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12 **DISTRICT COURT**
13 **CLARK COUNTY, NEVADA**

14 STATE OF NEVADA,) CASE NO.: A-20-821805-B
15) DEPT NO.: 16
16 Plaintiff,)
17 vs.)
18 C.R. BARD, INC.)
19 Defendant.) **BUSINESS COURT REQUESTED**
20) **ARBITRATION EXEMPTION—**
) **Action in Equity**
)

21 **CONSENT JUDGMENT**

22 Plaintiff, State of Nevada, acting by and through its Attorney General, AARON D.
23 FORD, Consumer Advocate ERNEST D. FIGUEROA, Senior Deputy Attorney General
24 LAURA M. TUCKER, and Chief Deputy Attorney General JOANN GIBBS, (hereinafter
25 “State” or “Plaintiff” or “Nevada Attorney General”), has brought this action pursuant to
26 the provisions of the Nevada Deceptive Trade Practices Act, NRS 598.0903 et seq., having
27 filed a Complaint against the Defendant.

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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 State of Nevada.

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

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

1 Judgment. This Judgment is made without trial or adjudication of any issue of fact or
2 law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an
3 action to enforce the terms of this Judgment.

4 1.8. No part of this Judgment shall create a private cause of action or confer any
5 right to any third party for violation of any federal or state statute except that a State
6 may file an action to enforce the terms of this Judgment. It is the intent of the Parties
7 that this Judgment shall not be binding or admissible in any other matter, including, but
8 not limited to, any investigation or litigation, other than in connection with the
9 enforcement of this Judgment.

10 1.9. This Judgment (or any portion thereof) shall in no way be construed to
11 prohibit BARD from making representations with respect to any BARD products in
12 Labeling that are required under Federal law, regulations, or policies or guidance having
13 the force of law, including in Food and Drug Administration (“FDA”) approved Labeling.

14 1.10. Nothing in this Judgment shall require BARD to:

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

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

20 2. DEFINITIONS

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

22 2.1. “Covered Conduct” means BARD’s marketing and promotional practices, and
23 dissemination of information to Health Care Providers (HCPs) and consumers, regarding
24 Urogynecologic Surgical Mesh products, including but not limited to the dissemination of
25 Marketing Materials, disclosure of Significant or Inherent Complications in Instructions
26 for Use (IFUs), Sponsorship of any programs, training any sales professionals, the
27 publication of any clinical or pre-clinical data, or the reporting of MDRs or adverse
28 events, through the Effective Date of the Judgment.

1 2.2. “Effective Date” means the date on which a copy of the Judgment, duly
2 executed by BARD and by the Signatory Attorney General, is approved by, and becomes
3 an Order of the Court.

4 2.3. “Health Care Provider” or “HCP” means any physician or other health care
5 practitioner who is licensed to provide health care services.

6 2.4. “BARD” means C. R. Bard, Inc. and Becton, Dickinson and Company and all
7 of their officers, directors, employees, representatives, agents, affiliates, parents,
8 subsidiaries, operating companies, assigns and successors.

9 2.5. “Labeling” means “all labels and other written, printed, or graphic matter (1)
10 upon any article or any of its containers or wrappers, or (2) accompanying such article,”
11 as defined under Section 201(m) of the Federal Food, Drug, and Cosmetic Act (FDCA).

12 2.6. “Marketing Materials” means any written, electronic, or verbal material or
13 statements either publicly disseminated (including videos, websites it hosts or controls, or
14 any other form of media) or made for the purpose of public dissemination in the United
15 States, in the course of marketing, promoting, or informing Health Care Providers,
16 consumers, or patients about Urogynecologic Surgical Mesh, including, but not limited to,
17 HCP training materials and training materials for sales representatives made for the
18 purpose of public dissemination and delivery to HCPs.

19 2.7. “Multistate Executive Committee” means the Attorneys General and their
20 staffs representing California, Florida, Indiana, Maryland, Ohio, South Carolina, Texas,
21 and Washington.

