IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT, IN AND FOR BROWARD COUNTY, FLORIDA

OFFICE OF THE ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	)	CASE NO.:

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF

NOW COMES the Plaintiff, Office of the Attorney General, State of Florida, Department of Legal Affairs ("Office of the Attorney General"), and brings this action against Defendant Boston Scientific Corporation for violating the Florida Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, Florida Statutes, and states as follows:

Public Interest

1. The Office of the Attorney General conducted an investigation of the matters alleged herein and determined that this enforcement action serves the public interest, as required by Section 501.207(2), Florida Statutes.

The Parties

2. Plaintiff, Office of the Attorney General, State of Florida, Department of Legal Affairs, is charged with, among other things, enforcing and seeking redress for violations of Florida's

consumer protection laws, including the Florida Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, Florida Statutes ("FDUTPA").

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

4. At all times relevant hereto, Defendant Boston Scientific transacted business in the State of Florida and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices, and that business is governed by FDUTPA.

Jurisdiction and Venue

5. This Court has jurisdiction over the Defendant pursuant to Sections 26.012, Florida Statutes and Chapter 501.201 *et seq*., Florida Statutes because Defendant Boston Scientific has transacted business within the State of Florida at all times relevant to the Complaint.

6. Venue is proper in Broward County pursuant to Section 47.051, Florida Statutes and Chapter 501.201 *et seq*., Florida Statutes because Defendant Boston Scientific has carried on a regular business in Broward County, Florida.

Background

7. "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.

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

9. 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.

10. 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.

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

14. 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.

15. Boston Scientific's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process.

Boston Scientific's Course of Conduct

16. 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.

17. Boston Scientific misrepresented the safety of its Surgical Mesh by misrepresenting the risks of its Surgical Mesh, including the following complications:

a. chronic pain;

b. voiding dysfunction; and

c. new onset of incontinence.

18. 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.

19. 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.

20. 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.

Violation of the Florida Deceptive and Unfair Trade Practices Act

21. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 20 as if they were set out at length herein.

22. In the course of marketing, promoting, selling, and distributing Surgical Mesh products,

Boston Scientific misrepresented the risks of Surgical Mesh products. Pursuant to Section 501.204, Florida Statutes of FDUTPA, such misrepresentations constitute unfair or deceptive trade practices that are prohibited by Section 501.204, Florida Statutes of FDUTPA.

23. The acts or practices described herein occurred in trade or commerce as defined in Section 501.203(8), Florida Statutes.

Request for Relief

WHEREFORE, Plaintiff respectfully requests that this Honorable Court enter an Order:

a. 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 FDUTPA;

b. 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;

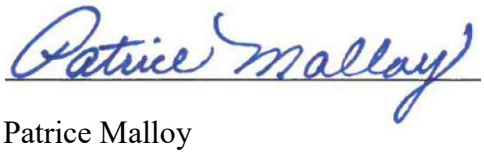
c. Ordering Defendant to pay civil penalties in the amount of up to $15,000.00 for each and every violation of FDUTPA;

d. Ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action, as provided by Section 501.2105(1), Florida Statutes of FDUTPA; and

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

Respectfully submitted,

ASHLEY MOODY
ATTORNEY GENERAL

By: 

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