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IN THE CHANCERY COURT OF DAVIDSON COUNTY, TENNESSEE
FOR THE TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

STATE OF TENNESSEE,	)	
***ex rel.* HERBERT H. SLATERY III,**	)	
Attorney General and Reporter,	)	
	)	
Plaintiff,	)	**CASE NO.** 21-0356-II
	)	
v.	)	**JUDGE** _____
	)	
BOSTON SCIENTIFIC	)	
CORPORATION,	)	
	)	
Defendant.	)	

COMPLAINT

NOW COMES the Plaintiff, the State of Tennessee, and brings this action against Defendant Boston Scientific Corporation for violating the Tennessee Consumer Protection Act of 1977 ("TCPA"), Tenn. Code Ann. § 47-18-101 *et seq.*, and states as follows:

The Parties

1. Plaintiff, the State of Tennessee, is charged with, among other things, enforcing and seeking redress for violations of Tennessee consumer protection laws, including the Tennessee Consumer Protection Act ("TCPA").

2. Defendant Boston Scientific Corporation ("Boston Scientific") is a Delaware corporation and headquartered at 300 Boston Scientific Way, Marlborough, MA 01752-1234.

3. At all times relevant hereto, Defendant Boston Scientific transacted business in the State of Tennessee and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices, and that business is governed by the TCPA.

Jurisdiction and Venue

4. This Court has jurisdiction over the Defendant pursuant to Tenn. Code Ann. § 16-10-101 because Defendant Boston Scientific has transacted business within the State of Tennessee at all times relevant to the Complaint.

5. Venue is proper in Davidson County pursuant to Tenn. Code Ann. § 47-18-108(a)(3) because Defendant Boston Scientific has carried on a regular business in Davidson County, Tennessee.

Background

6. "Surgical Mesh," as used in this Complaint, is a medical device that contains synthetic polypropylene mesh intended to be implanted in the pelvic floor to treat stress urinary incontinence ("SUI") and/or pelvic organ prolapse ("POP") manufactured and sold by Boston Scientific in the United States.

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

8. SUI is a leakage of urine during episodes of physical activity that increase abdominal pressure, such as coughing, sneezing, laughing, or exercising. SUI can happen when pelvic tissues and muscles supporting the bladder and urethra become weak and allow the neck of the bladder to descend during bursts of physical activity, and the descent can prevent the urethra from working properly to control the flow of urine. SUI can also result when the sphincter muscle that controls the urethra weakens and is not able to stop the flow of urine under normal circumstances and with an increase in abdominal pressure.

9. POP happens when the tissue and muscles of the pelvic floor fail to support the pelvic

organs resulting in the drop of the pelvic organs from their normal position. Not all women with POP have symptoms, while some experience pelvic discomfort or pain, pressure, and other symptoms.

10. In addition to addressing symptoms, such as wearing absorbent pads, there are a variety of non-surgical and surgical treatment options to address SUI and POP. Non-surgical options for SUI include pelvic floor exercises, pessaries, transurethral bulking agents, and behavior modifications. Surgery for SUI can be done through the vagina or abdomen to provide support for the urethra or bladder neck with either stitches alone, tissue removed from other parts of the body, tissue from another person, or with material such as surgical mesh, which is permanently implanted. Non-surgical options for POP include pelvic floor exercises and pessaries. Surgery for POP can be done through the vagina or abdomen using stitches alone or with the addition of surgical mesh.

11. Boston Scientific marketed and sold Surgical Mesh devices to be implanted transvaginally for the treatment of POP for approximately 10 years or more. Boston Scientific ceased the sale of Surgical Mesh devices to be implanted transvaginally for the treatment of POP after the Food and Drug Administration (FDA) ordered manufacturers of such products to cease the sale and distribution of the products in April 2019.

12. Boston Scientific began marketing and selling Surgical Mesh devices to be implanted transvaginally for the treatment of SUI by 2003, and continues to market and sell Surgical Mesh devices to be implanted transvaginally for the treatment of SUI.

13. The FDA applies different levels of scrutiny to medical devices before approving or clearing them for sale.

14. 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.