22 2.8. “Multistate Working Group” means the Attorneys General and their staffs
23 representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut,
24 Delaware, District of Columbia, Florida, Georgia, Hawaii², Idaho, Illinois, Indiana, Iowa,
25 Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota,

26 ² Hawaii is represented on this matter by its Office of Consumer Protection, an agency which is not part of
27 the state Attorney General’s Office, but which is statutorily authorized to undertake consumer protection
28 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.

1 Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New
2 Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon,
3 Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah³,
4 Vermont, Virginia, Washington, and Wisconsin.

5 2.9. "Parties" means BARD as defined in Section 2.4 and the Signatory Attorney
6 General.

7 2.10. "Post-effective Date Urogynecologic Surgical Mesh" means Urogynecologic
8 Surgical Mesh that enters the market in the United States after the Effective Date, and
9 that is not identical or substantially equivalent to Urogynecologic Surgical Mesh that was
10 on the market in the United States prior to the Effective Date.

11 2.11. "Significant Complications" means all complications of Urogynecologic
12 Surgical Mesh, including complications discovered subsequent to the Effective Date,
13 which constitute clinically significant risks material to a Health Care Provider's decision
14 to implant Urogynecologic Surgical Mesh.

15 2.12. "Inherent Mesh Complications" means Significant Complications that may
16 not be eliminated with surgical technique and are associated with the use of
17 Urogynecologic Surgical Mesh. Disclosure of such risks shall include an adequate
18 description of the chronicity, acuteness, and permanence of the risks. A non-verbatim
19 description of these risks shall include, but are not limited to, risks of:

- 20 • Exposure of mesh material into the vagina, which can be associated with
- 21 pain during intercourse for the woman and/or her partner
- 22 • Pain caused by exposure may be severe and may result in permanent sexual
- 23 dysfunction
- 24 • Erosion
- 25 • Implantation of Urogynecologic Surgical Mesh through the vagina may
- 26 cause bacterial contamination
- Infection
- Voiding dysfunction, including de novo urge incontinence
- Foreign body reaction

27 ³ With regard to Utah, the Utah Division of Consumer Protection is charged with administering and
28 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.

- 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 Nevada, or his/her authorized designee, who has agreed to this Judgment/Order.

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.

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1 2.15. "State Consumer Protection Laws" means the consumer protection laws
2 cited in footnote 4 under which the Attorneys General have conducted the investigation.⁴

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

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9 ⁴ ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ALASKA – Alaska Unfair
10 Trade Practices and Consumer Protection Act AS 45.50.471 – 45.50.561; ARIZONA - Consumer Fraud Act,
11 A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101,
12 et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado
13 Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – Connecticut Unfair Trade
14 Practices Act, Conn. Gen Stat. §§ 42-110a through 42-110q; DELAWARE – Delaware Consumer Fraud Act,
15 Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer
16 Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade
17 Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices
18 Act, O.C.G.A. Sections 10-1-390 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat.
19 Chpt. 481A and Haw. Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601
20 et seq.; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.;
21 INDIANA – Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA - Iowa
22 Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-
23 623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA –
24 Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade
25 Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann.,
26 Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN –
27 Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minn. Stat. §§325D.44,
28 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).

1 2.17. "Valid Scientific Evidence" means evidence from well-controlled
2 investigations, partially controlled studies, studies and objective trials without matched
3 controls, well-documented case histories conducted by qualified experts, or reports of
4 significant human experience with a marketed device, from which it can fairly and
5 responsibly be concluded by qualified experts that there is reasonable assurance to
6 substantiate that a representation is true.

7 2.18. Any reference to a written document shall mean a physical paper copy of the
8 document, electronic version of the document, or electronic access to such document.

9 **3. COMPLIANCE PROVISIONS**

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

11 3.1. BARD states that it ceased the marketing, promotion, sale, and distribution
12 of Urogynecologic Surgical Mesh in the United States and the manufacturing of
13 Urogynecologic Surgical Mesh for sale in the United States by December 30, 2016.

