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**STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT**

STATE OF WASHINGTON,

Plaintiff,

v.

C.R. BARD, INC.,

Defendant(s).

NO.

CONSENT DECREE

[CLERK’S ACTION REQUIRED]

JUDGMENT SUMMARY

- | | |
|------------------------------------|--|
| 1. Judgment Creditor | State of Washington |
| 2. Judgment Debtor | C.R. Bard, Inc. and
Becton, Dickinson and Company |
| 3. Principal Judgment Amount | \$60,000,000.00 |
| 4. Post Judgment Interest Rate | 12 percent per annum |
| 5. Attorneys for Judgment Creditor | Daniel L. Allen
Assistant Attorney General |
| 6. Attorneys for Judgment Debtor | Barry Boise
Troutman Pepper |

FINAL CONSENT JUDGMENT

Plaintiff, the State of Washington, acting by and through Attorney General Robert W. Ferguson, has filed a Complaint for a permanent injunction and other relief in this matter pursuant to Washington’s Consumer Protection Act, RCW 19.86 (“CPA”) alleging that

1 Defendant C. R. Bard, Inc. (“BARD” or “Defendant”), committed violations of the
2 CPA. Plaintiff, by its counsel, and BARD, by its counsel, have agreed to the entry of this
3 Consent Judgment (“Judgment”) by the Court without trial or adjudication of any issue of fact
4 or law, and without finding or admission of wrongdoing or liability of any kind.

5 **IT IS HEREBY ORDERED THAT:**

6 **I. FINDINGS**

7 1.1 The State of Washington, via the Washington Attorney General, Robert W.
8 Ferguson (“Attorney General”), by and through the Consumer Protection Division, is the
9 Plaintiff in this case. The Attorney General, by and through the Consumer Protection Division
10 is charged with, among other things, the responsibility of enforcing the Washington Consumer
11 Protection Act (CPA), RCW 19.86.

12 1.2 C.R. Bard, Inc. is the Defendant in this case, is wholly owned by Becton,
13 Dickinson and Company, and is headquartered at 1 Becton Drive, Franklin Lakes, New Jersey,
14 07417.

15 1.3 This Court has jurisdiction over the subject matter of this lawsuit and over all
16 Parties.

17 1.4 The terms of this Judgment shall be governed by the laws of the State of
18 Washington.

19 1.5 Entry of this Consent Judgment is in the public interest and reflects a negotiated
20 agreement among the Parties.

21 1.6 The Parties have agreed to resolve the issues resulting from the Covered Conduct
22 by entering into this Consent Judgment.¹

23 1.7 BARD is willing to enter into this Judgment regarding the Covered Conduct in
24

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

1 order to resolve the Attorney General’s concerns under the CPA as to the matters addressed in
2 this Judgment and thereby avoid significant expense, inconvenience, and uncertainty.

3 1.8 BARD is entering into this Judgment solely for the purpose of settlement, and
4 nothing contained herein may be taken as or construed to be an admission or concession of any
5 violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or
6 wrongdoing, all of which BARD expressly denies. BARD does not admit any violation of the
7 State Consumer Protection Laws set forth in footnote 4, and does not admit any wrongdoing that
8 was or could have been alleged by any Attorney General before the date of the Judgment under
9 those laws. No part of this Judgment, including its statements and commitments, shall constitute
10 evidence of any liability, fault, or wrongdoing by BARD.

11 1.9 This Judgment shall not be construed or used as a waiver or limitation of any
12 defense otherwise available to BARD in any other action, or of BARD’s right to defend itself
13 from, or make any arguments in, any other private individual, regulatory, governmental, or class
14 claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made
15 without trial or adjudication of any issue of fact or law or finding of liability of any kind.
16 Notwithstanding the foregoing, the State may file an action to enforce the terms of this Judgment.

