COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss

SUPERIOR COURT
CIVIL ACTION NO.

COMMONWEALTH OF MASSACHUSETTS)
)
Plaintiff,)
)
v.)
)
C.R. BARD, INC.)
)
Defendant.)

COMPLAINT

The Commonwealth of Massachusetts brings this action against Defendant C.R. Bard, Inc. for violations of G.L. c. 93A. The Commonwealth seeks a permanent injunction and other relief, and states as follows:

The Parties

1. Plaintiff, the Commonwealth of Massachusetts ("Commonwealth"), is charged with, among other things, enforcing and seeking redress for violations of Massachusetts consumer protection laws, including G.L. c. 93A.

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 Commonwealth and nationwide by marketing, promoting, advertising, offering for sale, selling, and

distributing transvaginal surgical mesh devices, and that business is governed by G.L. c. 93A, §4, G.L. c. 12, §10, and G.L. c. 223A, §3.

Jurisdiction and Venue

4. This Court has jurisdiction over the Defendant pursuant to G.L. c. 93A, §4, G.L. c. 12, §10, and G.L. c. 223A, §3 because Defendant C.R. Bard has transacted business in the Commonwealth at all times relevant to the Complaint.

5. Venue is proper in Suffolk County pursuant to G.L. c. 223 §5 and G.L. c. 93A, §4 because the parties have consented to venue here.

Background

6. "Surgical Mesh," as used in this Complaint, refers to 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 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.

8. 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.

9. 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.

10. 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.

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

12. 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.

13. The 510(k) review is a much less rigorous process than the PMA review process. Under the 510(k) 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.

14. 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

15. In marketing Surgical Mesh devices, C.R. Bard misrepresented the full range of risks and complications associated with the devices, including misrepresenting the risks of Surgical Mesh as compared with other surgeries or surgically implantable materials. C.R. Bard also made material omissions when it failed to disclose the risks of its Surgical Mesh.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

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

CAUSE OF ACTION
Violation of the G.L. c. 93A

22. Plaintiff restates the allegation in paragraphs 1-21.

23. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, C.R. Bard, Inc. 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 M.G.L. c. 93A, such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by G.L. c. 93A.

24. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, C.R. Bard, Inc. has made representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have. Pursuant to M.G.L. c. 93A, such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by M.G.L. c. 93A.

25. Defendant C.R. Bard, Inc. 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 M.G.L. c. 93A, such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by M.G.L. c. 93A.

26. The acts or practices described herein occurred in trade or commerce as defined in G.L. c. 93A, §1(b).

27. These acts or practices affected the public interest because they impacted numerous Commonwealth consumers.

Request for Relief

WHEREFORE, Plaintiff respectfully requests that the Court grant the following relief:

a. Adjudge and decree that Defendant has engaged in the acts or practices complained of herein, and that such constitute unfair and/or deceptive acts or practices in violation of G.L. c. 93A;

b. Issue a permanent injunction 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. Order Defendant to pay civil penalties pursuant to G.L. c. 93A;

d. Order Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action;

e. Grant such other and further relief as the Court may deem just and proper.

Dated: September 24, 2020

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS

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COMMONWEALTH OF MASSACHUSETTS

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v.

C. R. BARD, INC.

Defendant.

FINAL JUDGMENT BY CONSENT

Plaintiff, the Commonwealth of Massachusetts, has filed a Complaint for a permanent injunction and other relief in this matter pursuant to M.G.L. c. 93A alleging that Defendant C. R. Bard, Inc. ("BARD" or "Defendant"), committed violations of the aforementioned statute. Plaintiff, by its counsel, and BARD, by its counsel, have agreed to the entry of this Final Judgment ("Judgment") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind.

IT IS HEREBY ORDERED THAT:

1. FINDINGS

1.1. This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

1.2. The terms of this Judgment shall be governed by the laws of the Commonwealth of Massachusetts.

1.3. Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

1.4. The Parties have agreed to resolve the issues resulting from the Covered Conduct by entering into this Judgment.[1]

1.5. BARD is willing to enter into this Judgment regarding the Covered Conduct in order to resolve the Attorneys General's concerns under the State Consumer Protection Laws as to the matters addressed in this Judgment and thereby avoid significant expense, inconvenience, and uncertainty.