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

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

25 3.3. In promoting Urogynecologic Surgical Mesh, BARD shall not violate the
26 Nevada Deceptive Trade Practices Act, NRS 598.0903 et seq.

27 3.4. BARD shall not, in any Marketing Materials, make any claim comparing
28 safety or efficacy clinical outcomes with the use of Urogynecologic Surgical Mesh to any

1 non-mesh procedure safety or efficacy clinical outcomes, unless any such representation is
2 supported by Valid Scientific Evidence. BARD, however, may make comparisons in any
3 Marketing Materials not involving safety or efficacy clinical outcomes, if not false,
4 misleading, or deceptive.

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

10 3.6. In any Marketing Material that is intended to reach patients or consumers
11 other than or in addition to Health Care Providers, BARD shall also include descriptions
12 of Significant Complications and Inherent Mesh Complications in terms reasonably
13 understandable to a patient.

14 3.7. BARD shall not, in any Marketing Materials, misrepresent the extent to
15 which Inherent Mesh Complications are risks or complications common to all pelvic floor
16 or other surgeries.

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

23 3.9. BARD shall not represent or imply that such Urogynecologic Surgical Mesh
24 does not cause a foreign body reaction, including any chronic foreign body reaction, after
25 the Urogynecologic Surgical Mesh is implanted inside the body. However, for Post-
26 Effective Date Urogynecologic Surgical Mesh, BARD may represent or imply that such
27 Urogynecologic Surgical Mesh does not cause a foreign body reaction, including any
28 chronic foreign body reaction, after the Urogynecologic Surgical Mesh is implanted inside

1 the body, if such statement is supported by Valid Scientific Evidence.

2 3.10. BARD shall not, in any Marketing Materials, represent or imply that such
3 Urogynecologic Surgical Mesh is “soft” or that it has “multidirectional elasticity” within
4 the body after implantation or use any other phrases having an equivalent meaning.
5 However, for Post-Effective Date Urogynecologic Surgical Mesh, BARD may, in any
6 Marketing Materials, represent or imply that such Urogynecologic Surgical Mesh is “soft”
7 or that it has “multidirectional elasticity” within the body after implantation or use any
8 other phrases having an equivalent meaning, if such statement is supported by Valid
9 Scientific Evidence. Nothing shall prevent BARD from making claims to Health Care
10 Providers about the softness and elasticity of Urogynecologic Surgical Mesh prior to
11 implantation inside the body provided the claims do not suggest these properties are
12 retained in the body.

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

24 3.12. BARD shall not, in any Marketing Materials, misrepresent the FDA
25 approval or clearance status of its Urogynecologic Surgical Mesh devices or the extent to
26 which any of its Urogynecologic Surgical Mesh products have been studied or clinically
27 proven.

1 3.13. BARD shall not, in any Marketing Materials, misrepresent the complexity of
2 Urogynecologic Surgical Mesh implantation procedures or the level of surgical skill and/or
3 experience necessary to perform these procedures safely. Moreover, BARD employees
4 shall not encourage a Health Care Provider to perform Urogynecologic Surgical Mesh
5 implants without receiving adequate information and training on how to implant its
6 Urogynecologic Surgical Mesh.

7 3.14. In any training in which BARD provides risk information, either directly or
8 through third parties, to any Health Care Provider, BARD shall disclose all Significant
9 Complications and Inherent Mesh Complications of its Urogynecologic Surgical Mesh.

10 3.15. BARD shall, in the marketing and promotion of any Urogynecologic Surgical
11 Mesh product, ensure that its Marketing Materials and other communications do not
12 misrepresent FDA updates or communications regarding Urogynecologic Surgical Mesh.

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

14 3.16. To the extent not prohibited by federal law, BARD shall ensure that all IFUs
15 for its Urogynecologic Surgical Mesh products cleared through the 510(k) process include
16 a list of all known Significant Complications and Inherent Mesh Complications.