17 1.10 No part of this Judgment shall create a private cause of action or confer any right
18 to any third party for violation of any federal or state statute except that the State may file an
19 action to enforce the terms of this Judgment. It is the intent of the Parties that this Judgment shall
20 not be binding or admissible in any other matter, including, but not limited to, any investigation
21 or litigation, other than in connection with the enforcement of this Judgment.

22 1.11 This Judgment (or any portion thereof) shall in no way be construed to prohibit
23 BARD from making representations with respect to any BARD products in Labeling that are
24 required under Federal law, regulations, or policies or guidance having the force of law,
25 including in Food and Drug Administration (“FDA”) approved Labeling.

26 1.12 Nothing in this Judgment shall require BARD to:

1 (a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C.
2 § 301 *et seq.* (“FDCA”) or any regulation promulgated thereunder, or by the FDA; or

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

5 II. DEFINITIONS

6 The following definitions shall be used in construing the Judgment:

7 2.1 “Covered Conduct” means BARD’s marketing and promotional practices, and
8 dissemination of information to Health Care Providers (HCPs) and consumers, regarding
9 Urogynecologic Surgical Mesh products, including but not limited to the dissemination of
10 Marketing Materials, disclosure of Significant or Inherent Complications in Instructions for Use
11 (IFUs), Sponsorship of any programs, training any sales professionals, the publication of any
12 clinical or pre-clinical data, or the reporting of MDRs or adverse events, through the Effective
13 Date of the Judgment.

14 2.2 “Effective Date” means the date on which a copy of the Judgment, duly executed
15 by BARD and by the Signatory Attorney General, is approved by, and becomes a Judgment of
16 the Court.

17 2.3 “Health Care Provider” or “HCP” means any physician or other health care
18 practitioner who is licensed to provide health care services.

19 2.4 “BARD” means C. R. Bard, Inc. and Becton, Dickinson and Company and all of
20 their officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries,
21 operating companies, assigns and successors.

22 2.5 “Labeling” means “all labels and other written, printed, or graphic matter (1)
23 upon any article or any of its containers or wrappers, or (2) accompanying such article,” as
24 defined under Section 201(m) of the Federal Food, Drug, and Cosmetic Act (FDCA).

25 2.6 “Marketing Materials” means any written, electronic, or verbal material or
26 statements either publicly disseminated (including videos, websites it hosts or controls, or any

1 other form of media) or made for the purpose of public dissemination in the United States, in
2 the course of marketing, promoting, or informing Health Care Providers, consumers, or patients
3 about Urogynecologic Surgical Mesh, including, but not limited to, HCP training materials and
4 training materials for sales representatives made for the purpose of public dissemination and
5 delivery to HCPs.

6 2.7 “Multistate Executive Committee” means the Attorneys General and their staffs
7 representing California, Florida, Indiana, Maryland, Ohio, South Carolina, Texas, and
8 Washington.

9 2.8 “Multistate Working Group” means the Attorneys General and their staffs
10 representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware,
11 District of Columbia, Florida, Georgia, Hawaii², Idaho, Illinois, Indiana, Iowa, Kansas,
12 Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi,
13 Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York,
14 North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South
15 Carolina, South Dakota, Tennessee, Texas, Utah³, Vermont, Virginia, Washington, and
16 Wisconsin.

17 2.9 “Parties” means BARD as defined in Section 2.4 and the Signatory Attorney
18 General.

19 2.10 “Post-effective Date Urogynecologic Surgical Mesh” means Urogynecologic
20

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

26 ³With 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/Order. References to the
“States,” “Parties,” or “Attorneys General,” with respect to Utah, refers to the Utah Division of Consumer
Protection.

1 Surgical Mesh that enters the market in the United States after the Effective Date, and that is not
2 identical or substantially equivalent to Urogynecologic Surgical Mesh that was on the market in
3 the United States prior to the Effective Date.