1.6. BARD is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which BARD expressly denies. BARD does not admit any violation of the State Consumer Protection Laws set forth in footnote 4, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by BARD.

1.7. This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to BARD in any other action, or of BARD's right to defend itself from, or make any arguments in, any other private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

[1]This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 4.

1.8. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment. It is the intent of the Parties that this Judgment shall not be binding or admissible in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Judgment.

1.9. This Judgment (or any portion thereof) shall in no way be construed to prohibit BARD from making representations with respect to any BARD products in Labeling that are required under Federal law, regulations, or policies or guidance having the force of law, including in Food and Drug Administration ("FDA") approved Labeling.

1.10. Nothing in this Judgment shall require BARD to:

(a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") or any regulation promulgated thereunder, or by the FDA; or

(b) fail to take any specific action that is expressly permitted or is required by the FDCA or any regulation promulgated thereunder.

2. DEFINITIONS

The following definitions shall be used in construing the Judgment:

2.1. "Covered Conduct" means BARD's marketing and promotional practices, and dissemination of information to Health Care Providers (HCPs) and consumers, regarding Urogynecologic Surgical Mesh products, including but not limited to the dissemination of Marketing Materials, disclosure of Significant or Inherent Complications in Instructions for Use (IFUs), Sponsorship of any programs, training any sales professionals, the publication of any clinical or pre-clinical data, or the reporting of MDRs or adverse events, through the Effective Date of the Judgment.

2.2. "Effective Date" means the date on which a copy of the Judgment, duly executed by BARD and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

2.3. "Health Care Provider" or "HCP" means any physician or other health care practitioner who is licensed to provide health care services.

2.4. "BARD" means C. R. Bard, Inc. and Becton, Dickinson and Company and all of their officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies, assigns and successors.

2.5. "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article," as defined under Section 201(m) of the Federal Food, Drug, and Cosmetic Act (FDCA).

2.6. "Marketing Materials" means any written, electronic, or verbal material or statements either publicly disseminated (including videos, websites it hosts or controls, or any other form of media) or made for the purpose of public dissemination in the United States, in the course of marketing, promoting, or informing Health Care Providers, consumers, or patients about Urogynecologic Surgical Mesh, including, but not limited to, HCP training materials and training materials for sales representatives made for the purpose of public dissemination and delivery to HCPs.

2.7. "Multistate Executive Committee" means the Attorneys General and their staffs representing California, Florida, Indiana, Maryland, Ohio, South Carolina, Texas, and Washington.

2.8. "Multistate Working Group" means the Attorneys General and their staffs representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware,

District of Columbia, Florida, Georgia, Hawaii[2], Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah[3], Vermont, Virginia, Washington, and Wisconsin.

2.9. "Parties" means BARD as defined in Section 2.4 and the Signatory Attorney General.

2.10. "Post-effective Date Urogynecologic Surgical Mesh" means Urogynecologic Surgical Mesh that enters the market in the United States after the Effective Date, and that is not identical or substantially equivalent to Urogynecologic Surgical Mesh that was on the market in the United States prior to the Effective Date.

2.11. "Significant Complications" means all complications of Urogynecologic Surgical Mesh, including complications discovered subsequent to the Effective Date, which constitute clinically significant risks material to a Health Care Provider's decision to implant Urogynecologic Surgical Mesh.

2.12. "Inherent Mesh Complications" means Significant Complications that may not be eliminated with surgical technique and are associated with the use of Urogynecologic Surgical Mesh. Disclosure of such risks shall include an adequate description of the chronicity, acuteness,

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[2]Hawaii is represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

[3]With regard to Utah, the Utah Division of Consumer Protection is charged with administering and enforcing the Consumer Sales Practices Act, the statute relevant to this Judgment. References to the "States," "Parties," or "Attorneys General," with respect to Utah, refers to the Utah Division of Consumer Protection.

and permanence of the risks. A non-verbatim description of these risks shall include, but are not limited to, risks of:

- Exposure of mesh material into the vagina, which can be associated with pain during intercourse for the woman and/or her partner
- Pain caused by exposure may be severe and may result in permanent sexual dysfunction
- Erosion
- Implantation of Urogynecologic Surgical Mesh through the vagina may cause bacterial contamination
- Infection
- Voiding dysfunction, including de novo urge incontinence
- Foreign body reaction
- Inflammation
- Scar plating around mesh
- Clinical consequences of mesh contracture
- Acute and/or chronic pain
- Pelvic pain, which in some patients may not resolve
- Pain with intercourse, which in some patients may not resolve
- Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur

Such description shall also note that the occurrence of one or more of these complications may require treatment or surgical intervention:

i. In some instances, the complication may persist as a permanent condition after the surgical intervention or other treatment;

ii. Removal of mesh or correction of mesh-related complications may involve multiple surgeries; and

iii. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications

However, for Post-Effective Date Urogynecologic Surgical Mesh, a non-verbatim description of these risks may include, but are not limited to, the risks listed in the bullet points above, depending upon the available Valid Scientific Evidence.

2.13. "Signatory Attorney General" means the Attorney General of the Commonwealth of Massachusetts, or her authorized designee, who has agreed to this Judgment.

2.14. "Sponsor" or "Sponsorship" means to pay for in whole or in part, to provide financial support or subsidization, or to provide goods or materials of value in support, but does not include de minimis support.

2.15. "State Consumer Protection Laws" means the consumer protection laws cited in footnote 4 under which the Attorneys General have conducted the investigation.[4]

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[4]ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ALASKA – Alaska Unfair Trade Practices and Consumer Protection Act AS 45.50.471 – 45.50.561; ARIZONA - Consumer Fraud Act, A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen Stat. §§ 42-110a through 42-110q; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices Act, O.C.G.A. Sections 10-1-390 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601 et seq.; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; INDIANA – Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minn. Stat. §§325D.44, 325F.69; MISSISSIPPI - Mississippi Consumer Protection Act, Miss. Code Ann.§ 75-24-1, et seq.; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 et seq.; MONTANA – Montana Consumer Protection Act §§ 30-14-101 et seq.; NEBRASKA – Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. §§ 87-301 et seq.; NEVADA – Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE – NH RSA §358-A et seq; NEW JERSEY – New Jersey Consumer Fraud Act, NJSA 56:8-1 et seq.; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C. 1345.01, et seq.; OKLAHOMA – Oklahoma Consumer Protection Act 15 O.S. §§ 751 et seq.; OREGON – Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 et seq.; RHODE ISLAND – Deceptive Trade Practices Act, Rhode Island Gen. Laws § 6-13.1-1, et seq.; SOUTH CAROLINA – South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10 et seq.; SOUTH DAKOTA – South Dakota Deceptive Trade Practices and Consumer Protection, SDCL ch. 37-24; TENNESSEE – Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. And Com. Code 17.41, et seq.; UTAH - Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 et seq.; VERMONT – Vermont Consumer Protection Act, 9 V.S.A. § 2451, et seq.; VIRGINIA-Virginia Consumer Protection Act, Va Code Ann. §59.1-196 et seq.; WASHINGTON – Unfair Business Practices/Consumer Protection Act, RCW §§ 19.86 et seq.; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

2.16. "Urogynecologic Surgical Mesh" means any medical device cleared or approved by the FDA (as the term "device" is defined in 21 U.S.C. § 321(h)) that contains synthetic, multi-strand, knitted, or woven mesh and that is indicated to be used for implantation in the pelvic floor to treat stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP) sold or marketed in the United States.

2.17. "Valid Scientific Evidence" means evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, or reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance to substantiate that a representation is true.

2.18. Any reference to a written document shall mean a physical paper copy of the document, electronic version of the document, or electronic access to such document.

3. COMPLIANCE PROVISIONS

A. Exit from Urogynecologic Surgical Mesh Business

3.1. BARD states that it ceased the marketing, promotion, sale, and distribution of Urogynecologic Surgical Mesh in the United States and the manufacturing of Urogynecologic Surgical Mesh for sale in the United States by December 30, 2016.