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

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

26 3.18. BARD shall, when citing to any clinical study, clinical data, or preclinical
27 data, present a fair and balanced view of available scientific literature with respect to the
28 safety, efficacy, risks and complications of Urogynecologic Surgical Mesh.

1 3.19. BARD shall, when citing to any clinical study, clinical data, or preclinical
2 data regarding Urogynecologic Surgical Mesh in its Marketing Materials, not
3 misrepresent the results, scope, or clinical significance of any particular clinical study,
4 clinical data, or preclinical data, including by implying a more favorable result than
5 supported by the study or data.

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

11 3.21. BARD shall not cite to any clinical study, clinical data, or preclinical data
12 regarding Urogynecologic Surgical Mesh for which BARD has not complied with the
13 requirements of Section 3.D.

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

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

1 clinical data that BARD has Sponsored, authored, or edited, in whole or in part, shall
2 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.
5 BARD shall also retain any design history files and clinical records, including but not
6 limited to clinical data, relating to its post-December 30, 2016 Urogynecologic Surgical
7 Mesh devices and any Urogynecologic Surgical Mesh devices that existed prior to
8 December 30, 2016 (or substantially equivalent to such devices) over which it has or
9 should have possession, custody or control for 15 years past the last sale date of the
10 Urogynecologic Surgical Mesh devices to which those files and records apply, unless a
11 longer period is required by applicable law. BARD shall retain any non-clinical data
12 relating to its post-December 30, 2016 Urogynecologic Surgical Mesh devices and any
13 Urogynecologic Surgical Mesh devices that existed prior to December 30, 2016 (or
14 substantially equivalent to such devices) over which it has or should have possession,
15 custody or control until December 30, 2031, if not introduced prior to that date. If
16 introduced prior to December 30, 2031, then BARD shall retain non-clinical data for 15
17 years past the last sale date, unless a longer period is required by applicable law.

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

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

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

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1 **F. Monitoring and Compliance**

2 3.27. BARD shall be responsible for ensuring monitoring and compliance with the
3 provisions of this Judgment/Order.

4 **4. PAYMENT**

5 4.1. BARD shall pay a total amount of \$60 million as follows: 1) the initial
6 payment of \$15 million shall be paid by the later of October 30, 2020, or 30 days after the
7 Effective Date; 2) the second payment of \$15 million shall be paid by April 1, 2021; and 3)
8 the final payment of \$30 million shall be paid by October 30, 2021. These payments will
9 be divided and paid by BARD to each Signatory Attorney General of the Multistate
10 Working Group in amounts to be designated by and in the sole discretion of the
11 Multistate Executive Committee.⁵ Said payments shall be used by the States as
12 attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied
13 to, the consumer protection enforcement including future consumer protection
14 enforcement, consumer education, litigation or local consumer aid fund or revolving fund,
15 used to defray the costs of the inquiry leading hereto, or for any lawful purpose, at the
16 sole discretion of each Signatory Attorney General. The Parties acknowledge that the
17 payments described herein are not a fine, penalty, or payment in lieu thereof.

18 **5. ENFORCEMENT**

19 5.1. For the purposes of resolving disputes with respect to compliance with this
20 Judgment, should any of the Signatory Attorneys General have a reasonable basis to
21 believe that BARD has engaged in a practice that violates a provision of this Judgment
22 subsequent to the Effective Date, then such Attorney General shall notify BARD in
23 writing of the specific objection, identify with particularity the provision of this Judgment
24 that the practice appears to violate, and give BARD thirty (30) days to respond to the
25 notification; provided, however, that a Signatory Attorney General may take any action if
26 the Signatory Attorney General believes that, because of the specific practice, a threat to
27 the health or safety of the public requires immediate action.

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⁵ The total payment, over three installments, to the State of Nevada shall be \$803,620.