4 2.11 “Significant Complications” means all complications of Urogynecologic Surgical
5 Mesh, including complications discovered subsequent to the Effective Date, which constitute
6 clinically significant risks material to a Health Care Provider’s decision to implant
7 Urogynecologic Surgical Mesh.

8 2.12 “Inherent Mesh Complications” means Significant Complications that may not
9 be eliminated with surgical technique and are associated with the use of Urogynecologic Surgical
10 Mesh. Disclosure of such risks shall include an adequate description of the chronicity, acuteness,
11 and permanence of the risks. A non-verbatim description of these risks shall include, but are not
12 limited to, risks of:

- 13 • Exposure of mesh material into the vagina, which can be associated with pain
14 during intercourse for the woman and/or her partner
- 15 • Pain caused by exposure may be severe and may result in permanent sexual
16 dysfunction
- 17 • Erosion
- 18 • Implantation of Urogynecologic Surgical Mesh through the vagina may cause
19 bacterial contamination
- 20 • Infection
- 21 • Voiding dysfunction, including de novo urge incontinence
- 22 • Foreign body reaction
- 23 • Inflammation
- 24 • Scar plating around mesh
- 25 • Clinical consequences of mesh contracture
- 26 • Acute and/or chronic pain

- 1 • Pelvic pain, which in some patients may not resolve
- 2 • Pain with intercourse, which in some patients may not resolve
- 3 • Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal
- 4 scarring, tightening and/or shortening may occur

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

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

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

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

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

16 2.13 “Signatory Attorney General” means the Attorney General of Washington, or
17 his/her authorized designee, who has agreed to this Judgment.

18 2.14 “Sponsor” or “Sponsorship” means to pay for in whole or in part, to provide
19 financial support or subsidization, or to provide goods or materials of value in support, but does
20 not include de minimis support.

21 2.15 “State Consumer Protection Laws” means the consumer protection laws cited in
22 footnote 4 under which the Attorneys General have conducted the investigation.⁴

23
24 ⁴ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ALASKA – Alaska
25 Unfair Trade Practices and Consumer Protection Act AS 45.50.471 – 45.50.561; ARIZONA - Consumer Fraud
26 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.

1 2.16 “Urogynecologic Surgical Mesh” means any medical device cleared or approved
2 by the FDA (as the term “device” is defined in 21 U.S.C. § 321(h)) that contains synthetic, multi-
3 strand, knitted, or woven mesh and that is indicated to be used for implantation in the pelvic
4 floor to treat stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP) sold or
5 marketed in the United States.

6 2.17 “Valid Scientific Evidence” means evidence from well-controlled investigations,
7 partially controlled studies, studies and objective trials without matched controls, well-
8 documented case histories conducted by qualified experts, or reports of significant human
9

10 CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer Protection
11 Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade Practices Act,
12 Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices Act, O.C.G.A.
13 Sections 10-1-390 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and
14 Haw. Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601 et seq.; ILLINOIS –
15 Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; INDIANA – Deceptive
16 Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA - Iowa Consumer Fraud Act, Iowa Code
17 Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky
18 Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer
19 Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.;
20 MARYLAND - Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.;
21 MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act,
22 MCL § 445.901 et seq.; MINNESOTA – Minn. Stat. §§325D.44, 325F.69; MISSISSIPPI - Mississippi Consumer
23 Protection Act, Miss. Code Ann. § 75-24-1, et seq.; MISSOURI – Missouri Merchandising Practices Act, Mo.
24 Rev. Stat. §§ 407.010 et seq.; MONTANA – Montana Consumer Protection Act §§ 30-14-101 et seq.;
25 NEBRASKA – Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform Deceptive Trade
26 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).

1 experience with a marketed device, from which it can fairly and responsibly be concluded by
2 qualified experts that there is reasonable assurance to substantiate that a representation is true.

3 2.18 Any reference to a written document shall mean a physical paper copy of the
4 document, electronic version of the document, or electronic access to such document.