3.2. In the event that BARD engages in any conduct involving the manufacture, promotion, marketing, sale, or distribution of Urogynecologic Surgical Mesh, either directly or indirectly through any third parties, in the United States, it shall be bound by the following provisions contained in Sections 3.4 through 3.27 of this Judgment for ten (10) years from the date of first sale of an Urogynecologic Surgical Mesh product in the United States or for twenty (20) years from the Effective Date of this Agreement, whichever is less. Section 3.3 is not time restricted. Nothing in this Judgment shall be construed to require BARD, for any Urogynecologic

Surgical Mesh product approved through the FDA Premarket Approval process, to utilize product labeling different from that which is approved by the FDA.

B. Marketing, Information, and Training

3.3. In promoting Urogynecologic Surgical Mesh, BARD shall not violate M.G.L. c. 93A.

3.4. BARD shall not, in any Marketing Materials, make any claim comparing safety or efficacy clinical outcomes with the use of Urogynecologic Surgical Mesh to any non-mesh procedure safety or efficacy clinical outcomes, unless any such representation is supported by Valid Scientific Evidence. BARD, however, may make comparisons in any Marketing Materials not involving safety or efficacy clinical outcomes, if not false, misleading, or deceptive.

3.5. BARD shall not, in any Marketing Materials, misrepresent the safety or efficacy of its Urogynecologic Surgical Mesh by omitting Significant Complications or Inherent Mesh Complications, as appropriate given the length, context, medium, and placement of the Marketing Material and in all instances where the Marketing Material purports to address the subject of complications.

3.6. In any Marketing Material that is intended to reach patients or consumers other than or in addition to Health Care Providers, BARD shall also include descriptions of Significant Complications and Inherent Mesh Complications in terms reasonably understandable to a patient.

3.7. BARD shall not, in any Marketing Materials, misrepresent the extent to which Inherent Mesh Complications are risks or complications common to all pelvic floor or other surgeries.

3.8. BARD shall not, in any Marketing Materials, represent or imply that Significant Complications or Inherent Mesh Complications can be eliminated with surgical experience or technique alone. However, for Post-Effective Date Urogynecologic Surgical Mesh, BARD may,

in any Marketing Materials, represent or imply that Significant Complications can be eliminated with surgical experience or technique alone, if such statement is supported by Valid Scientific Evidence.

3.9. BARD shall not represent or imply that such Urogynecologic Surgical Mesh does not cause a foreign body reaction, including any chronic foreign body reaction, after the Urogynecologic Surgical Mesh is implanted inside the body. However, for Post-Effective Date Urogynecologic Surgical Mesh, BARD may represent or imply that such Urogynecologic Surgical Mesh does not cause a foreign body reaction, including any chronic foreign body reaction, after the Urogynecologic Surgical Mesh is implanted inside the body, if such statement is supported by Valid Scientific Evidence.

3.10. BARD shall not, in any Marketing Materials, represent or imply that such Urogynecologic Surgical Mesh is "soft" or that it has "multidirectional elasticity" within the body after implantation or use any other phrases having an equivalent meaning. However, for Post-Effective Date Urogynecologic Surgical Mesh, BARD may, in any Marketing Materials, represent or imply that such Urogynecologic Surgical Mesh is "soft" or that it has "multidirectional elasticity" within the body after implantation or use any other phrases having an equivalent meaning, if such statement is supported by Valid Scientific Evidence. Nothing shall prevent BARD from making claims to Health Care Providers about the softness and elasticity of Urogynecologic Surgical Mesh prior to implantation inside the body provided the claims do not suggest these properties are retained in the body.

3.11. BARD shall not, in any Marketing Materials, represent or imply that such Urogynecologic Surgical Mesh, including its collagen Urogynecologic Surgical Mesh, helps the body more readily accept a foreign body implant, or reduces the risk of foreign body reaction,

erosion, infection, or any other Urogynecologic Surgical Mesh complications, including any Significant Complications or Inherent Complications. However, for Post-Effective Date Urogynecologic Surgical Mesh, BARD may, in any Marketing Materials, represent or imply that such Urogynecologic Surgical Mesh, including its collagen Urogynecologic Surgical Mesh, helps the body more readily accept a foreign body implant, or reduces the risk of foreign body reaction, erosion, infection, or any other Urogynecologic Surgical Mesh complications, including any Significant Complications or Inherent Complications, if such statement is supported by Valid Scientific Evidence.

