**VIRGINIA:**

**IN THE CIRCUIT COURT FOR THE CITY OF RICHMOND**



**COMMONWEALTH OF VIRGINIA,**
***EX REL.* MARK R. HERRING,**
**ATTORNEY GENERAL,**

**Plaintiff,**

**v.**

**C.R. BARD, INC.,**

**Defendant.**

**CIVIL ACTION NO. _____**

## COMPLAINT

Commonwealth of Virginia, by, through, and at the relation of the Attorney General of Virginia, Mark R. Herring (the "Plaintiff" or the "Commonwealth" ) brings this action against Defendant C.R. Bard, Inc. ("Bard") for violating the Virginia Consumer Protection Act ("VCPA"), Virginia Code §§ 59.1-196 through 59.1-207. In support thereof, Plaintiff states as follows:

## PARTIES

1. The Plaintiff, the Commonwealth of Virginia *ex rel.* Mark R. Herring, Attorney General, is charged with enforcing the VCPA, which prohibits fraudulent or deceptive acts or practices made by a supplier in connection with a consumer transaction. Pursuant to Virginia Code § 59.1-203, the Attorney General may initiate civil law enforcement proceedings in the name of the Commonwealth to enjoin violations of the VCPA and to secure such equitable and other relief as may be appropriate in each case.

2. Defendant Bard is a New Jersey company and wholly-owned 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.

3. At all times relevant hereto, Defendant Bard transacted business in the Commonwealth of Virginia and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices.

## JURISDICTION AND VENUE

4. This Court has jurisdiction over the Defendant and to grant the relief requested herein pursuant to Virginia Code §§ 8.01-620, 17.1-513, 59.1-203, and 59.1-206.

5. Venue is preferred in this Court pursuant to Virginia Code § 8.01-261(15)(c) because some or all of the acts to be enjoined are, or were, being done in the City of Richmond. Venue is permissible in this Court pursuant to § 8.01-262(3) and (4) because the Defendant regularly conducts substantial business activity within the City of Richmond and the cause of action arose, in part, in the City of Richmond.

6. Prior to the commencement of this action, the Plaintiff gave the Defendant written notice, through communications by a multi-state group of Attorneys General, that these proceedings were contemplated and a reasonable opportunity to appear before the Office of the Attorney General to demonstrate that no violations of the VCPA had occurred, or to execute an appropriate Assurance of Voluntary Compliance, pursuant to Virginia Code § 59.1-203(B). The Defendant has not established that no violation of the VCPA occurred and has agreed to execute an acceptable Consent Judgment in lieu of an Assurance of Voluntary Compliance.

## FACTS

7. "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.

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

9. SUI is a leakage of urine during episodes of physical activity that increase abdominal pressure, such as coughing, sneezing, laughing, or exercising.

10. 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.

11. 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.

13. Not all women with POP have symptoms, while some experience pelvic discomfort or pain, pressure, and other symptoms.

14. 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.

15. Non-surgical options for SUI include pelvic floor exercises, pessaries, transurethral bulking agents, and behavior modifications.

16. 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.

17. Non-surgical options for POP include pelvic floor exercises and pessaries.

18. Surgery for POP can be done through the vagina or abdomen using stitches alone or with the addition of Surgical Mesh.

19. 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.

20. The Food and Drug Administration ("FDA") applies different levels of scrutiny to medical devices before approving or clearing them for sale.

21. The most rigorous level of scrutiny is the pre-market approval ("PMA") process, which requires a manufacturer to submit detailed information to the FDA regarding the safety and effectiveness of its device.

22. 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.

23. 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.

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

25. In marketing its 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 or surgically implantable materials.

26. 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.

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

28. 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.

29. 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.

30. 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.

31. 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.

32. Throughout its marketing of 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.

33. 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.

34. 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; 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.

35. 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.

36. That same year, Bard ceased marketing transvaginal POP Surgical Mesh products.

37. 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.

38. Bard discontinued sales of all transvaginal mesh devices for the treatment of SUI in 2016.

**CAUSE OF ACTION: VIRGINIA CONSUMER PROTECTION ACT**

39. Plaintiff re-alleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 38.

40. Defendant Bard was, at all times relative hereto, a "supplier" engaged in "consumer transactions" in the Commonwealth, as those terms are defined in § 59.1-198 of the VCPA.

41. Virginia Code § 59.1-200(A)(5) prohibits a supplier from misrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits in connection with a consumer transaction.

42. Bard, in the course of marketing, promoting, selling, and distributing Surgical Mesh products in the Commonwealth, violated Virginia Code § 59.1-200(A)(5) by misrepresenting that its Surgical Mesh products had characteristics, uses, or benefits that they did not have.

43. Virginia Code § 59.1-200(A)(14) prohibits a supplier from using any deception,

fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

44. Bard, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, violated Virginia Code § 59.1-200(A)(14) by using deception, fraud, false pretense, false promise, or misrepresentations, including but not limited to misrepresenting and failing to disclose the full range of risks and complications associated with Surgical Mesh, as well as their frequency and severity.

45. Bard willfully engaged in the acts and practices described in this Complaint in violation of the VCPA.

46. Individual consumers were harmed as a result of Bard's violations of the VCPA.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Commonwealth of Virginia, respectfully requests this Court:

A. Permanently enjoin and restrain the Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive or misleading conduct, acts, or practices which violate the VCPA in the marketing, promotion, selling, and distributing of its Surgical Mesh products, pursuant to Virginia Code § 59.1-203;

B. Order the Defendant to pay civil penalties of up to $2,500 for each and every willful violation of the VCPA, pursuant to Virginia Code § 59.1-206(A);

C. Order the Defendant to pay the Commonwealth's attorney's fees, costs, and expenses for the prosecution and investigation of this action, pursuant to Virginia Code § 59.1-206(C); and

D. Grant Plaintiff such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

**COMMONWEALTH OF VIRGINIA,**
***EX REL.* MARK R. HERRING,**
**ATTORNEY GENERAL**

By: _____
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## CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of September, 2020, a true copy of the Commonwealth's **Complaint**, as well as the proposed **Consent Judgment**, were sent by electronic mail, with a copy by U.S First Class Mail to:

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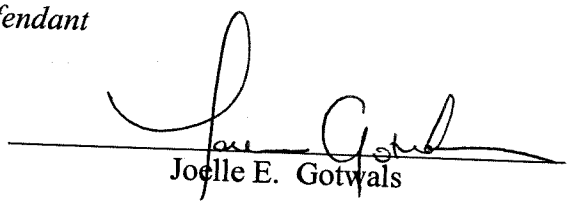

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