STATE OF VERMONT

SUPERIOR COURT **CIVIL DIVISION**
Washington Unit

STATE OF VERMONT,	)	**Docket No._____**
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
BOSTON SCIENTIFIC CORPORATION,	)	
	)	
	)	
Defendant.	)	

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF

The State of Vermont ("Plaintiff" or "State"), by and through the Vermont Attorney General, and brings this action against Defendant Boston Scientific Corporation ("Defendant" or "BSC") for violating the Vermont Consumer Protection Act, 9 V.S.A. § 2453 (the "CPA") which prohibits unfair and deceptive acts and practices. Defendant has violated the CPA by engaging in unfair and deceptive acts and practices, including deceiving consumers by misrepresenting the safety and efficacy of its Surgical Mesh devices (defined below) and failing to disclose risks and complications associated with their use. The State seeks civil penalties, injunctive relief, disgorgement, fees, costs, and other appropriate relief, as follows:

I. PARTIES, JURISDICTION, AND VENUE

A. Plaintiff

1. The Vermont Attorney General is authorized under the Vermont Consumer Protection Act, 9 V.S.A. § 2458, to sue to enforce the CPA's prohibitions on unfair and deceptive acts and practices in commerce.

2. The Vermont Attorney General also has the right to appear in any civil action in which the State has an interest. 3 V.S.A. § 157. The Vermont Attorney General has an interest in ensuring that entities that do business in the State of Vermont do so in a lawful manner.

B. Defendant

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

4. At all times relevant hereto, Defendant BSC transacted business in the State of Vermont and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal Surgical Mesh devices, and that business is governed by the CPA.

C. Jurisdiction and Venue

5. This Court has jurisdiction over the Defendant because it has transacted substantial business in the State of Vermont and the unlawful acts alleged herein have been committed in the State of Vermont.

6. Defendant was, at all times relevant hereto, engaged in trade or commerce int the State of Vermont. Defendant knowingly placed its Surgical Mesh

devices into the stream of commerce through designing, manufacturing, marketing, packaging, and selling such devices, including in the State of Vermont. Ultimately, its Surgical Mesh devices were surgically placed into Vermont consumers. Defendant derived profits from Vermont consumers, including patients, hospitals, clinics, and health care providers from the sale of its Surgical Mesh devices.

7. Venue lies in the Washington Unit of the Superior Court of the State of Vermont pursuant to 12 V.S.A. § 402.

II. BACKGROUND

8. "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 BSC in the United States.

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

10. 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.

11. 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.

12. 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.

13. BSC marketed and sold Surgical Mesh devices to be implanted transvaginally for the treatment of POP for approximately 10 years or more. BSC 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.

14. BSC 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.

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

16. 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.

17. The 510(k) review is a much less rigorous process than the PMA review process. Under the 510(k) review 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 equivalency, not safety.

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

III. BOSTON SCIENTIFIC CORPORATION'S COURSE OF CONDUCT

19. In marketing Surgical Mesh devices, BSC 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.

20. BSC 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.

21. BSC also made material omissions when it failed to disclose the risks of its Surgical Mesh.

22. BSC 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.

23. Throughout its marketing of Surgical Mesh, BSC 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.

24. 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 Surgical Mesh used in transvaginal POP repair introduces risks not present in traditional non-Surgical Mesh surgery for POP repair.

25. 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[1] (high risk) devices and to require manufacturers to submit a PMA application to

[1] The FDA defines Class III devices a products which "usually sustain or support life, are implanted or present a potential unreasonable risk of illness or injury." Just 10% of devices regulated by the FDA fall into Class III. https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing (last visited on March 23, 2021).

support the safety and effectiveness of surgical mesh for the transvaginal repair of POP in order to continue marketing the devices.

26. 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 BSC had not demonstrated a reasonable assurance of safety and effectiveness for these devices under the PMA standard. On or around April 16, 2019, BSC announced it would stop global sales of its transvaginal Surgical Mesh products indicated for POP.

IV. CAUSES OF ACTION

COUNT ONE

Violations of the Vermont Consumer Protection Act (Deceptive Acts and Practices)

27. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though set forth herein.

28. The Vermont Consumer Protection Act prohibits unfair and deceptive acts and practices in commerce. 9 V.S.A. § 2453(a).

29. Defendant engaged in deceptive acts and/or practices in commerce by making material misrepresentations and omissions in its marketing, promoting, and selling its Surgical Mesh devices, including by:

a. representing its Surgical Mesh devices were safe while misrepresenting and omitting risks and complications caused by its Surgical Mesh devices;

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

c. making material omissions by failing to disclose the risks and complications of its Surgical Mesh devices.

30. Defendant's misrepresentations and omissions about its Surgical Mesh devices were likely to mislead doctors and consumers and were material in that they were likely to affect consumers' decision to use Defendant's Surgical Mesh. The meaning ascribed by consumers to Defendant's claims about its Surgical Mesh devices was reasonable given the nature of those claims.

COUNT TWO

Violations of the Vermont Consumer Protection Act (Unfair Business Practices)

31. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though set forth herein.

32. The Vermont Consumer Protection Act prohibits unfair acts or practices in commerce. 9 V.S.A. § 2453(a).

33. Business conduct is considered an unfair business practice if it offends public policy; or is immoral, unethical, oppressive, or unscrupulous; or causes substantial injury to consumers.

34. These acts and/or practices affected the public interest because they impact numerous Vermont consumers.

35. Defendant engaged in unfair acts or practices in commerce in the course of marketing, promoting, selling, and distributing its Surgical Mesh devices.

36. These acts or practices may be deemed unfair because they offend the public policy reflected in § 2453 (a) of the CPA, which protects consumers from deceptive marketing and to ensure an honest marketplace; and are immoral, unethical, and unscrupulous.

37. In addition, because of Defendant's conduct, Vermont consumers have suffered substantial injury by reason of the health effects and risks associated with the use of Defendant's Surgical Mesh, as well as the associated financial costs.

V. REQUEST FOR RELIEF

WHEREFORE, the State of Vermont respectfully requests the Court enter judgment in its favor and the following relief:

a. A judgment in its favor and against Defendant on each cause of action asserted in the Complaint;

b. 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 acts and practices described in the Complaint;

c. A judgment requiring Defendant to disgorge all funds acquired and/or retained as a result of any acts or practices found to be unlawful;

d. Statutory civil penalties in the amount of $10,000 for each violation of the Vermont Consumer Protection Act;

e. The award of costs and fees to the State of Vermont; and

f. Such other and further relief as the Court deems appropriate.

Dated: March 23, 2021.

STATE OF VERMONT

Thomas J. Donovan, Jr.
Attorney General

Respectfully submitted: _____

Merideth C. Chaudoir
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, Vermont 05609
Tel. No.: 802-828-1422
E-mail: merideth.chaudoir@vermont.gov