SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK,
by LETITIA JAMES, Attorney General of the
State of New York,

SUMMONS

Plaintiff,

-against-

Index No._____
IAS Part _____
Justice:_____

BOSTON SCIENTIFIC CORPORATION,

Plaintiff designates New York County as the Place of Trial

Defendant.

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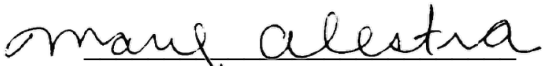
TO: THE ABOVE NAMED DEFENDANT:

YOU ARE HEREBY SUMMONED to answer in this action and serve a copy of your answer, or if the complaint is not served with the summons to serve a notice of appearance, on the plaintiff's attorney within twenty (20) days after the service of the summons, exclusive of the day of service. If the summons is not personally served upon you, or if the summons is served upon you outside of the State of New York, then your answer or notice of appearance must be served within thirty (30) days. In case of your failure to appear or answer, judgment will be taken against you by default, for the relief demanded in the complaint.

Dated: New York, New York
March 23, 2021

Respectfully submitted,

LETITIA JAMES
Attorney General of the
State of New York
Attorney for Plaintiff

By: 

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SUPREME COURT OF THE STATE OF NEW YORK
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THE PEOPLE OF THE STATE OF NEW YORK,
by LETITIA JAMES, Attorney General of the
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Plaintiff,

-against- Index No. _____

BOSTON SCIENTIFIC CORPORATION,

Defendant.

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COMPLAINT

Plaintiff, the People of the State of New York, acting by and through Attorney General Letitia James ("the NYAG") brings this action against Defendant Boston Scientific Corporation for violating New York Executive Law § 63(12) ("Executive Law § 63(12)") and Article 22-A of the New York General Business Law ("GBL"), GBL §§ 349 and 350, and states as follows:

The Parties

1. Plaintiff is the People of the State of New York, acting by and through the NYAG.

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 New York and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices.

Jurisdiction and Venue

4. This action is brought for and on behalf of the People of the State of New York, acting by and through the NYAG, pursuant to the provisions of Executive Law § 63(12) and GBL §§ 349 and 350.

5. This Court has jurisdiction over the Defendant pursuant to Executive Law § 63(12) and GBL §§ 349 and 350. Executive Law § 63(12) empowers the NYAG to seek injunctive relief, restitution, disgorgement, damages, and costs when any person or business entity has engaged in or otherwise demonstrated repeated or persistent fraudulent or illegal acts in the transaction of business. GBL Article 22-A, §§ 349 and 350 authorizes the NYAG to seek injunctive relief, restitution, and civil penalties for deceptive acts or practices and false advertising.

6. Defendant has waived its right to receive pre-litigation notice pursuant to GBL §§ 349(c) and 350-c.

Background

7. "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.

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

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

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

15. 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.

16. 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.

17. 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

18. 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.

19. 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.

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

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

FIRST CAUSE OF ACTION
VIOLATION OF GENERAL BUSINESS LAW § 350

26. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 25 as if they were set out at length herein.

27. GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in [New York]."

28. GBL § 350-a further provides that "false advertising" is advertising that is "misleading in a material respect."

29. By engaging in the advertising alleged above, Defendants have engaged in false advertising in violation of GBL § 350.

SECOND CAUSE OF ACTION
VIOLATION OF GENERAL BUSINESS LAW § 349

30. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 25 as if they were set out at length herein.

31. GBL § 349 declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in [New York]."

32. By engaging in the acts and practices alleged above, Defendants have engaged in deceptive and misleading practices in violation of GBL § 349.

THIRD CAUSE OF ACTION
VIOLATION OF EXECUTIVE LAW § 63(12) (FRAUD)

33. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 25 as if they were set out at length herein.

34. Executive Law §63(12) authorizes the Attorney General to seek injunctive relief whenever any person engages in repeated fraudulent or illegal conduct or otherwise demonstrates persistent fraud or illegality in the carrying on, conducting, or transaction of business.

35. By the acts and practices alleged above, Defendants have engaged in repeated and persistent fraudulent and illegal conduct in violation of Executive Law § 63(12).

Request for Relief

36. WHEREFORE, the NYAG respectfully requests that this Court issue an Order and Judgment pursuant to Executive Law § 63(12) and GBL §§ 349, 350 and 350-d:

a. 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 false, misleading or deceptive practices in the marketing, promoting, selling and distributing of Defendant's Surgical Mesh devices;

b. Ordering Defendant to pay a civil penalty to the State of New York pursuant to GBL § 350-d in the sum of five thousand dollars ($5,000) for each violation of GBL § 349 and GBL § 350;

c. Ordering Defendant to pay costs and reasonable attorneys' fees incurred by the Plaintiff in connection with the investigation and litigation of this matter; and;

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

Respectfully submitted,

LETITIA JAMES
Attorney General of the State of New York
Attorney for Plaintiff

By: Mary Alestra

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Of Counsel:

JANE M. AZIA
Bureau Chief
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LAURA J. LEVINE
Deputy Bureau Chief
Bureau of Consumer Frauds and Protection

Dated: New York, New York
March 23, 2021