5 **III. COMPLIANCE PROVISIONS**

6 **A. Exit from Urogynecologic Surgical Mesh Business**

7 3.1 BARD states that it ceased the marketing, promotion, sale, and distribution of
8 Urogynecologic Surgical Mesh in the United States and the manufacturing of Urogynecologic
9 Surgical Mesh for sale in the United States by December 30, 2016.

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

19 **B. Marketing, Information, and Training**

20 3.3 In promoting Urogynecologic Surgical Mesh, BARD shall not violate the
21 Washington CPA, RCW 19.86.

22 3.4 BARD shall not, in any Marketing Materials, make any claim comparing safety
23 or efficacy clinical outcomes with the use of Urogynecologic Surgical Mesh to any non-mesh
24 procedure safety or efficacy clinical outcomes, unless any such representation is supported by
25 Valid Scientific Evidence. BARD, however, may make comparisons in any Marketing Materials
26 not involving safety or efficacy clinical outcomes, if not false, misleading, or deceptive.

1 3.5 BARD shall not, in any Marketing Materials, misrepresent the safety or efficacy
2 of its Urogynecologic Surgical Mesh by omitting Significant Complications or Inherent Mesh
3 Complications, as appropriate given the length, context, medium, and placement of the
4 Marketing Material and in all instances where the Marketing Material purports to address the
5 subject of complications.

6 3.6 In any Marketing Material that is intended to reach patients or consumers other
7 than or in addition to Health Care Providers, BARD shall also include descriptions of Significant
8 Complications and Inherent Mesh Complications in terms reasonably understandable to a
9 patient.

10 3.7 BARD shall not, in any Marketing Materials, misrepresent the extent to which
11 Inherent Mesh Complications are risks or complications common to all pelvic floor or other
12 surgeries.

13 3.8 BARD shall not, in any Marketing Materials, represent or imply that Significant
14 Complications or Inherent Mesh Complications can be eliminated with surgical experience or
15 technique alone. However, for Post-Effective Date Urogynecologic Surgical Mesh, BARD may,
16 in any Marketing Materials, represent or imply that Significant Complications can be eliminated
17 with surgical experience or technique alone, if such statement is supported by Valid Scientific
18 Evidence.

19 3.9 BARD shall not represent or imply that such Urogynecologic Surgical Mesh does
20 not cause a foreign body reaction, including any chronic foreign body reaction, after the
21 Urogynecologic Surgical Mesh is implanted inside the body. However, for Post-Effective Date
22 Urogynecologic Surgical Mesh, BARD may represent or imply that such Urogynecologic
23 Surgical Mesh does not cause a foreign body reaction, including any chronic foreign body
24 reaction, after the Urogynecologic Surgical Mesh is implanted inside the body, if such statement
25 is supported by Valid Scientific Evidence.

26 3.10 BARD shall not, in any Marketing Materials, represent or imply that such

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

10 3.11 BARD shall not, in any Marketing Materials, represent or imply that such
11 Urogynecologic Surgical Mesh, including its collagen Urogynecologic Surgical Mesh, helps the
12 body more readily accept a foreign body implant, or reduces the risk of foreign body reaction,
13 erosion, infection, or any other Urogynecologic Surgical Mesh complications, including any
14 Significant Complications or Inherent Complications. However, for Post-Effective Date
15 Urogynecologic Surgical Mesh, BARD may, in any Marketing Materials, represent or imply that
16 such Urogynecologic Surgical Mesh, including its collagen Urogynecologic Surgical Mesh,
17 helps the body more readily accept a foreign body implant, or reduces the risk of foreign body
18 reaction, erosion, infection, or any other Urogynecologic Surgical Mesh complications,
19 including any Significant Complications or Inherent Complications, if such statement is
20 supported by Valid Scientific Evidence.

21 3.12 BARD shall not, in any Marketing Materials, misrepresent the FDA approval or
22 clearance status of its Urogynecologic Surgical Mesh devices or the extent to which any of its
23 Urogynecologic Surgical Mesh products have been studied or clinically proven.

