ORIGINAL

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NO FEE PURSUANT TO GOVERNMENT CODE §6103

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant,

Case No. RG21092570

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF

(BUS. & PROF. CODE, §§ 17200 et seq. and 17500 et seq.)

Plaintiff, the People of the State of California ("Plaintiff" or the "People"), acting by and through Matthew Rodriquez, Acting Attorney General of the State of California, is informed and believes and thereupon alleges as follows:

I. PARTIES

1. Plaintiff is the People of the State of California.

2. The People bring this action by Matthew Rodriquez, Acting Attorney General of the State of California, pursuant to the provisions of California Business and Professions Code Sections 17200 et seq. and 17500 et seq.

3. Defendant Boston Scientific Corporation is a Delaware corporation headquartered in Marlborough, Massachusetts. At all times relevant to this proceeding, BSC has transacted and continues to transact business throughout California, including in Alameda County.

II. JURISDICTION AND VENUE

4. This Court has original jurisdiction over this action pursuant to article vi, section 10 of the California Constitution.

5. This Court has jurisdiction over Defendant Boston Scientific Corporation (hereinafter "BSC" or "Defendant") because BSC transacted business within the County of Alameda and elsewhere in the state California at all times relevant to this Complaint. BSC transacts business in California by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices manufactured by BSC. Defendant – by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices in the state of California – intentionally availed itself of the California market so as to render the exercise of jurisdiction over Defendant by the California courts consistent with traditional notions of fair play and substantial justice.

6. Venue for this action properly lies in this Court pursuant to Code of Civil Procedure section 395.5 because Defendant transacts business in California or some of the transactions upon which this action is based occurred in California, including the County of Alameda.

7. Venue is also proper in this Court pursuant to Code of Civil Procedure section 393, subdivision (a), because violations of law that occurred in the County of Alameda are a part of the cause upon which the Plaintiff seeks the recovery of penalties imposed by statute.

III. BACKGROUND

8. "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 BSC in the United States.

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

10. 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.

11. 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.

12. 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.

13. BSC marketed and sold Surgical Mesh devices to be implanted transvaginally for the treatment of POP for approximately 10 years or more. BSC 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.

14. BSC 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.

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

16. 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.

17. 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.

18. BSC's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process. BSC marketed and sold Surgical Mesh devices without adequate testing.

III. BSC'S COURSE OF CONDUCT

19. In marketing Surgical Mesh devices, BSC 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.

20. BSC 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.

21. BSC also made material omissions when it failed to disclose the risks of its Surgical Mesh.

22. BSC 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.

23. Throughout its marketing of Surgical Mesh, BSC 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.

24. 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.

25. 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.

26. 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 BSC had not demonstrated a reasonable assurance of safety and effectiveness for these devices under the PMA standard. On or around April 16, 2019, BSC announced it would stop global sales of its transvaginal mesh products indicated for POP.

FIRST CAUSE OF ACTION
Violations of Business and Professions Code Section 17500
(Untrue or Misleading Representations)

27. The People reallege and incorporate by reference each and every allegation contained in the preceding paragraphs 1 through 26 as though fully set forth herein.

28. Defendant has engaged in and continues to engage in, has aided and abetted and continues to aid and abet, and has conspired to and continues to conspire to engage in acts or practices that constitute violations of Business and Professions Code section 17500.

29. Defendant, in the course of engaging in the marketing, promoting, selling, and distributing of Surgical Mesh products, with the intent to induce members of the public to purchase Defendant's products, has made and caused to be made omissions and misrepresentations concerning Defendant's products and matters of fact, which Defendant knew, or by the exercise of reasonable care should have known, were false, deceptive, or misleading at the time they were made, by the following:

(a) advertising, promoting, communicating or otherwise representing in a way that is unfair, false, misleading, and/or deceptive (i) its Surgical Mesh devices and (ii) the safety of its Surgical Mesh;

(b) representing its Surgical Mesh devices have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities the devices do not have;

(c) representing that its Surgical Mesh are of a particular standard, quality, or grade, when they are of another; and

(d) failing to disclose information concerning its Surgical Mesh, which was known at the time of the offer and sale of its Surgical Mesh products, when the failure was

intended to induce the consumer into the transaction into which the consumer would not have entered had the information been disclosed.

SECOND CAUSE OF ACTION
Violations of Business and Professions Code Section 17200
(Acts of Unfair Competition)

30. The People reallege and incorporate by reference each and every allegation contained in the preceding paragraphs 1 through 29 as though fully set forth herein.

31. The Unfair Competition Law, Business and Professions Code section 17200 et seq., provides that unfair competition shall mean and include, among other acts, any unlawful or unfair business act or practice and any act prohibited by Business and Professions Code section 17500.

32. Defendant, has engaged in the following unlawful and unfair acts and practices, among others, each of which constitute acts of unfair competition in violation of Business and Professions Code section 17200:

(a) Defendant's actions constitute multiple violations of Business and Professions Code section 17500 as alleged in the First Cause of Action, which allegations are incorporated herein as if set forth in full.

(b) Defendant, in the course of its business, has unfairly and unconscionably worked with certain of its opioid manufacturing clients to aggressively promote and sell more opioids to more patients for longer periods of time, in violation of Business and Professions Code section 17200.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that:

1. An injunction be issued pursuant to Business and Professions Code sections 17203 and 17535 restraining and enjoining Defendant and their agents, employees, and all other persons or entities, corporate or otherwise, in active concert or participation with any of them, from violating Business and Professions Code sections 17200 et seq. or 17500 et seq.

2. Pursuant to Business and Professions Code sections 17206 and 17536, Defendant be assessed a civil penalty of two thousand five hundred ($2,500) for each violation of Business and Professions Code sections 17200 et seq. and 17500 et seq., as proved at trial.

3. The Court Order Defendant to pay Plaintiff's costs.

4. Plaintiff is given such other and further relief as the nature of this case may require and that this Court deems equitable and proper to fully and successfully dissipate the effects of the alleged violations of Business and Professions Code sections 17200 et seq. and 17500 et seq.

Dated: March 16, 2021

Respectfully Submitted,

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