STATE OF VERMONT

SUPERIOR COURT
WASHINGTON UNIT

CIVIL DIVISION
Docket No. _____

STATE OF VERMONT,)
)
Plaintiff,)
)
v.)
C.R. BARD, INC.,)
)
Defendant.)

COMPLAINT

The State of Vermont ("Plaintiff" or "State") by and through the Vermont Attorney General, brings this action against Defendant C.R. Bard, Inc. ("Defendant" or "BARD") for violations of the Vermont Consumer Protection Act, 9 V.S.A § 2453 (the "CPA") which prohibits unfair and deceptive acts and practices. Defendant has violated the CPA by engaging in unfair and deceptive acts and practices, including deceiving consumers by misrepresenting the safety and efficacy of its mesh devices and failing to disclose risks and complications associated with their use. The State seeks civil penalties, injunctive relief, disgorgement, fees, costs, and other appropriate relief.

I. PARTIES, JURISDICTION AND VENUE

A. Plaintiff

1. The Vermont Attorney General is authorized under the Vermont Consumer Protection Act, 9 V.S.A § 2458, to sue to enforce the CPA's prohibitions on unfair and deceptive acts and practices in commerce.

2. The Vermont Attorney General also has the right to appear in any civil action in which the State has an interest. 3 V.S.A § 157. The Attorney General has an interest in ensuring that entities that do business in Vermont do so in a lawful manner.

B. Defendant

3. Defendant BARD is a New Jersey company and subsidiary of Becton, Dickinson and Company ("Becton"). 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.

4. At all times relevant hereto, Defendant BARD transacted business in the State of Vermont and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices ("Surgical Mesh"), and that business is governed by the CPA.

C. Jurisdiction and Venue

5. This Court has jurisdiction over the Defendant because it has transacted substantial business in the State of Vermont and the unlawful acts alleged herein have been committed in the State.

6. Defendant was, at all times relevant hereto, engaged in trade or commerce int the State. Defendant knowingly placed its Surgical Mesh devices into the stream of commerce through designing, manufacturing, marketing, packaging, and selling such devices, including in the State of Vermont. Ultimately, its devices were surgically placed into Vermont consumers. Defendant derived profits from

Vermont consumers, including patients, hospitals, clinics, and health care providers from the sale of its Surgical Mesh devices.

7. Venue lies in the Washington Unit of the Superior Court of the State of Vermont pursuant to 12 V.S.A. § 402.

II. BACKGROUND

8. "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, often transvaginally, 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.

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 implanted surgical mesh.

13. 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.

14. The Food and Drug Administration (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 process 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. BARD's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process. However, as is discussed below, BARD marketed and sold Surgical Mesh devices without more rigorous testing or disclosing the safety risks of using its Surgical Mesh.

III. BARD'S COURSE OF CONDUCT

18. In marketing Surgical Mesh devices, 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 and/or surgically implantable materials.

19. BARD misrepresented the safety of its Surgical Mesh by misrepresenting the risks of using its Surgical Mesh, thereby making false and/or misleading representations about its safety and risks.

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

21. 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 of the Surgical Mesh through the vagina;

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.

22. 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. BARD misrepresented or failed to disclose to doctors and patients that complications for one or more of its Surgical Mesh devices may persist as a permanent condition after surgical intervention or other treatment. BARD misrepresented or failed to disclose to patients and healthcare providers that removal of one or more of its Surgical Mesh devices may not be possible, and that additional surgeries may not resolve complications.

23. Throughout its marketing of its Surgical Mesh, 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.

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 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.

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. That same year, 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.

26. BARD discontinued sales of all transvaginal mesh devices for the treatment of SUI in 2016.

IV. CAUSES OF ACTION

COUNT ONE
Violations of the Vermont Consumer Protection Act (Deceptive Acts and Practices)

27. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though set forth herein.

28. The Vermont Consumer Protection Act prohibits unfair and deceptive acts and practices in commerce. 9 V.S.A. § 2453(a).

29. Defendant engaged in deceptive acts or practices in commerce by making material misrepresentations and omissions in its marketing, promoting, and selling its Surgical Mesh devices, including by:

a. representing its Surgical Mesh devices were safe while misrepresenting and omitting risks and complications caused by its Surgical Mesh devices;

b. misrepresenting the risks of Surgical Mesh as compared with the risks of other surgeries or surgically implantable materials; and

c. making material omissions by failing to disclose the risks and complications of its Surgical Mesh.

30. Defendant's misrepresentations and omissions about its Surgical Mesh devices were likely to mislead doctors and consumers and were material in that they were likely to affect consumers' decision to use Defendant's Surgical Mesh.

The meaning ascribed by consumers to Defendant's claims about its Surgical Mesh devices was reasonable given the nature of those claims.

COUNT TWO

Violations of the Vermont Consumer Protection Act (Unfair Business Practices)

31. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though set forth herein.

32. The Vermont Consumer Protection Act prohibits unfair acts or practices in commerce. 9 V.S.A. § 2453(a).

33. Business conduct is considered an unfair business practice if it offends public policy; or is immoral, unethical, oppressive, or unscrupulous; or causes substantial injury to consumers.

34. Defendant engaged in unfair acts or practices in commerce in the course of marketing, promoting, selling, and distributing its Surgical Mesh devices.

35. These acts or practices may be deemed unfair because they: offend the public policy reflected in § 2453 (a) of the CPA, which protects consumers from deceptive marketing and to ensure an honest marketplace; and are immoral, unethical, and unscrupulous.

36. In addition, because of Defendant's conduct, Vermont consumers have suffered substantial injury by reason of the health effects and risks associated with the use of Defendant's Surgical Mesh, as well as the associated financial costs.

V. REQUEST FOR RELIEF

WHEREFORE, the State of Vermont respectfully requests the Court enter judgment in its favor and the following relief:

a. A judgment in its favor and against Defendant on each cause of action asserted in the Complaint;

b. A permanent injunction prohibiting Defendant from engaging in unfair or deceptive acts and practices described in the Complaint;

c. A judgment requiring Defendant to disgorge all funds acquired and/or retained as a result of any acts or practices found to be unlawful;

d. Statutory civil penalties in the amount of $10,000 for each violation of the Vermont Consumer Protection Act;

e. The award of costs and fees to the State of Vermont; and

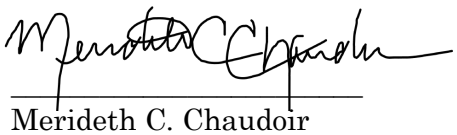
f. Such other and further relief as the Court deems appropriate.

Dated: September 24, 2020.

STATE OF VERMONT

Thomas J. Donovan, Jr.
Attorney General

Respectfully submitted:



Merideth C. Chaudoir
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, Vermont 05609
E-mail: merideth.chaudoir@vermont.gov