24 3.13 BARD shall not, in any Marketing Materials, misrepresent the complexity of
25 Urogynecologic Surgical Mesh implantation procedures or the level of surgical skill and/or
26 experience necessary to perform these procedures safely. Moreover, BARD employees shall not

1 encourage a Health Care Provider to perform Urogynecologic Surgical Mesh implants without
2 receiving adequate information and training on how to implant its Urogynecologic Surgical
3 Mesh.

4 3.14 In any training in which BARD provides risk information, either directly or
5 through third parties, to any Health Care Provider, BARD shall disclose all Significant
6 Complications and Inherent Mesh Complications of its Urogynecologic Surgical Mesh.

7 3.15 BARD shall, in the marketing and promotion of any Urogynecologic Surgical
8 Mesh product, ensure that its Marketing Materials and other communications do not
9 misrepresent FDA updates or communications regarding Urogynecologic Surgical Mesh.

10 **C. Disclosures to Health Care Providers**

11 3.16 To the extent not prohibited by federal law, BARD shall ensure that all IFUs for
12 its Urogynecologic Surgical Mesh products cleared through the 510(k) process include a list of
13 all known Significant Complications and Inherent Mesh Complications.

14 3.17 BARD shall evaluate emerging risk information on an ongoing basis and,
15 consistent with such risk information, shall update the warnings and precautions section of IFUs
16 and all Marketing Material to include Significant Complications associated with its
17 Urogynecologic Surgical Mesh products as soon as practicable. If Bard obtains, receives, or is
18 aware of any new risk information that necessitates a more immediate disclosure for public
19 health and safety purposes, Bard shall notify HCPs of this information through other means, such
20 as notices or “dear doctor letters,” as appropriate given the nature of the new information and
21 unless otherwise directed by the FDA.

22 **D. Studies, Clinical Data, and Sponsorship**

23 3.18 BARD shall, when citing to any clinical study, clinical data, or preclinical data,
24 present a fair and balanced view of available scientific literature with respect to the safety,
25 efficacy, risks and complications of Urogynecologic Surgical Mesh.

26 3.19 BARD shall not, when citing to any clinical study, clinical data, or preclinical

1 data regarding Urogynecologic Surgical Mesh in its Marketing Materials, misrepresent the
2 results, scope, or clinical significance of any particular clinical study, clinical data, or preclinical
3 data, including by implying a more favorable result than supported by the study or data.

4 3.20 BARD shall, when submitting a clinical study, clinical data, or preclinical data
5 regarding Urogynecologic Surgical Mesh for publication, disclose BARD's role as a Sponsor
6 and any author's potential conflict of interest consistent with the disclosure requirements for the
7 International Committee of Medical Journal Editors (ICMJE) or, if different, the disclosure
8 policies of the relevant publication.

9 3.21 BARD shall not cite to any clinical study, clinical data, or preclinical data
10 regarding Urogynecologic Surgical Mesh for which BARD has not complied with the
11 requirements of Section IIID.

12 3.22 BARD shall not cite to any clinical study, clinical data, or preclinical data
13 regarding Urogynecologic Surgical Mesh for which any author/consultant, to the extent BARD
14 knows, has not complied with the applicable publication's conflict disclosure requirements
15 unless BARD discloses the conflict in a clear and conspicuous manner when citing to such study
16 or data.

17 3.23 In all contracts for consulting services regarding Urogynecologic Surgical Mesh
18 between BARD and any Health Care Provider or other author/consultant, BARD shall include a
19 Sponsorship disclosure provision under which the Health Care Provider or other
20 author/consultant agrees that he or she shall, in terms likely to be read and understood by the
21 audience, disclose in any public presentation or submission for publication BARD's sponsorship
22 of the contracted-for activities. BARD shall also include a disclosure clause under which the
23 Health Care Provider or other author/consultant acknowledges that BARD may publicly report
24 the fact that BARD made value transfers to him or her. To the extent within its control, BARD
25 shall ensure that any HCP or author/consultant who submits for publication a clinical study,
26

1 clinical data, or pre-clinical data that BARD has Sponsored, authored, or edited, in whole or in
2 part, shall comply with the publication's conflict disclosure requirements.