15. The 510(k) review is a much less rigorous process than the PMA review process. Under this process, a manufacturer is exempt from the PMA process and instead provides premarket notification to the FDA that a medical device is "substantially equivalent" to a legally marketed device. While PMA approval results in a finding of safety and effectiveness based on the manufacturer's submission and any other information before the FDA, 510(k) clearance occurs after a finding of substantial equivalence to a legally marketed device. The 510(k) process is focused on equivalence, not safety.

16. Boston Scientific's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process. Boston Scientific marketed and sold Surgical Mesh devices without adequate testing.

Boston Scientific's Course of Conduct

17. In marketing Surgical Mesh devices, Boston Scientific misrepresented and failed to disclose the full range of risks and complications associated with the devices, including misrepresenting the risks of Surgical Mesh as compared with the risks of other surgeries or surgically implantable materials.

18. Boston Scientific misrepresented the safety of its Surgical Mesh by misrepresenting the risks of its Surgical Mesh, thereby making false and/or misleading representations about its risks.

19. Boston Scientific also made material omissions when it failed to disclose the risks of its Surgical Mesh.

20. Boston Scientific misrepresented and/or failed to adequately disclose serious risks and complications of one or more of its transvaginally-placed Surgical Mesh products, including the following:

a. heightened risk of infection;

b. rigid scar plate formation;

c. mesh shrinkage;

d. voiding dysfunction;

e. de novo incontinence;

f. urinary tract infection;

g. risk of delayed occurrence of complications; and

h. defecatory dysfunction.

21. Throughout its marketing of Surgical Mesh, Boston Scientific continually failed to disclose risks and complications it knew to be inherent in the devices and/or misrepresented those inherent risks and complications as caused by physician error, surgical technique, or perioperative risks.

22. In 2008, the FDA issued a Public Health Notification to inform doctors and patients about serious complications associated with surgical mesh placed through the vagina to treat POP or SUI. In 2011, the FDA issued a Safety Communication to inform doctors and patients that serious complications associated with surgical mesh for the transvaginal repair of POP are not rare, and that a systematic review of published literature showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair and that mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.

23. In 2012, the FDA ordered post-market surveillance studies by manufacturers of surgical mesh to address specific safety and effectiveness concerns related to surgical mesh used for the transvaginal repair of POP. In 2016, the FDA issued final orders to reclassify transvaginal POP devices as Class III (high risk) devices and to require manufacturers to submit a PMA application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP in order to continue marketing the devices.

24. In April 2019, the FDA ordered manufacturers of surgical mesh devices intended for transvaginal repair of POP to cease the sale and distribution of those products in the United States. The FDA determined that Boston Scientific had not demonstrated a reasonable assurance of safety and effectiveness for these devices under the PMA standard. On or around April 16, 2019, Boston Scientific announced it would stop global sales of its transvaginal mesh products indicated for POP.

Violation of the TCPA

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

26. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific 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. Such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by §§ 47-18-104(a), (b)(5), and (b)(27) of the TCPA.

27. In the course of marketing, promoting, selling, and distributing Surgical Mesh products,

Boston Scientific has made representations concerning the characteristics, uses, benefits, and/or qualities of Surgical Mesh products that they did not have. Such false statements and misrepresentations constitute unfair or deceptive trade practices that are prohibited by §§ 47-18-104(a), (b)(5), and (b)(27) of the TCPA.

28. Defendant Boston Scientific 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. Such material omissions and misrepresentations constitute unfair or deceptive trade practices that are prohibited by §§ 47-18-104(a) and (b)(27) of the TCPA.

29. The acts or practices described herein occurred in trade or commerce as defined in Tenn. Code Ann. § 47-18-103(19).

30. These acts or practices affected the public interest because they impacted numerous Tennessee consumers.

Request for Relief

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

a. This Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101 and 47-18-116;

b. Adjudging and decreeing 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 Tenn. Code Ann. §§ 47-18-104(a), (b)(5), and (b)(27);

c. Issuing 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, promoting, selling and distributing of Defendant's

Surgical Mesh devices;

d. Ordering Defendant to pay civil penalties in the amount of $1,000 for each and every violation of TCPA, as provided by Tenn. Code Ann. § 47-18-108(b)(3);

e. Ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action, as provided by §§ 47-18-108(a)(5) and (b)(4) of the TCPA;

