GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street - 5th Floor
P.O. Box 45029
Newark, New Jersey 07101
Attorney for Plaintiffs

By: Patricia Schiripo (014401990)
Deputy Attorney General/ Chief Consumer Fraud Prosecution Section
(973) 648-7819

SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO.: MER-C-

GURBIR S. GREWAL, Attorney General of the State of New Jersey, and KAITLIN A. CARUSO, Acting Director of the New Jersey Division of Consumer Affairs,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

Civil Action

COMPLAINT

Plaintiffs Gurbir S. Grewal, Attorney General of the State of New Jersey ("Attorney General") with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Kaitlin A Caruso, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark New Jersey by way of Complaint state:

PARTIES AND JURISDICTION

1. The Attorney General is charged with enforcing the Consumer Fraud Act, N.J.S.A. 56: 8-1 to -226 ("CFA"). The Director is charged with administering the CFA on behalf of the Attorney General. The Attorney and the Director are collectively the "Plaintiffs".

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

At all times relevant hereto, Defendant Boston Scientific transacted business in the State of New Jersey and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices. Venue is proper in Mercer County, pursuant to R. 4:3-2, because it is a county in which the Defendant has carried on regular business.

3. Upon information and belief, John and Jane Does 1 through 10 are fictitious individuals meant to represent the owners, officers, directors, shareholders, founders, mangers agents, servants, employees, representatives and/or independent contractors of Boston Scientific who have been involved in the conduct that gives rise to this Complaint, but are heretofore unknown to the Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

4. Upon information and belief, XYZ Corporations 1 through 10 are fictitious corporations meant to represent any additional corporations that have been involved in the conduct that gives rise to this Complaint, but are heretofore unknown to the Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

GENERAL ALLEGATIONS

5. "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.

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

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

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

13. 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.

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 marketed and sold Surgical Mesh devices without adequate testing.

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, thereby making false and/or misleading representations about its risks.

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

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

COUNT I

VIOLATION OF THE CFA BY DEFENDANT (UNCONSCIONABLE COMMERCIAL PRACTICES, DECEPTION, MISREPRESENTATIONS AND MATERIAL OMISSIONS)

24. Plaintiffs reallege and incorporate by reference each and every allegation contained in the preceding paragraphs 1 through 23 as if they were set out at length herein.

25. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise....

26. The CFA defines merchandise as including "objects, goods, wares, commodities, services or anything else offered directly or indirectly to the public for sale . . . ." N.J.S.A. 56:8-1(c).

27. Defendant has been engaged in the marketing, promoting, advertising, offering for sale, sale and distribution of merchandise, including surgical mesh, within the meaning of N.J.S.A. 56:8-1(c).

28. In the course of marketing, promoting, selling, advertising 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.

30. In the course of marketing, promoting, selling, advertising and distributing Surgical Mesh products, Boston Scientific has made representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have.

31. 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.

32. Each unconscionable commercial practice, act of deception, misrepresentation and material omission constitutes a separate violation of the CFA, N.J.S.A 56:8-2.

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that this Court enter judgment against Defendant as follows:

(a) Finding that the acts, practices and omissions of Defendant constitutes multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 to -226;

(b) Permanently enjoining the Defendant and its owners, officers, directors, shareholders, founders, members, managers, agents, servants, employees, representatives, independent contractors and all other persons or entities directly under their control from engaging in, continuing to engage in or doing any acts or practices in violation of the CFA, N.J.S.A. 56:8-1 to -226;

(c) Directing Defendant to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any practice alleged herein to be unlawful and found to be unlawful, as authorized by the CFA;

(d) Directing Defendant to pay the maximum statutory civil penalties for each violation of the CFA, in accordance with N.J.S.A. 56:8-13;

(e) Directing Defendant to disgorge all profits unlawfully acquired or retained as authorized by the CFA, N.J.S.A. 56:8-8;

(f) Directing Defendant to pay costs and attorneys' fees for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and

(g) Granting such other relief as the interests of justice may require.

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorneys for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General

Dated: March 23, 2021
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify, in accordance with R. 4:5-1, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who should be joined in this action.

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General

Dated: March 23, 2021
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future, in accordance with R. 1:38-7(b).

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General

Dated: March 23, 2021
Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Patricia A. Schiripo is designated as trial counsel on behalf of Plaintiffs in this action.

GURBIR S. GREWAL
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Attorney for Plaintiffs

By: Patricia Schiripo
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Deputy Attorney General

Dated: March 23, 2021
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