3 3.24 In accordance with applicable law, BARD shall register BARD-sponsored
4 clinical studies regarding its Urogynecologic Surgical Mesh with ClinicalTrials.gov. BARD
5 shall also retain any design history files and clinical records, including but not limited to clinical
6 data, relating to its post-December 30, 2016 Urogynecologic Surgical Mesh devices and any
7 Urogynecologic Surgical Mesh devices that existed prior to December 30, 2016 (or substantially
8 equivalent to such devices) over which it has or should have possession, custody or control for
9 15 years past the last sale date of the Urogynecologic Surgical Mesh devices to which those files
10 and records apply, unless a longer period is required by applicable law. BARD shall retain any
11 non-clinical data relating to its post-December 30, 2016 Urogynecologic Surgical Mesh devices
12 and any Urogynecologic Surgical Mesh devices that existed prior to December 30, 2016 (or
13 substantially equivalent to such devices) over which it has or should have possession, custody
14 or control until December 30, 2031, if not introduced prior to that date. If introduced prior to
15 December 30, 2031, then BARD shall retain non-clinical data for 15 years past the last sale date,
16 unless a longer period is required by applicable law.

17 **E. BARD Internal Policies and Training**

18 3.25 BARD shall ensure that its independent contractors, agents, and employees, who
19 sell, market, or promote Urogynecologic Surgical Mesh or otherwise train, provide information
20 to, or communicate with Health Care Providers regarding Urogynecologic Surgical Mesh, are
21 adequately informed and trained regarding their obligations to report all patient complaints
22 and/or adverse events to BARD.

23 3.26 BARD shall ensure that its company practices regarding the reporting of patient
24 complaints relating to Urogynecologic Surgical Mesh as MDR reportable adverse events are
25 consistent with FDA requirements.
26

1 representatives, agents, affiliates, parents, subsidiaries, operating companies, predecessors,
2 assigns and successors (collectively, the “Releasees”) from the following: all civil causes of
3 action, claims, damages, restitution, disgorgement, fines, costs, attorney’s fees, or penalties that
4 the Washington Attorney General has asserted or could have asserted against the Releasees under
5 the State Consumer Protection Laws, or any amendments thereto, or by common law claims
6 concerning deceptive or fraudulent trade practices, that the Signatory Attorney General has the
7 authority to release resulting from the Covered Conduct up to and including the Effective Date.
8 For purposes of this Section 6.1, Releasees do not include Covidien Ltd. or Medtronic PLC, or
9 their past and present officers, directors, employees, representatives, agents, affiliates, parents,
10 subsidiaries, operating companies, predecessors, assigns and successors.

11 6.2 Claims Not Covered. Notwithstanding any term of this Judgment, specifically
12 reserved and excluded from the release in Paragraph 6.1 as to any entity or person, including
13 Releasees, are any and all of the following:

14 (a) Any criminal liability that any person or entity, including Releasees, has or may
15 have to the State of Washington;

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

19 i. State or federal antitrust violations;

20 ii. Claims involving “best price,” “average wholesale price,” “wholesale acquisition
21 cost,” or any reporting practices;

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

25 iv. State false claims violations; and

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

1 (c) Actions of, or on behalf of, state program payors of the State of Washington
2 arising from the purchase of Urogynecologic Surgical Mesh.

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

5 6.3 Nothing contained in this Judgment shall relieve BARD of the obligations it
6 maintains under any other Judgment or agreement relating to any BARD product.