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

14 6.2. Claims Not Covered. Notwithstanding any term of this Judgment,
15 specifically reserved and excluded from the release in Paragraph 6.1 as to any entity or
16 person, including Releasees, are any and all of the following:

- 17 (a) Any criminal liability that any person or entity, including Releasees, has or
18 may have to the State of Nevada;
- 19 (b) Any civil or administrative liability that any person and/or entity, including
20 Releasees, has or may have to the State of Nevada not expressly covered by
21 the release in Section 6.1, including, but not limited to, any and all of the
22 following claims:
- 23 i. State or federal antitrust violations;
 - 24 ii. Claims involving "best price," "average wholesale price," "wholesale
25 acquisition cost," or any reporting practices;
 - 26 iii. Medicaid claims, including but not limited to federal Medicaid drug
27 rebate statute violations, Medicaid fraud or abuse (whether common
28 law, statutory or otherwise), and/or kickback violations related to any
state's Medicaid program;

1 iv. State false claims violations; and

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

3 (c) Actions of, or on behalf of, state program payors of the State of Nevada
4 arising from the purchase of Urogynecologic Surgical Mesh.

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

7 6.3. Nothing contained in this Judgment shall relieve BARD of the obligations it
8 maintains under any other Judgment or agreement relating to any BARD product.

9 **7. ADDITIONAL PROVISIONS**

10 7.1. Nothing in this Judgment shall be construed to authorize or require any
11 action by BARD in violation of applicable federal, state, or other laws.

12 7.2. Modification. The Judgment may be modified by a stipulation of the Parties
13 as approved by the Court, or by court proceedings resulting in a modified judgment of the
14 Court.

15 7.3. BARD shall not cause or encourage third parties, nor knowingly permit
16 third parties acting on its behalf, to engage in practices from which BARD is prohibited
17 by this Judgment.

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

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

28

1 7.6. Entire Agreement: This Judgment represents the full and complete terms of
2 the settlement entered into by the Parties hereto. In any action undertaken by the
3 Parties, no prior versions of this Judgment and no prior versions of any of its terms that
4 were not entered by the Court in this Judgment, may be introduced for any purpose
5 whatsoever.

6 7.7. Jurisdiction: This Court retains jurisdiction of this Judgment and the
7 Parties hereto for the purpose of enforcing and modifying this Judgment and for the
8 purpose of granting such additional relief as may be necessary and appropriate.

9 7.8. Counterparts: This Judgment may be executed in counterparts, and a
10 facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect
11 as, an original signature.

12 7.9. Notice: All Notices under this Judgment shall be provided to the following
13 via email and Overnight Mail:

14 Defendant:

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

19 Copy to BARD's attorneys at

20 Troutman Pepper via electronic mail sent to:
21 Barry H. Boise (barry.boise@troutman.com)

22 Signatory Attorney General:

23 Laura M. Tucker
24 Senior Deputy Attorney General
25 Office of the Nevada Attorney General's Bureau of Consumer Protection
26 8945 W. Russell Road, Suite 204
27 Las Vegas, NV 89148
28 702-486-6525
LMTucker@ag.nv.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

1 implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later
2 than 120 days after the Effective Date of this Judgment/Order.

3 Approved:
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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.

Frankie Sue DelPapa

Frankie Sue DelPapa
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Reno, NV 89503
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renofsdp@aol.com

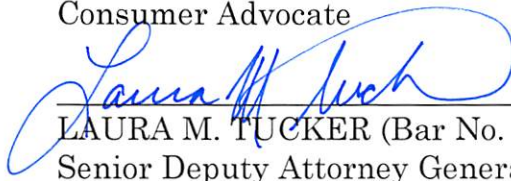
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For Plaintiff:

AARON D. FORD
Attorney General
ERNEST D. FIGUEROA
Consumer Advocate



LAURA M. TUCKER (Bar No. 013268)
Senior Deputy Attorney General

Date: 09/17/2020