DISTRICT COURT, CITY AND COUNTY OF DENVER, COLORADO 1437 Bannock Street Denver, CO 80202 STATE OF COLORADO, *ex rel* PHILIP J. WEISER, ATTORNEY GENERAL, Plaintiff v. BOSTON SCIENTIFIC CORPORATION, Defendant	DATE FILED: March 23, 2021 7:29 AM FILING ID: 6C8B599A7A03B CASE NUMBER: 2021CV30953 ▲ **COURT USE ONLY** ▲
PHILIP J. WEISER, Attorney General OLIVIA D. WEBSTER, *35867 Senior Assistant Attorney General II Ralph L. Carr Colorado Judicial Center 1300 Broadway, Floor Denver, CO 80203 Telephone: 720-508-6000 E-Mail: Libby.Webster@coag.gov *Counsel of Record	Case No.
COMPLAINT	

Plaintiff, the State of Colorado, upon relation of Philip J. Weiser, Attorney General for the State of Colorado ("Plaintiff"), states and alleges Defendant Boston Scientific Corporation has violated the Colorado Consumer Protection Act ("CCPA"), Colo. Rev. Stat. § 6-1-101 *et. seq*, and states as follows:

The Parties

1. This action is brought for and on behalf of the State of Colorado, by Philip J. Weiser, Attorney General of the State of Colorado, pursuant to the provisions of the CCPA, and his common law authority as Attorney General to represent the State of Colorado and seek redress for violations of Colorado's consumer protection laws.

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 State of Colorado and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices, and that business is governed by the CCPA.

Jurisdiction and Venue

4. Venue for this action properly lies in the City and County of Denver pursuant to C.R.S. § 6-1-103 and C.R.C.P. 98 because Defendant transacts business in the City and County of Denver or some of the transactions upon which this action is based occurred in the City and County of Denver.

5. This court has jurisdiction over the Defendant pursuant to C.R.S. §§ 6-1-103 and 6-1-110 because the Defendant has transacted business within Colorado at all times relevant to this complaint.

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 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 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.

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.

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 Colorado 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 tendency and capacity to deceive consumers.

27. Specifically, Boston Scientific knowingly or recklessly made false representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products. Pursuant to C.R.S. § 6-1-105(1)(e), such false statements constitute unfair or deceptive trade practices prohibited under the CCPA.

28. Boston Scientific also failed to disclose material information concerning the risks and complications associated with Surgical Mesh products, which information was known at the time the representations were made and failure to disclose such information was intended to induce consumers to enter into transactions. Pursuant to C.R.S. § 6-1-105(1)(u), such omissions and misrepresentations constitute unfair or deceptive trade practices prohibited under the CCPA.

29. The acts or practices described herein occurred in the course of Boston Scientific's business. C.R.S. § 6-1-105(1).

Request for Relief

30. WHEREFORE, the Plaintiff, the State of Colorado, request upon final hearing that this Court will enter a Permanent Injunction and Final Judgment, as follows:

A. An order that Defendant's conduct violates the Colorado Consumer Protection Act, including C.R.S. § 6-1-105(1) (e) and (u).

B. An order pursuant to C.R.S. § 6-1-110(1) for an injunction or other orders to "prevent the use or employment of [the Defendant] of any such deceptive trade practice… ."

C. An order pursuant to C.R.S. § 6-1-112(1)(a) for civil penalties payable to the general fund of Colorado;

D. An order pursuant to C.R.S. § 6-1-113(4) requiring Defendant to pay the costs and attorney fees incurred by the Attorney General;

E. Any such further relief as this Court may deem just and proper to effectuate the purposes of the CCPA.

31. WHEREFORE, Plaintiff respectfully requests that this 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 CCPA;

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. An order pursuant to C.R.S. § 6-1-110(1) for an injunction or other orders or judgments to "prevent the use or employment of [the Defendant] of any such deceptive trade practice… ."

d. An order pursuant to C.R.S. § 6-1-112(1)(a) for civil penalties payable to the general fund of this state;

e. An order pursuant to C.R.S. § 6-1-113(4) requiring Defendant to pay the costs and attorney fees incurred by the Attorney General;

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

Respectfully submitted this 23rd day of March, 2021.

PHILP J. WEISER
Attorney General

s/Olivia D. Webster
OLIVIA D WEBSTER*
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