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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, *ex rel.* MARK BRNOVICH, Attorney General, Plaintiff, v. C.R. BARD, Inc., Defendant.	Case No. **COMPLAINT**

Plaintiff, State of Arizona *ex rel.* Mark Brnovich, the Attorney General (the "State"), alleges the following for its Civil Complaint (the "Complaint") against Defendant C.R. Bard, Inc. ("C.R. Bard").

Jurisdiction and Venue

1. The State brings this action pursuant to the Arizona Consumer Fraud Act, Arizona Revised Statutes ("A.R.S.") §§ 44-1521 to 44-1534, to obtain injunctive relief to permanently enjoin and prevent the unlawful acts and practices alleged in this Complaint, and to obtain other relief, including restitution, disgorgement of profits, gains, gross receipts, or other benefits, civil penalties, and costs and attorneys' fees.

2. This Court has subject-matter jurisdiction.

3. This Court may issue appropriate orders both prior to and following a determination of liability pursuant to A.R.S. § 44-1528.

4. C.R. Bard caused events to occur in this state out of which the claims which are the subject of this Complaint arose.

5. Venue is proper in Maricopa County pursuant to A.R.S. § 12-401(17).

Parties

6. Plaintiff is the State of Arizona *ex rel.* Mark Brnovich, the Attorney General of Arizona, who is authorized to bring this action under the Arizona Consumer Fraud Act (the "CFA"), A.R.S. §§ 44-1521 to 44-1534.

7. 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.

8. At all times relevant hereto, C.R. Bard transacted business in the State of Arizona and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices, and that business is governed by the CFA.

Background

9. "Surgical Mesh," as used in this Complaint, is a medical device sold or marketed in the United States 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").

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 five 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. Although 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 devices, 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.

20. 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.

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

22. 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.

23. C.R. 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. 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.

24. 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.

25. 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.

26. 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.

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

Claims For Relief

28. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 27 as if they were set out at length herein.

29. The conduct described in the preceding paragraphs of this Complaint constitutes deception, deceptive or unfair acts or practices, fraud, false pretenses, false promises, misrepresentations, or concealment, suppression or omission of material facts with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of merchandise in violation of A.R.S. §§ 44-1521 to 44-1534, including, but not limited to:

a. C.R. Bard engaged in deceptive acts or practices by making false and deceptive statements about the risks, characteristics, uses, benefits and/or qualities of Surgical Mesh products;

b. C.R. Bard concealed, suppressed, or omitted material facts, including the risks and complications associated with Surgical Mesh products, and did so with intent that others rely on such concealments, suppressions, or omission.

Prayer for Relief

WHEREFORE, the State respectfully requests that the Court:

32. Pursuant to A.R.S. § 44-1528(A)(1), issue a permanent injunction, enjoining and restraining (a) C.R. Bard, (b) its officers, agents, servants, employees, attorneys, and (c) all persons in active concert or participation with anyone described in part (a) or (b) of this paragraph, directly or indirectly, from engaging in false, misleading, or deceptive practices in the marketing, promotion, selling and distributing of Surgical Mesh devices;

33. Pursuant to A.R.S. § 44-1531, order Defendant to pay to the State of Arizona a civil penalty of up to $10,000 for each willful violation of A.R.S. § 44-1522;

34. Pursuant to A.R.S. § 44-1534, order Defendant to reimburse the State for its costs and attorneys' fees incurred in the investigation and prosecution of Defendant's activities alleged in this Complaint; and

35. Award the State such further relief as the Court deems just and proper under the circumstances.

DATED this 24th day of September, 2020.

MARK BRNOVICH
Attorney General

By: Kaitlin Hollywood
Kaitlin Hollywood
Assistant Attorney General
Attorney for the State of Arizona