IN THE DISTRICT COURT OF LANCASTER COUNTY, NEBRASKA

STATE OF NEBRASKA, ex rel. DOUGLAS J. PETERSON, ATTORNEY GENERAL,	)	Case No. _____
Plaintiff,	)	**COMPLAINT**
v.	)	
BOSTON SCIENTIFIC CORPORATION,	)	
Defendant.	)	

NOW COMES the Plaintiff, the State of Nebraska, ex rel. Douglas J. Peterson, Attorney General, by and through the undersigned Assistant Attorney General brings this action against Defendant Boston Scientific Corporation for violating provisions of Nebraska's Consumer Protection Act, Neb. Rev. Stat. § 59-1601 *et seq*. and Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301 *et seq*., and states as follows:

The Parties

1. Plaintiff, the State of Nebraska, Douglas J. Peterson, is charged with, among other things, enforcing and seeking redress for violations of Nebraska consumer protection laws, including Nebraska's Consumer Protection Act, Neb. Rev. Stat. § 59-1601 *et seq.* and Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301 *et seq.*.

2. Defendant Boston Scientific Corporation ("Boston Scientific") is a Delaware corporation and headquartered at 300 Boston Scientific Way, Marlborough, MA 01752-1234.

3. At all times relevant hereto, Defendant Boston Scientific transacted business in the State of Nebraska and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices.

Jurisdiction and Venue

4. This Court has jurisdiction over the Defendant and the subject matter of this action pursuant to Neb. Rev. Stat. § 59-1608 and Neb. Rev. Stat. § 87-303.05(1) because Defendant Boston Scientific has transacted business within the State of Nebraska at all times relevant to this Complaint.

5. Venue for this action is proper in this Court pursuant to Neb. Rev. Stat. § 59-1608.01 and Neb. Rev. Stat. § 87-303.05(1) because Defendant Boston Scientific transacts business in Lancaster County, Nebraska and throughout Nebraska and/or some of the transactions upon which this action arose occurred in Lancaster County, Nebraska and throughout Nebraska.

Background

6. "Surgical Mesh," as used in this Complaint, is a medical device that contains synthetic polypropylene mesh intended to be implanted in the pelvic floor to treat stress urinary incontinence ("SUI") and/or pelvic organ prolapse ("POP") manufactured and sold by Boston Scientific in the United States.

7. SUI and POP are common conditions that pose lifestyle limitations and are not life-threatening.

8. SUI is a leakage of urine during episodes of physical activity that increase abdominal pressure, such as coughing, sneezing, laughing, or exercising. SUI can happen when pelvic tissues and muscles supporting the bladder and urethra become weak and allow the neck of

the bladder to descend during bursts of physical activity, and the descent can prevent the urethra from working properly to control the flow of urine. SUI can also result when the sphincter muscle that controls the urethra weakens and is not able to stop the flow of urine under normal circumstances and with an increase in abdominal pressure.

9. POP happens when the tissue and muscles of the pelvic floor fail to support the pelvic organs resulting in the drop of the pelvic organs from their normal position. Not all women with POP have symptoms, while some experience pelvic discomfort or pain, pressure, and other symptoms.

10. In addition to addressing symptoms, such as wearing absorbent pads, there are a variety of non-surgical and surgical treatment options to address SUI and POP. Non-surgical options for SUI include pelvic floor exercises, pessaries, transurethral bulking agents, and behavior modifications. Surgery for SUI can be done through the vagina or abdomen to provide support for the urethra or bladder neck with either stitches alone, tissue removed from other parts of the body, tissue from another person, or with material such as surgical mesh, which is permanently implanted. Non-surgical options for POP include pelvic floor exercises and pessaries. Surgery for POP can be done through the vagina or abdomen using stitches alone or with the addition of surgical mesh.

11. Boston Scientific marketed and sold Surgical Mesh devices to be implanted transvaginally for the treatment of POP for approximately 10 years or more. Boston Scientific ceased the sale of Surgical Mesh devices to be implanted transvaginally for the treatment of POP after the Food and Drug Administration ("FDA") ordered manufacturers of such products to cease the sale and distribution of the products in April 2019.

12. Boston Scientific began marketing and selling Surgical Mesh devices to be implanted transvaginally for the treatment of SUI by 2003 and continues to market and sell Surgical Mesh devices to be implanted transvaginally for the treatment of SUI.

13. The FDA applies different levels of scrutiny to medical devices before approving or clearing them for sale.

14. The most rigorous level of scrutiny is the premarket approval ("PMA") process, which requires a manufacturer to submit detailed information to the FDA regarding the safety and effectiveness of its device.

15. The 510(k) review is a much less rigorous process than the PMA review process. Under this process, a manufacturer is exempt from the PMA process and instead provides premarket notification to the FDA that a medical device is "substantially equivalent" to a legally marketed device. While PMA approval results in a finding of safety and effectiveness based on the manufacturer's submission and any other information before the FDA, 510(k) clearance occurs after a finding of substantial equivalence to a legally marketed device. The 510(k) process is focused on equivalence, not safety.

16. Boston Scientific's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process. Boston Scientific marketed and sold Surgical Mesh devices without adequate testing.

Boston Scientific's Course of Conduct

17. In marketing Surgical Mesh devices, Boston Scientific misrepresented and failed to disclose the full range of risks and complications associated with the devices, including misrepresenting the risks of Surgical Mesh as compared with the risks of other surgeries or surgically implantable materials.