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

Respectfully submitted,

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IN THE CHANCERY COURT OF DAVIDSON COUNTY, TENNESSEE
FOR THE TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

STATE OF TENNESSEE, *ex rel.* **HERBERT H. SLATERY III, Attorney General and Reporter,**	)	
Plaintiff,	)	**CASE NO.** 21-0256-II
v.	)	**JUDGE** _____
BOSTON SCIENTIFIC CORPORATION,	)	
Defendant.	)	

CONSENT JUDGMENT

Plaintiff, the State of Tennessee, Plaintiff, the State of Tennessee ("Tennessee" or "Plaintiff") has filed a Complaint for a permanent injunction and other relief in this matter pursuant to the various provisions of the Tennessee Consumer Protection Act of 1977 ("TCPA"), Tenn. Code Ann. § 47-18-101 *et seq*., alleging that Defendant Boston Scientific Corporation ("BSC" or "Defendant") committed violations of the Act. Plaintiff, by its counsel, and Defendant, by its counsel, have agreed to the entry of this Consent 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:

I. 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/Order shall be governed by the laws of the State of Tennessee.

1.3 The State of Tennessee contends that entry of this Judgment is in the public interest. The Judgment reflects a negotiated agreement among the Parties.

1.4 BSC is willing to enter into this Judgment regarding the Covered Conduct to resolve the Attorney 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.

1.5 The Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Judgment.[1]

1.6 BSC 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 BSC expressly denies. BSC 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 BSC. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose. This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to BSC in any other action, or of BSC's right to defend itself from, or make any arguments in, any private individual or class action claims or suits, or any other governmental or regulatory investigations or suits, relating to the subject matter or terms of this Judgment. This Judgment is made without

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

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.

1.7 It is the intent of the Parties that this Judgment not be admissible in other cases or binding on BSC in any respect other than in connection with the enforcement of this Judgment.

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.

1.9 This Judgment (or any portion thereof) shall in no way be construed to prohibit BSC from making representations with respect to any of BSC's products in Labeling that are required under Federal law, regulations, and policies or guidance having the force of law.

1.10 Nothing in this Judgment/Order shall require BSC to:

(a) take any action that is prohibited by the Federal 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 action that is required by the FDA, or by the FDCA or any regulation promulgated thereunder.

II. DEFINITIONS

The following definitions shall be used in construing the Judgment:

2.1 "Covered Conduct" means BSC's marketing and promotional practices and dissemination of information to Health Care Providers ("HCPs") or consumers regarding BSC Surgical Mesh products through the Effective Date of the Judgment.

2.2 "Effective Date" means the date on which a copy of the Judgment, duly executed by BSC 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 who in the course of his or her practice may prescribe or implant BSC Surgical Mesh.

2.4 "BSC" or "Defendant" means Boston Scientific Corporation, and all of its officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies, assigns, and successors.

2.5 "Labeling" as used in this Judgment shall carry the same definition as that contained in the Federal FDCA, specifically "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" and as interpreted by the courts and through FDA policy and guidance to encompass, among other things, "posters, tags, pamphlets, circulars, booklets, brochures, instruction books, [and] direction sheets."

2.6 "Marketing Materials" means any written or electronic material, or written or verbal statements either publicly disseminated or made by or on behalf of BSC for the purpose of public dissemination to induce a sale or purchase in the United States in the course of marketing, promoting, or informing Health Care Providers, nurses, physician's assistants, other medical professionals, and consumers about BSC Surgical Mesh, including: Directions for Use ("DFUs"), pamphlets, brochures, Frequently Asked Questions ("FAQs"), sales representative training materials containing material or statements intended to be publicly disseminated, HCP training materials, communications with HCPs, presentations (including poster presentations and abstract presentations), seminars, videos, advertisements in any form of media, and websites hosted or controlled by BSC.

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, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah[3], Vermont, Virginia, Washington, and Wisconsin.

