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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN DIEGO

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, v. **C.R. BARD, INC.**, Defendant.	Case No. **COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF**

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

JURISDICTION AND VENUE

1. The People bring this action, by Xavier Becerra, 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.

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

3. This Court has jurisdiction over defendant C.R. Bard, Inc. (hereinafter referred to as "C.R. Bard" or "Defendant"). C.R. Bard, at all relevant times, transacted business in the County of San Diego and elsewhere in the State of California. C.R. Bard transacts business in California by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices manufactured by C.R. Bard. 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.

4. The violations of law alleged in this Complaint occurred in the County of San Diego and elsewhere throughout California.

5. Venue is proper in this Court pursuant to Code of Civil Procedure section 395.5 because Defendant's marketing and sales activities included the San Diego region and therefore Defendant's liability arises in the County of San Diego.

6. 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 San Diego are a part of the cause upon which the Plaintiff seeks the recovery of penalties imposed by statute.

PARTIES

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

8. Defendant C.R. Bard, Inc. is a New Jersey company and wholly-owned subsidiary of Becton, Dickinson and Company ("Becton"). C.R. Bard and its parent company, Becton, have their principal place of business and executive offices located at 1 Becton Drive, Franklin Lakes, New Jersey 07417.

BACKGROUND

9. "Surgical Mesh," as used in this Complaint, is a medical device that contains synthetic, multi-strand, knitted, or woven mesh that is intended to be implanted in the pelvic floor

to treat stress urinary incontinence ("SUI") and/or pelvic organ prolapse ("POP") and that is sold or marketed in the United States.

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

11. 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.

12. 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.

13. 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.

14. C.R. Bard marketed and sold Surgical Mesh devices to be implanted transvaginally for the treatment of POP for approximately 5 years or more and for the treatment of SUI for approximately ten years or more.

15. The Food and Drug Administration (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. C.R. Bard's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process. C.R. Bard marketed and sold Surgical Mesh devices without adequate testing.

C.R. BARD'S COURSE OF CONDUCT

19. In marketing Surgical Mesh, C.R. Bard misled women and doctors about the serious and life-altering risks of the devices.

20. C.R. Bard 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.

21. C.R. Bard 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.

22. C.R. Bard also made material omissions when it failed to disclose the risks of its Surgical Mesh.

23. C.R. Bard misrepresented and/or failed to adequately disclose serious risks and complications of one or more of its Surgical Mesh products, including the following:

a. a lifelong risk of erosion;

b. chronic pain;

c. vaginal shortening;

d. dyspareunia (pain with intercourse);

e. chronic foreign body reaction;

f. tissue contraction;

g. urge and de novo incontinence;

h. infection and inflammation; and

i. vaginal scarring.

24. C.R. Bard misrepresented or failed to disclose that complications for one or more of its Surgical Mesh devices may persist as a permanent condition after surgical intervention or other treatment. C.R. Bard's Surgical Mesh products are intended to be permanent implants and were designed for integration into the body and tissue ingrowth, making them difficult, if not impossible, to surgically remove. C.R. Bard misrepresented or failed to disclose that removal of one or more of its Surgical Mesh devices may not be possible, and that additional surgeries may not resolve complications.

25. Throughout its marketing of Surgical Mesh, C.R. Bard 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.

26. Thousands of women implanted with surgical mesh have suffered serious complications resulting from these devices.

27. 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 and 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.

28. 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. That same year, C.R. Bard ceased marketing transvaginal POP Surgical Mesh products. 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.

29. C.R. Bard discontinued sales of all transvaginal mesh devices for the treatment of SUI in 2016.

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

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. 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.

32. 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)

33. The People reallege and incorporate by reference each and every allegation contained in the preceding paragraphs 1 through 32 as though fully set forth herein.

34. The Unfair Competition Law, Business and Professions Code section 17200, provides that "unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising, and any act prohibited by" Business and Professions Code section 17500.

35. Defendant, in the course of engaging in the marketing, promoting, selling, and distributing of Surgical Mesh products, has engaged in the following unlawful, unfair, or fraudulent acts and practices, among others, each of which constitutes 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's actions constitute multiple violations of Civil Code section 1770, subdivision (a)(5), by representing that Defendant's products have sponsorship, approval, characteristics, uses, benefits, or qualities that they do not have; and

c. Defendant's actions constitute multiple violations of Civil Code section 1770, subdivision (a)(7), by representing that Defendant's products are of a particular standard, quality, or grade, when they are of another.

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 its 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: September 23, 2020

Respectfully Submitted,

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