, characteristics, uses, benefits, and qualities that it did not have and, pursuant to ORS
26 646.608(1)(e), such misrepresentations constitute unlawful trade practices.

1 25.
2 Medtronic, in the course of minimizing and misrepresenting risks, made false,
3 misleading, or other representations about Infuse's side effects that had the capacity, tendency, or
4 effect of deceiving or misleading consumers. Pursuant to ORS 646.608(1)(e), such
5 misrepresentations constitute unlawful trade practices.

6 26.
7 Medtronic, in the course of overstating the findings of scientific studies in marketing
8 messages, made false, misleading, or other representations about scientific studies that had the
9 capacity or tendency to deceive or mislead health care providers and patients. Pursuant to ORS
10 646.608(1)(e), such misrepresentations constitute unlawful trade practices.

11 **PRAYER FOR RELIEF**

12 27.
13 WHEREFORE, the plaintiff prays that this honorable Court enter an Order:
14 (a) Issuing a permanent injunction prohibiting Medtronic, its agents, employees,
15 and all other persons and entities, corporate or otherwise, in active concert or
16 participation with any of them, from engaging in unfair or deceptive conduct;
17 (b) Ordering Medtronic to pay reasonable attorney fees and costs for the
18 prosecution and investigation of this action, as provided by ORS 646.632(8)
19 and ORCP 68;
20 (c) Ordering Medtronic to pay civil penalties of up to \$25,000 for each willful
21 violation of the Oregon UTPA, ORS 646.605 to 646.656; and

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1 (d) Granting such other and further relief as the Court deems equitable and proper.

2
3 DATED: December 12, 2017

4 Respectfully submitted,

5 FOR THE STATE OF OREGON

6 ELLEN F. ROSENBLUM,
7 Attorney General

8 

9 _____
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