IOWA DISTRICT COURT FOR POLK COUNTY

STATE OF IOWA ex rel. Thomas J. Miller, Attorney General	:	Case No. EQCE 086215
Plaintiff,	:	PETITION
vs.	:	
C.R. BARD, INC.	:	
Defendant.	:	

COMES NOW Plaintiff, the State of Iowa ex rel. Thomas J. Miller, Attorney General, and brings this action against Defendant C.R. Bard, Inc. for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, and states as follows:

Parties

1. Plaintiff, the State of Iowa ex rel. Thomas J. Miller, Attorney General, is charged with, among other things, enforcing and seeking redress for violations of Iowa consumer protection laws, including the Iowa Consumer Fraud Act, Iowa Code section 714.16 (CFA).
2. Defendant C.R. Bard, Inc. (C.R. Bard) 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.
3. At all times relevant hereto, Defendant C.R. Bard transacted business in the State of Iowa and nationwide by marketing, promoting, advertising, offering for sale, selling, and

distributing transvaginal surgical mesh devices, and that business is governed by the Iowa Consumer Fraud Act, Iowa Code section 714.16

Jurisdiction and Venue

4. This Court has jurisdiction over the Defendant pursuant to Iowa Code section 714.16 because Defendant C.R. Bard has transacted business within Iowa at all times relevant to the Petition.
5. Venue is proper in Polk County, Iowa pursuant to Iowa Code section 714.16(10) because Defendant C.R. Bard has carried on a regular business in Polk County, Iowa.

Background

6. "Surgical Mesh," as used in this Petition, 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.
7. SUI and POP are common conditions that pose lifestyle limitations and are not life-threatening.
8. 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.
9. 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.

10. 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.
11. 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.
12. The Food and Drug Administration (FDA) applies different levels of scrutiny to medical devices before approving or clearing them for sale.
13. 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.
14. 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.

15. 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

16. 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.
17. 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.
18. C.R. Bard also made material omissions when it failed to disclose the risks of its Surgical Mesh.
19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

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

Violation of the Iowa Consumer Fraud Act

25. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 24 as if they were set out at length herein.

26. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, C.R. Bard made false statements about, misrepresented, and/or made other representations about the risks of Surgical Mesh products that had the effect, capacity, or tendency, of deceiving or misleading consumers. Pursuant to Iowa Code section 714.16(2)(a), such false statements and misrepresentations constitute unlawful practices prohibited by the Iowa Consumer Fraud Act.

27. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, C.R. Bard has made representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have. Pursuant to Iowa Code section

714.16(2)(a) such false statements and misrepresentations constitute unlawful practices prohibited by the Iowa Consumer Fraud Act.

28. Defendant C.R. Bard made material omissions concerning the risks and complications associated with Surgical Mesh products and those material omissions had the effect, capacity, or tendency of deceiving consumers. Pursuant to Iowa Code section 714.16(2)(a), such material omissions constitute unlawful practices prohibited by the Iowa Consumer Fraud Act.

29. These acts or practices affected the public interest because they impacted numerous Iowa consumers.

Request for Relief

30. WHEREFORE, Plaintiff respectfully requests that this Court enter an Order:

    a. Adjudging and decreeing that Defendant has engaged in the acts or practices complained of herein, and that such constitute unlawful practices in violation of the Iowa Consumer Fraud Act, Iowa Code section 714.16(2)(a);

    b. Issuing a permanent injunction pursuant to Iowa Code section 714.16(7), prohibiting Defendant, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive trade practices in the marketing, promotion, selling and distributing of Defendant's Surgical Mesh devices;

    c. Ordering Defendant to pay civil penalties in the amount of up to $40,000.00 for each and every violation of the Iowa Consumer Fraud Act pursuant to Iowa Code section 714.16(7);

    d. Ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action pursuant to Iowa Code section

714.16(11);

e. Ordering Defendant to provide monetary restitution to consumers impacted by the acts and practices detailed above; and

f. Ordering such other and further relief as the Court may deem just and proper.

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

By:

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