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**NO FEE PURSUANT TO
GOVERNMENT CODE §6103**

8
9 IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
10
11 IN AND FOR THE COUNTY OF ALAMEDA
12

13 **THE PEOPLE OF THE STATE OF
CALIFORNIA,**

14
15 Plaintiff,

16 v.

17 **BOSTON SCIENTIFIC CORPORATION,**

18
19 Defendant,

Case No.

**COMPLAINT FOR PERMANENT
INJUNCTION AND OTHER RELIEF**

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

20
21 Plaintiff, the People of the State of California (“Plaintiff” or the “People”), acting by and
22 through Matthew Rodriquez, Acting Attorney General of the State of California, is informed and
23 believes and thereupon alleges as follows:

24 **I. PARTIES**

- 25 1. Plaintiff is the People of the State of California.
- 26 2. The People bring this action by Matthew Rodriquez, Acting Attorney General of
27 the State of California, pursuant to the provisions of California Business and Professions Code
28 Sections 17200 et seq. and 17500 et seq.

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

3 10. SUI is a leakage of urine during episodes of physical activity that increase
4 abdominal pressure, such as coughing, sneezing, laughing, or exercising. SUI can happen when
5 pelvic tissues and muscles supporting the bladder and urethra become weak and allow the neck of
6 the bladder to descend during bursts of physical activity, and the descent can prevent the urethra
7 from working properly to control the flow of urine. SUI can also result when the sphincter
8 muscle that controls the urethra weakens and is not able to stop the flow of urine under normal
9 circumstances and with an increase in abdominal pressure.

10 11. POP happens when the tissue and muscles of the pelvic floor fail to support the
11 pelvic organs resulting in the drop of the pelvic organs from their normal position. Not all
12 women with POP have symptoms, while some experience pelvic discomfort or pain, pressure,
13 and other symptoms.

14 12. In addition to addressing symptoms, such as wearing absorbent pads, there are a
15 variety of non-surgical and surgical treatment options to address SUI and POP. Non-surgical
16 options for SUI include pelvic floor exercises, pessaries, transurethral bulking agents, and
17 behavior modifications. Surgery for SUI can be done through the vagina or abdomen to provide
18 support for the urethra or bladder neck with either stitches alone, tissue removed from other parts
19 of the body, tissue from another person, or with material such as surgical mesh, which is
20 permanently implanted. Non-surgical options for POP include pelvic floor exercises and
21 pessaries. Surgery for POP can be done through the vagina or abdomen using stitches alone or
22 with the addition of surgical mesh.

23 13. BSC marketed and sold Surgical Mesh devices to be implanted transvaginally for
24 the treatment of POP for approximately 10 years or more. BSC ceased the sale of Surgical Mesh
25 devices to be implanted transvaginally for the treatment of POP after the Food and Drug
26 Administration (FDA) ordered manufacturers of such products to cease the sale and distribution
27 of the products in April 2019.

28

1 22. BSC misrepresented and/or failed to adequately disclose serious risks and
2 complications of one or more of its transvaginally-placed Surgical Mesh products, including the
3 following:

- 4 (a) heightened risk of infection;
- 5 (b) rigid scar plate formation;
- 6 (c) mesh shrinkage;
- 7 (d) voiding dysfunction;
- 8 (e) de novo incontinence;
- 9 (f) urinary tract infection;
- 10 (g) risk of delayed occurrence of complications; and
- 11 (h) defecatory dysfunction.

12 23. Throughout its marketing of Surgical Mesh, BSC continually failed to disclose
13 risks and complications it knew to be inherent in the devices and/or misrepresented those inherent
14 risks and complications as caused by physician error, surgical technique, or perioperative risks.

15 24. In 2008, the FDA issued a Public Health Notification to inform doctors and
16 patients about serious complications associated with surgical mesh placed through the vagina to
17 treat POP or SUI. In 2011, the FDA issued a Safety Communication to inform doctors and
18 patients that serious complications associated with surgical mesh for the transvaginal repair of
19 POP are not rare, and that a systematic review of published literature showed that transvaginal
20 POP repair with mesh does not improve symptomatic results or quality of life over traditional
21 non-mesh repair and that mesh used in transvaginal POP repair introduces risks not present in
22 traditional non-mesh surgery for POP repair.

23 25. In 2012, the FDA ordered post-market surveillance studies by manufacturers of
24 surgical mesh to address specific safety and effectiveness concerns related to surgical mesh used
25 for the transvaginal repair of POP. In 2016, the FDA issued final orders to reclassify transvaginal
26 POP devices as Class III (high risk) devices and to require manufacturers to submit a PMA
27 application to support the safety and effectiveness of surgical mesh for the transvaginal repair of
28 POP in order to continue marketing the devices.

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

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

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

8 31. The Unfair Competition Law, Business and Professions Code section 17200 et
9 seq., provides that unfair competition shall mean and include, among other acts, any unlawful or
10 unfair business act or practice and any act prohibited by Business and Professions Code section
11 17500.

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

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

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

22 **PRAYER FOR RELIEF**

23 **WHEREFORE**, Plaintiff prays that:

24 1. An injunction be issued pursuant to Business and Professions Code sections 17203
25 and 17535 restraining and enjoining Defendant and their agents, employees, and all other persons
26 or entities, corporate or otherwise, in active concert or participation with any of them, from
27 violating Business and Professions Code sections 17200 et seq. or 17500 et seq.
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1 2. Pursuant to Business and Professions Code sections 17206 and 17536, Defendant be
2 assessed a civil penalty of two thousand five hundred (\$2,500) for each violation of Business and
3 Professions Code sections 17200 et seq. and 17500 et seq., as proved at trial.

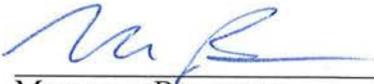
4 3. The Court Order Defendant to pay Plaintiff's costs.

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

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Dated: March 16, 2021

Respectfully Submitted,
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