7 VII. ADDITIONAL PROVISIONS

8 7.1 Nothing in this Judgment shall be construed to authorize or require any action by
9 BARD in violation of applicable federal, state, or other laws.

10 7.2 Modification. The Judgment may be modified by a stipulation of the Parties as
11 approved by the Court, or by court proceedings resulting in a modified judgment of the Court.

12 7.3 BARD shall not cause or encourage third parties, nor knowingly permit third
13 parties acting on its behalf, to engage in practices from which BARD is prohibited by this
14 Judgment.

15 7.4 The acceptance of this Judgment by the State of Washington shall not be deemed
16 approval by the State of Washington of any of BARD's advertising or business practices.
17 Further, neither BARD nor anyone acting on its behalf shall state or imply, or cause to be stated
18 or implied, that the State of Washington or any other governmental unit of Washington has
19 approved, sanctioned or authorized any practice, act, advertisement, or conduct of BARD.

20 7.5 Any failure by any party to this Judgment to insist upon the strict performance by
21 any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of
22 the provisions of this Judgment, and such party, notwithstanding such failure, shall have the right
23 thereafter to insist upon the specific performance of any and all of the provisions of this
24 Judgment.

25 7.6 Entire Agreement: This Judgment represents the full and complete terms of the
26 settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior

1 versions of this Judgment and no prior versions of any of its terms that were not entered by the
2 Court in this Judgment, may be introduced for any purpose whatsoever.

3 7.7 Jurisdiction: This Court retains jurisdiction of this Judgment and the Parties
4 hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting
5 such additional relief as may be necessary and appropriate.

6 7.8 Counterparts: This Judgment may be executed in counterparts, and a facsimile or
7 .pdf signature shall be deemed to be, and shall have the same force and effect as, an original
8 signature.

9 7.9 Notice: All Notices under this Judgment shall be provided to the following via
10 email and Overnight Mail:

11 Defendant:

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

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

19 Signatory Attorney General:

20 Daniel L. Allen (Daniel.Allen@atg.wa.gov)
21 Breena M. Roos (Breena.Roos@atg.wa.gov)

22 7.10 To the extent that any provision of this Judgment obligates BARD to change any
23 policy(ies) or procedure(s) and to the extent not already accomplished, BARD shall implement
24 the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after
25 the Effective Date of this Judgment.
26

APPROVAL BY COURT

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

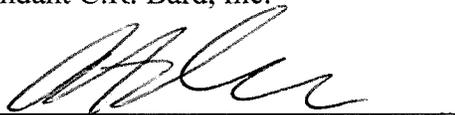
Judge

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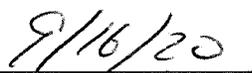
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Approved:

For Defendant C.R. Bard, Inc.



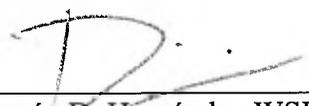
Greg A. Dadika
Senior Vice President, Chief Legal Counsel
Becton Dickinson and Company
Greg.Dadika@bd.com



Date

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Local Counsel for C.R. Bard, Inc.



Román D. Hernández WSBA #39939
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Email: roman.hernandez@troutman.com

9/22/2020
Date

1
2 For Plaintiff State of Washington

3 Daniel L. Allen
4 Daniel L. Allen
5 Assistant Attorney General
6 State of Washington
7 Consumer Protection Division
8 800 5th Ave, Suite 2000
9 Seattle, WA 98104
10 Telephone: 206-254-0575
11 Email: DanielA1@atg.wa.gov

9/23/20
Date

9 Presented by:

10 ROBERT W. FERGUSON
11 Attorney General

12 Daniel L. Allen
13 Daniel L. Allen WSBA #45036
14 Assistant Attorney General
15 Attorneys for Plaintiff State of Washington
16 800 Fifth Avenue, Suite 2000
17 Seattle, WA 98104
18 (206) 254-0575

Notice of Presentment Waived and
Approved as to Form by:

Román D. Hernández
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