3.12. BARD shall not, in any Marketing Materials, misrepresent the FDA approval or clearance status of its Urogynecologic Surgical Mesh devices or the extent to which any of its Urogynecologic Surgical Mesh products have been studied or clinically proven.

3.13. BARD shall not, in any Marketing Materials, misrepresent the complexity of Urogynecologic Surgical Mesh implantation procedures or the level of surgical skill and/or experience necessary to perform these procedures safely. Moreover, BARD employees shall not encourage a Health Care Provider to perform Urogynecologic Surgical Mesh implants without receiving adequate information and training on how to implant its Urogynecologic Surgical Mesh.

3.14. In any training in which BARD provides risk information, either directly or through third parties, to any Health Care Provider, BARD shall disclose all Significant Complications and Inherent Mesh Complications of its Urogynecologic Surgical Mesh.

3.15. BARD shall, in the marketing and promotion of any Urogynecologic Surgical Mesh product, ensure that its Marketing Materials and other communications do not misrepresent FDA updates or communications regarding Urogynecologic Surgical Mesh.

C. Disclosures to Health Care Providers

3.16. To the extent not prohibited by federal law, BARD shall ensure that all IFUs for its Urogynecologic Surgical Mesh products cleared through the 510(k) process include a list of all known Significant Complications and Inherent Mesh Complications.

3.17. BARD shall evaluate emerging risk information on an ongoing basis and, consistent with such risk information, shall update the warnings and precautions section of IFUs and all Marketing Material to include Significant Complications associated with its Urogynecologic Surgical Mesh products as soon as practicable. If Bard obtains, receives, or is aware of any new risk information that necessitates a more immediate disclosure for public health and safety purposes, Bard shall notify HCPs of this information through other means, such as notices or "dear doctor letters," as appropriate given the nature of the new information and unless otherwise directed by the FDA.

D. Studies, Clinical Data, and Sponsorship

3.18. BARD shall, when citing to any clinical study, clinical data, or preclinical data, present a fair and balanced view of available scientific literature with respect to the safety, efficacy, risks and complications of Urogynecologic Surgical Mesh.

3.19. BARD shall, when citing to any clinical study, clinical data, or preclinical data regarding Urogynecologic Surgical Mesh in its Marketing Materials, not misrepresent the results, scope, or clinical significance of any particular clinical study, clinical data, or preclinical data, including by implying a more favorable result than supported by the study or data.

3.20. BARD shall, when submitting a clinical study, clinical data, or preclinical data regarding Urogynecologic Surgical Mesh for publication, disclose BARD's role as a Sponsor and any author's potential conflict of interest consistent with the disclosure requirements for the

International Committee of Medical Journal Editors (ICMJE) or, if different, the disclosure policies of the relevant publication.

3.21. BARD shall not cite to any clinical study, clinical data, or preclinical data regarding Urogynecologic Surgical Mesh for which BARD has not complied with the requirements of Section IIID.

3.22. BARD shall not cite to any clinical study, clinical data, or preclinical data regarding Urogynecologic Surgical Mesh for which any author/consultant, to the extent BARD knows, has not complied with the applicable publication's conflict disclosure requirements unless BARD discloses the conflict in a clear and conspicuous manner when citing to such study or data.

3.23. In all contracts for consulting services regarding Urogynecologic Surgical Mesh between BARD and any Health Care Provider or other author/consultant, BARD shall include a Sponsorship disclosure provision under which the Health Care Provider or other author/consultant agrees that he or she shall, in terms likely to be read and understood by the audience, disclose in any public presentation or submission for publication BARD's sponsorship of the contracted-for activities. BARD shall also include a disclosure clause under which the Health Care Provider or other author/consultant acknowledges that BARD may publicly report the fact that BARD made value transfers to him or her. To the extent within its control, BARD shall ensure that any HCP or author/consultant who submits for publication a clinical study, clinical data, or pre-clinical data that BARD has Sponsored, authored, or edited, in whole or in part, shall comply with the publication's conflict disclosure requirements.

