IN THE COURT OF COMMON PLEAS
FRANKLIN COUNTY, OHIO

STATE OF OHIO, *ex rel.* DAVE YOST, ATTORNEY GENERAL 30 East Broad Street State Office Tower – 14th Floor Columbus, Ohio 43215 Plaintiff, v. C.R. BARD, INC. 1 Becton Drive Franklin Lakes, New Jersey 07417 Defendant.	)	CASE NO.: JUDGE: **COMPLAINT FOR DECLARATORY JUDGMENT, INJUNCTIVE RELIEF, CIVIL PENALTIES AND COSTS**

COMPLAINT

1. Plaintiff, State of Ohio, by and through the Attorney General of Ohio, Dave Yost and his Consumer Protection Section, brings this action to enjoin Defendant C.R. Bard, Inc. from engaging in unfair or deceptive acts or practices in the course of offering and selling consumer goods and services, and to obtain relief for consumers as a result of Defendant's unfair or deceptive acts or practices.

PARTIES

2. Plaintiff is the State of Ohio, by and through the Attorney General of Ohio, Dave Yost and his Consumer Protection Section, who brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him pursuant to R.C. 1345.07 of the Consumer Sales Practices Act.

3. 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.

4. Defendant C.R. Bard transacts business in Ohio and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, selling and distributing transvaginal surgical mesh devices.

JURISDICTION AND VENUE

6. Plaintiff, State of Ohio, by and through the Attorney General of Ohio, Dave Yost and his Consumer Protection Section, having reasonable cause to believe that violations of Ohio's consumer laws have occurred, brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him pursuant to R.C. 1345.07 of the Consumer Sales Practices Act.

7. The actions of Defendant, hereinafter described, have occurred in the State of Ohio, County of Franklin and various other counties, and as set forth below, are in violation of the Consumer Sales Practices Act, R.C. 1345.01 et seq.

8. C.R. Bard is a "supplier" as that term is defined in R.C. 1345.01(C) as C.R. Bard was, at all times relevant herein, engaged in the business of effecting "consumer transactions" by manufacturing, marketing, promoting, advertising, offering for sale, and selling, medical devices, including transvaginal surgical mesh devices, in the State of Ohio for purposes that were primarily for personal, family or household use within the meaning specified in R.C. 1345.01(A) and (D).

9. Jurisdiction over the subject matter of this action lies with this Court pursuant to R.C. 1345.04 of the Consumer Sales Practices Act.

10. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(C), in that some

of the transactions complained of herein and out of which this action arose, occurred in Franklin County.

ALLEGATIONS

Background

11. "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.

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

13. 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.

14. 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.

15. 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.

16. 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.

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

18. 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.

19. 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.

20. 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

21. 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.

22. 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.

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

24. 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.

25. 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.

26. 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.

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.

CAUSE OF ACTION

UNFAIR OR DECEPTIVE CONSUMER SALES PRACTICES

COUNT ONE

30. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 29.

31. C.R. Bard, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under the Consumer Sales Practices Act R.C. 1345.01 et seq., including but not limited to representing that its Surgical Mesh had sponsorship, approval, performance characteristics, accessories, uses, or benefits that it did not have. C. R. Bard violated R.C. 1345.02(B)(1) when it misrepresented the sponsorship, approval, performance characteristics, benefits or qualities of their Surgical Mesh devices.

COUNT TWO

32. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 29.

33. C.R. Bard, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under the Consumer Sales

Practices Act R.C. 1345.01 et seq., including but not limited to representing that its Surgical Mesh had a particular standard, quality, or grade that it did not have. C. R. Bard violated R.C. 1345.02(B)(2) when it misrepresented the particular standard, quality, or grade of their Surgical Mesh devices.

COUNT THREE

34. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 29.

35. C.R. Bard, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices and is therefore unlawful under the Consumer Sales Practices Act R.C. 1345.01 et seq., 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. C. R. Bard violated R.C. 1345.02(A) when it misrepresented and failed to disclose the full range of risks and complications associated with its Surgical Mesh devices.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

1. Adjudge and decree that the Defendant has engaged in acts or practices in violation of the Consumer Sales Practices Act., R. C. 1345.01 *et seq.,* as previously set forth.
2. Permanently enjoin and restrain the Defendant from engaging in unfair or deceptive consumer sales practices set forth herein and from violating the Consumer Sales Practices Act.
3. Adjudge and decree that the Defendant is liable to the State for the reasonable costs and expenses of the investigation and prosecution of the Defendant's actions.
5. Assess, fine and impose upon the Defendant a civil penalty pursuant to R. C. 1345.07(D) of Twenty-Five Thousand Dollars ($25,000.00) for each unfair or deceptive act or practice alleged herein.
6. Order that all costs in this cause be taxed against the Defendant.
7. Grant Plaintiff such other and further relief as this Court deems just, equitable and appropriate.

Respectfully Submitted,

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