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SUPERIOR COURT OF ARIZONA

IN MARICOPA COUNTY

STATE OF ARIZONA, *ex rel.* MARK BRNOVICH, Attorney General, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	Case No. **COMPLAINT**

Plaintiff, State of Arizona ex rel. Mark Brnovich, the Attorney General (the "State"), alleges the following for its Civil Complaint (the "Complaint") against Defendant Boston Scientific Corporation ("Boston Scientific").

JURISDICTION AND VENUE

1. The State brings this action pursuant to the Arizona Consumer Fraud Act, Arizona Revised Statutes ("A.R.S.") §§ 44-1521 to -1534 to obtain injunctive relief to permanently enjoin and prevent the unlawful acts and practices alleged in this Complaint, and to obtain other relief, including restitution, disgorgement of profits, gains, gross receipts, or other benefits, civil penalties, and costs and attorneys' fees.

2. This Court has subject-matter jurisdiction.

3. This Court may issue appropriate orders both prior to and following a determination of liability pursuant to A.R.S. § 44-1528.

4. Boston Scientific caused events to occur in this state out of which the claims which are the subject of this Complaint arose.

5. Venue is proper in Maricopa County pursuant to A.R.S. § 12-401(17).

PARTIES

6. Plaintiff is the State of Arizona ex rel. Mark Brnovich, the Attorney General of Arizona, who is authorized to bring this action under the Arizona Consumer Fraud Act (the "ACFA"), A.R.S. §§ 44-1521 to -1534.

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

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

BACKGROUND

9. "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.

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

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

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

17. 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.

18. 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.

19. 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

20. 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.

21. 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.

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

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

…

CLAIM FOR RELIEF

VIOLATIONS OF THE ARIZONA CONSUMER FRAUD ACT, A.R.S. §§ 44-1521 to -1534

28. The State realleges all prior allegations of this Complaint as though fully set forth herein.

29. The conduct described in the preceding paragraphs of this Complaint constitutes deception, deceptive or unfair acts or practices, fraud, false pretenses, false promises, misrepresentations, or concealment, suppression or omission of material facts with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of merchandise in violation of A.R.S. §§ 44-1521 to -1534, including, but not limited to:

a. Defendant Boston Scientific engaged in deceptive and unfair acts and practices in the course of marketing, promoting, selling, and distributing Surgical Mesh products by 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. Defendant Boston Scientific engaged in deceptive and unfair acts and practices in the course of marketing, promoting, selling, and distributing Surgical Mesh products by making representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have; and

c. Defendant Boston Scientific concealed, suppressed, or omitted material facts, including 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, and did so with intent that others rely on such concealments, suppressions, or omissions.

30. While engaging in the acts and practices alleged in this Complaint, Boston Scientific knew or should have known that that its conduct was of the nature prohibited by A.R.S. § 44-1522, subjecting itself to enforcement and penalties as provided in A.R.S. § 44-1531(A).

PRAYER FOR RELIEF

WHEREFORE, the State respectfully requests that the Court:

31. Pursuant to A.R.S. § 44-1528(A)(1), issue a permanent injunction, enjoining and restraining (a) Boston Scientific, (b) its officers, agents, servants, employees, attorneys, and (c) all persons in active concert or participation with anyone described in part (a) or (b) of this paragraph, directly or indirectly, from engaging in deceptive, misleading, or unfair acts or practices, or concealments, suppressions, or omissions, that violate the CFA, A.R.S. § 44-1522(A) in the marketing, promoting, selling and distributing of Boston Scientific's Surgical Mesh devices;

32. Pursuant to A.R.S. § 44-1531, order Boston Scientific to pay to the State of Arizona a civil penalty of up to $10,000 for each willful violation of A.R.S. § 44-1522;

33. Pursuant to A.R.S. § 44-1534, order Boston Scientific to reimburse the State for its costs and attorneys' fees incurred in the investigation and prosecution of Boston Scientific's activities alleged in this Complaint; and

34. Award the State such further relief the Court deems just and proper under the circumstances.

DATED this 23rd day of March, 2021.

MARK BRNOVICH
Attorney General

By: _____
Dylan Jones
Assistant Attorney General
Attorneys for the State of Arizona