Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIV. ___
CIVIL ACTION NO. _____

COMMONWEALTH OF KENTUCKY	)
	)
Plaintiff,	)
	)
v.	)
	)
BOSTON SCIENTIFIC CORPORATION,	)
	)
Defendant.	)

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF

NOW COMES the Plaintiff, the Commonwealth of Kentucky, and brings this action against Defendant Boston Scientific Corporation for violating the Kentucky Consumer Protection Act (KRS 367.110, *et seq*.), the "Consumer Protection Act" or UDAP, and states as follows:

The Parties

1. Plaintiff, the Commonwealth of Kentucky, is charged with, among other things, enforcing and seeking redress for violations of Kentucky's consumer protection laws, including the Kentucky Consumer Protection Act.

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 Commonwealth of Kentucky and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices, and that business is governed by the Kentucky Consumer Protection Act.

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000001 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000001 of 000008

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

Jurisdiction and Venue

4. This Court has jurisdiction over the Defendant pursuant to KRS 367.190 because Defendant Boston Scientific has transacted business within the Commonwealth of Kentucky at all times relevant to the Complaint.

5. Venue is proper in Franklin Circuit Court pursuant to KRS 367.190(1) because Defendant Boston Scientific has carried on a regular business in Kentucky.

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

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000002 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000002 of 000008

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

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000003 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000003 of 000008

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.

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000004 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000004 of 000008

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.

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000005 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000005 of 000008

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.

Violation of the Kentucky Consumer Protection Act

25. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding 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 made false statements about, misrepresented, and/or made other representations about the risks of Surgical Mesh products that had the effect, capacity, or tendency, of deceiving or misleading consumers. Pursuant to KRS 367.170 of the Kentucky Consumer Protection Act, such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by KRS 367.170 of the Kentucky Consumer Protection Act.

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

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000006 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000006 of 000008

Boston Scientific has made representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have. Pursuant to KRS 367.170 of the Kentucky Consumer Protection Act, such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by KRS 367.170 of the Kentucky Consumer Protection Act.

28. Defendant Boston Scientific made 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. Pursuant to KRS 367.170 of the Kentucky Consumer Protection Act, such omissions constitute unfair or deceptive trade practices that are prohibited by KRS 367.170 of the Kentucky Consumer Protection Act.

29. The acts or practices described herein occurred in trade or commerce as defined in KRS 367.110(2).

30. These acts or practices affected the public interest because they impacted numerous Kentucky consumers.

Request for Relief

31. 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 KRS 367.170;

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

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000007 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000007 of 000008

Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

Surgical Mesh devices;

c. Ordering Defendant to pay civil penalties in the amount of up to $10,000.00 for each and every violation of KRS 367.170 of the Kentucky Consumer Protection Act;

d. Ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action, as provided by the Kentucky Consumer Protection Act;

e. 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.

Respectfully submitted,

By: _____

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Filed 21-CI-00234 03/23/2021 Amy Feldman, Franklin Circuit Clerk

7664052B-24B1-459E-B7CB-070D72C8CEC4 : 000008 of 000035
Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)
COM : 000008 of 000008