18. Boston Scientific misrepresented the safety of its Surgical Mesh by misrepresenting the risks of its Surgical Mesh, thereby making false and/or misleading representations about its risks.

19. Boston Scientific also made material omissions when it failed to disclose the risks of its Surgical Mesh.

20. Boston Scientific misrepresented and/or failed to adequately disclose serious risks and complications of one or more of its transvaginally-placed Surgical Mesh products, including the following:

a. heightened risk of infection;
b. rigid scar plate formation;
c. mesh shrinkage;
d. voiding dysfunction;
e. de novo incontinence;
f. urinary tract infection;
g. risk of delayed occurrence of complications; and
h. defecatory dysfunction.

21. Throughout its marketing of Surgical Mesh, Boston Scientific continually failed to disclose risks and complications it knew to be inherent in the devices and/or misrepresented those inherent risks and complications as caused by physician error, surgical technique, or perioperative risks.

22. In 2008, the FDA issued a Public Health Notification to inform doctors and patients about serious complications associated with surgical mesh placed through the vagina to treat POP or SUI. In 2011, the FDA issued a Safety Communication to inform doctors and patients that serious complications associated with surgical mesh for the transvaginal repair of POP are not rare, and that a systematic review of published literature showed that transvaginal POP repair with mesh

does not improve symptomatic results or quality of life over traditional non-mesh repair and that mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.

23. In 2012, the FDA ordered post-market surveillance studies by manufacturers of surgical mesh to address specific safety and effectiveness concerns related to surgical mesh used for the transvaginal repair of POP. In 2016, the FDA issued final orders to reclassify transvaginal POP devices as Class III (high risk) devices and to require manufacturers to submit a PMA application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP in order to continue marketing the devices.

24. In April 2019, the FDA ordered manufacturers of surgical mesh devices intended for transvaginal repair of POP to cease the sale and distribution of those products in the United States. The FDA determined that Boston Scientific had not demonstrated a reasonable assurance of safety and effectiveness for these devices under the PMA standard. On or around April 16, 2019, Boston Scientific announced it would stop global sales of its transvaginal mesh products indicated for POP.

Count I
Violations of the Consumer Protection Act,
Neb. Rev. Stat. § 59-1601 et seq.

25. Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs 1 through 24 as if they were set out at length herein.

26. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific engaged in conduct that constitutes deceptive or misleading practices,

which is therefore unlawful under the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601 et seq., including but not limited to:

a. Making false statements about, misrepresenting, and/or making other representations about the risks of Surgical Mesh products that had the effect, capacity, or tendency, of deceiving or misleading consumers;

b. Making representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have; and

c. Making material omissions concerning the risks and complications associated with Surgical Mesh products, and those material omissions had the effect, capacity, or tendency of deceiving consumers.

27. The acts or practices described herein occurred in trade or commerce as defined in Neb. Rev. Stat. § 59-1601(2) of the Nebraska Consumer Protection Act.

28. These acts or practices affected the public interest because they impacted numerous Nebraska consumers.

Count II
Violations of the Uniform Deceptive Trade Practices Act,
Neb. Rev. Stat. § 87-301 et seq.

29. Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs 1 through 24 as if they were set out at length herein.

30. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific engaged in conduct that constitutes deceptive or misleading practices,

which is therefore unlawful under the Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301 et seq., including but not limited to:

a. Making false statements about, misrepresenting, and/or making other representations about the risks of Surgical Mesh products that had the effect, capacity, or tendency, of deceiving or misleading consumers;

b. Making representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have; and

c. Making material omissions concerning the risks and complications associated with Surgical Mesh products, and those material omissions had the effect, capacity, or tendency of deceiving consumers.

31. The acts or practices described herein occurred in the course of business, vocation, or occupation as set forth in Neb. Rev. Stat. § 87-302(a) of the Nebraska Uniform Deceptive Trade Practices Act.

Request for Relief

32. WHEREFORE, Plaintiff respectfully requests this Court enter an Order:

a. Pursuant to Neb. Rev. Stat. § 59-1608 and Neb. Rev. Stat. § 87-303.05, adjudging and decreeing that Defendant has engaged in the acts or practices complained of herein, and that such constitute unfair and/or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1602 and Neb. Rev. Stat. § 87-302;

b. Pursuant to Neb. Rev. Stat. § 59-1608 and Neb. Rev. Stat. § 87-303.05, issuing a permanent injunction prohibiting Defendant, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive trade practices

in the marketing, promoting, selling and distributing of Defendant's Surgical Mesh devices;

c. Pursuant to Neb. Rev. Stat. § 59-1614 and Neb. Rev. Stat. § 87-303.11, ordering Defendant to pay civil penalties in the amount of $2,000.00 for each and every violation of the Consumer Protection Act and the Uniform Deceptive Trade Practices Act;

d. Pursuant to Neb. Rev. Stat. § 59-1608 and Neb. Rev. Stat. § 87-303, ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action;

e. Pursuant to Neb. Rev. Stat. § 59-1608, ordering Defendant to provide monetary restitution to consumers impacted by the acts and practices detailed above;

f. Ordering such other and further relief as the Court may deem just and proper.

Dated this 23rd day of March, 2021.

BY: Douglas J. Peterson, #18146
Attorney General of Nebraska

BY: */s/ Michaela J. Lutz*
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