

STATE OF SOUTH CAROLINA

IN THE COURT OF COMMON PLEAS
FIFTH JUDICIAL CIRCUIT

COUNTY OF RICHLAND

Case No. 2021-CP-40-

State of South Carolina,

Plaintiff,

vs.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

SUMMONS

TO THE DEFENDANT ABOVE-NAMED:

YOU ARE HEREBY SUMMONED and required to answer the complaint herein, a copy of which is herewith served upon you, and to serve a copy of your answer to this complaint upon the subscriber, at the address shown below, within thirty (30) days after service hereof, exclusive of the day of such service, and if you fail to answer the complaint, judgment by default will be rendered against you for the relief demanded in the complaint.

/s/Kristin M. Simons

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March 23, 2021

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COMPLAINT

NOW COMES the Plaintiff, the State of South Carolina, and brings this action against Boston Scientific Corporation for violating the South Carolina Unfair Trade Practices Act, § 39-5-10 *et. seq.* of the South Carolina Code of Laws (“SCUTPA”) and states as follows:

The Parties

1. Plaintiff, the State of South Carolina, is charged with, among other things, enforcing and seeking redress for violations of South Carolina consumer protection laws, including the South Carolina Unfair Trade Practices Act, § 39-5-10 *et. seq.* of the South Carolina Code of Laws.
2. Defendant Boston Scientific Corporation (“Boston Scientific”) is a Delaware corporation 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 South Carolina and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices, and that business is

governed by the South Carolina Unfair Trade Practices Act, § 39-5-10 *et. seq.* of the South Carolina Code of Laws.

Jurisdiction and Venue

4. This Court has jurisdiction over the Defendant pursuant to S.C. Code Ann. § 36-2-803 because Defendant Boston Scientific transacted business within the State of South Carolina at all times relevant to the Complaint.
5. Venue is proper in Richland County pursuant to S.C. Code Ann. § 15-7-30 because Defendant Boston Scientific transacted business in Richland County, South Carolina.

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 may occur when pelvic tissues and muscles supporting the bladder and urethra become weak.
9. POP occurs when the tissue and muscles of the pelvic floor fail to adequately support the pelvic organs resulting in the drop of the pelvic organs from their normal position, and which may cause 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 Food and Drug Administration (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. When a medical device is “substantially equivalent” to a legally marketed device, the manufacturer is exempt from the PMA process and the device undergoes review under the much less rigorous 510(k) 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 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 and 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. That same year, Boston Scientific ceased marketing transvaginal POP Surgical Mesh products. 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.

Violations of the South Carolina Unfair Trade Practices 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. Such false statements and

misrepresentations constitute unfair methods of competition and unfair or deceptive acts or practices prohibited by § 39-5-20 of SCUTPA.

27. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific made representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have. Such false statements and misrepresentations constitute unfair methods of competition and unfair or deceptive acts or practices prohibited by § 39-5-20 of SCUTPA.

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 and which constitutes an unfair method of competition and unfair or deceptive act or practice prohibited by § 39-5-20 of SCUTPA.

29. The acts or practices described herein occurred in trade or commerce as defined in S.C. Code Ann. § 39-5-10(b).

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

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 the South Carolina Unfair Trade Practices Act;
- 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, promotion, selling and distributing of Defendant's Surgical Mesh devices;

- c. Ordering Defendant to pay civil penalties in the amount of up to \$5,000 for each and every violation of SCUTPA pursuant to § 39-5-110 of SCUTPA;
- d. Ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action, as provided by § 39-5-140 of SCUTPA; and
- e. Ordering such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/Kristin M. Simons

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