3.24. In accordance with applicable law, BARD shall register BARD-sponsored clinical studies regarding its Urogynecologic Surgical Mesh with ClinicalTrials.gov. BARD shall also retain any design history files and clinical records, including but not limited to clinical data,

relating to its post-December 30, 2016 Urogynecologic Surgical Mesh devices and any Urogynecologic Surgical Mesh devices that existed prior to December 30, 2016 (or substantially equivalent to such devices) over which it has or should have possession, custody or control for 15 years past the last sale date of the Urogynecologic Surgical Mesh devices to which those files and records apply, unless a longer period is required by applicable law. BARD shall retain any non-clinical data relating to its post-December 30, 2016 Urogynecologic Surgical Mesh devices and any Urogynecologic Surgical Mesh devices that existed prior to December 30, 2016 (or substantially equivalent to such devices) over which it has or should have possession, custody or control until December 30, 2031, if not introduced prior to that date. If introduced prior to December 30, 2031, then BARD shall retain non-clinical data for 15 years past the last sale date, unless a longer period is required by applicable law.

E. BARD Internal Policies and Training

3.25. BARD shall ensure that its independent contractors, agents, and employees, who sell, market, or promote Urogynecologic Surgical Mesh or otherwise train, provide information to, or communicate with Health Care Providers regarding Urogynecologic Surgical Mesh, are adequately informed and trained regarding their obligations to report all patient complaints and/or adverse events to BARD.

3.26. BARD shall ensure that its company practices regarding the reporting of patient complaints relating to Urogynecologic Surgical Mesh as MDR reportable adverse events are consistent with FDA requirements.

F. Monitoring and Compliance

3.27. BARD shall be responsible for ensuring monitoring and compliance with the provisions of this Judgment.

4. PAYMENT

4.1. BARD shall pay a total amount of $60 million as follows: 1) the initial payment of $15 million shall be paid by the later of October 30, 2020 or 30 days after the Effective Date; 2) the second payment of $15 million shall be paid by April 1, 2021; and 3) the final payment of $30 million shall be paid by October 30, 2021. These payments will be divided and paid by BARD to each Signatory Attorney General of the Multistate Working Group in amounts to be designated by and in the sole discretion of the Multistate Executive Committee. The payment to the Commonwealth under this paragraph shall be $1,119,493[5] comprised of (i) $1,000,000 to be deposited into the General Fund, including for the costs of the investigation and attorney's fees, and (ii) $119,493 for the purpose of assisting the Office of the Attorney General to discharge its duties, in accordance with G.L. c. 12, § 4A, and to be used in the sole discretion of the Attorney General to (1) promote initiatives designed to improve care and treatment related to prescription medications or lower costs for or otherwise assist Massachusetts health care consumers, or (2) support efforts to enforce compliance with state and federal laws and regulations that protect such individuals, including, but not limited to, through grants or other distributions to one or more political subdivisions of the Commonwealth, non-profit organizations, or to the Local Consumer Aid Fund, as established by G.L. c. 12, § 11G.

5. ENFORCEMENT

5.1. For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that BARD has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date, then such Attorney General shall notify BARD in writing of the specific objection,

[5] The total payment, over three installments, to the Commonwealth of Massachusetts shall be $1,119,493.

identify with particularity the provision of this Judgment that the practice appears to violate, and give BARD thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

5.2. Upon receipt of written notice, BARD shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why BARD believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how BARD intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the Commonwealth of Massachusetts' Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and BARD reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

5.3. The Attorney General may agree, in writing, to provide BARD with additional time beyond the thirty (30) days to respond to a notice provided under section 5.1 above.

5.4. Upon giving BARD thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of BARD that relate to BARD's compliance with each provision of this Judgment pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General shall provide a list of those documents to BARD.

5.5. The State may assert any claim that BARD has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by

law for violations of the Judgment, but only after providing BARD an opportunity to respond to the notification described in paragraph 5.1 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

6. RELEASE

6.1. Released Claims. By its execution of this Judgment, the Commonwealth of Massachusetts releases and forever discharges BARD and its past and present officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies, predecessors, assigns and successors (collectively, the "Releasees") from the following: all civil causes of action, claims, damages, restitution, disgorgement, fines, costs, attorney's fees, or penalties that the Commonwealth of Massachusetts Attorney General has asserted or could have asserted against the Releasees under the State Consumer Protection Laws, or any amendments thereto, or by common law claims concerning deceptive or fraudulent trade practices, that the Signatory Attorney General has the authority to release resulting from the Covered Conduct up to and including the Effective Date. For purposes of this Section 6.1, Releasees do not include Covidien Ltd. or Medtronic PLC, or their past and present officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies, predecessors, assigns and successors.

6.2. Claims Not Covered. Notwithstanding any term of this Judgment, specifically reserved and excluded from the release in Paragraph 6.1 as to any entity or person, including Releasees, are any and all of the following:

(a) Any criminal liability that any person or entity, including Releasees, has or may have to the Commonwealth of Massachusetts;

(b) Any civil or administrative liability that any person and/or entity, including Releasees, has or may have to the Commonwealth of Massachusetts not expressly covered by the release in Section 6.1, including, but not limited to, any and all of the following claims:

i. State or federal antitrust violations;

ii. Claims involving "best price," "average wholesale price," "wholesale acquisition cost," or any reporting practices;

iii. Medicaid claims, including but not limited to federal Medicaid drug rebate statute violations, Medicaid fraud or abuse (whether common law, statutory or otherwise), and/or kickback violations related to any state's Medicaid program;

iv. State false claims violations; and

v. Claims to enforce the terms and conditions of this Judgment.

(c) Actions of, or on behalf of, state program payors of the Commonwealth of Massachusetts arising from the purchase of Urogynecologic Surgical Mesh.

(d) Any claims individual consumers have or may have under above-cited State Consumer Protection Laws against any person or entity, including the Releasees.

6.3. Nothing contained in this Judgment shall relieve BARD of the obligations it maintains under any other Judgment or agreement relating to any BARD product.

7. ADDITIONAL PROVISIONS

7.1. Nothing in this Judgment shall be construed to authorize or require any action by BARD in violation of applicable federal, state, or other laws.

7.2. Modification. The Judgment may be modified by a stipulation of the Parties as approved by the Court, or by court proceedings resulting in a modified judgment of the Court.

7.3. BARD shall not cause or encourage third parties, nor knowingly permit third parties acting on its behalf, to engage in practices from which BARD is prohibited by this Judgment.

7.4. The acceptance of this Judgment by the Commonwealth shall not be deemed approval by the Commonwealth of Massachusetts of any of BARD's advertising or business practices. Further, neither BARD nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that the Commonwealth of Massachusetts or any other governmental unit of the Commonwealth of Massachusetts has approved, sanctioned or authorized any practice, act, advertisement, or conduct of BARD.

7.5. Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this Judgment, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment.

7.6. Entire Agreement: This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment and no prior versions of any of its terms that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

7.7. Jurisdiction: This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

7.8. Counterparts: This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

7.9. Notice: All Notices under this Judgment shall be provided to the following via email and Overnight Mail:

Defendant:
Greg A. Dadika
Senior Vice President, Chief Legal Counsel
Becton Dickinson and Company
Greg.Dadika@bd.com

Copy to BARD's attorneys at
Troutman Pepper via electronic mail sent to:
Barry H. Boise.(barry.boise@troutman.com)

Signatory Attorney General:
Michael W. Wong
Assistant Attorney General
Massachusetts Office of the Attorney General
michael.w.wong@mass.gov

7.10. To the extent that any provision of this Judgment obligates BARD to change any policy(ies) or procedure(s) and to the extent not already accomplished, BARD shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment.

APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this _____ day of _____, 2020.

_____
Judge

Approved:

For Defendant C.R. Bard, Inc.

9/16/20

Greg A. Dadika
Senior Vice President, Chief Legal Counsel
Becton Dickinson and Company
Greg.Dadika@bd.com

Date

Local Counsel for C.R. Bard, Inc.

Wynter L. Deagle

September 18, 2020
Date

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For Plaintiff Commonwealth of Massachusetts

/Michael W. Wong/ 9/24/20

Michael W. Wong
Assistant Attorney General
Massachusetts Office of the Attorney General
michael.w.wong@mass.gov

Date