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

2.10 "Significant Complications" means complications of BSC Surgical Mesh, including complications discovered subsequent to the Effective Date, which:

a. are required to be included in product labeling or advertisements pursuant to FDA regulations;

b. can result in a "serious injury" as defined by 21 CFR § 803.3; or

c. include the following complications, which may be ongoing:

i. Pain (pelvic, vaginal, groin/thigh, dyspareunia) (acute or chronic);

ii. Foreign body reaction (acute or chronic);

iii. Erosion into organs; exposure/extrusion into vagina;

iv. Dyspareunia;

v. Scarring/scar contracture;

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[2] Hawaii is being represented in 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/Order. References to the "States," "Parties," or "Attorneys General," with respect to Utah, refers to the Utah Division of Consumer Protection.

vi. Mesh contracture;

vii. Tissue contracture;

viii. Fistula formation (acute or chronic);

ix. Inflammation (acute or chronic);

x. Vaginal shortening or stenosis, which may result in dyspareunia and/or sexual dysfunction;

xi. Pain with intercourse that may not resolve;

xii. Exposed mesh may cause pain or discomfort to the patient's partner during intercourse;

xiii. Infection;

xiv. Sexual dysfunction; including the inability to have intercourse;

xv. De novo detrusor instability;

xvi. Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder);

xvii. Bruising, bleeding (vaginal, hematoma formation);

xviii. Abscess;

xix. Dehiscence of vaginal incision;

xx. Perforation or laceration of vessels, nerves, bladder, urethra, or bowel may occur during placement; and

xxi. Failure to resolve a patient's stress urinary incontinence.

In addition, because BSC Surgical Mesh is a permanent implant, Significant Complications must acknowledge that:

i. The occurrence of one or more of these complications may require treatment or surgical intervention. 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;

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

2.11 "Inherent Mesh Complications" shall include significant complications associated with the use of the mesh material that may not be eliminated with surgical technique (as opposed to non-mesh surgery).

2.12 "Signatory Attorney General" means the Attorney General of Tennessee, or their authorized designee, who has agreed to this Judgment.

2.13 "Sponsor" is the organization or person who initiates a study and who has authority and control over a study relating to BSC Surgical Mesh.

2.14 "Support" shall mean financial or product support, or as otherwise defined as support in a contractual agreement with an HCP or consultant relating to BSC Surgical Mesh.

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

2.16 "BSC Surgical Mesh" means any medical device (as the term "device" is defined in 21 U.S.C. § 321(h)) that contains synthetic polypropylene mesh intended to be implanted in the pelvic floor to treat stress urinary incontinence ("SUI") and/or pelvic organ prolapse ("POP") manufactured and sold by BSC 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, and 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 of the safety and effectiveness of a device under its conditions of use.

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.; 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.; and WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

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

III. COMPLIANCE PROVISIONS

A. General Provisions

3.1 Sections 3.3 through 3.26 shall be effective for six years following the effective date of this Judgment. Section 3.2 is not time restricted.

3.2 BSC shall not violate the TCPA, Tenn. Code Ann. § 47-18-101 *et seq.*, in Marketing Materials or when promoting BSC Surgical Mesh.

B. Marketing and Promotional Activities

3.3 BSC shall include all Significant Complications and all Inherent Mesh Complications in its Marketing Materials either by including a list of such complications or a reference to the applicable DFU if the inclusion of a list is not reasonably practicable given the length of the Marketing Material and the media used, such as in reminder ads. Provided however that in all instances where the Marketing Material purports to address the subject of complications, BSC shall include all Significant Complications and all Inherent Mesh Complications. Additionally, in all Marketing Materials that are intended to reach consumers other than or in addition to HCPs and that address the subject of complications, BSC shall include descriptions of the Significant Complications and Inherent Mesh Complications in terms reasonably understandable to a consumer.

3.4 BSC shall not, in any Marketing Materials, state or in any way represent that any Inherent Mesh Complications are a risk common to any pelvic floor or other surgery not involving the use of surgical mesh or other graft material.

3.5 BSC shall not, in any Marketing Materials, state or in any way represent that Inherent Mesh Complications can be eliminated with surgical experience or technique alone.

3.6 BSC shall not, in any Marketing Materials, state or in any way represent that BSC Surgical Mesh does not cause a foreign body reaction, including a chronic foreign body reaction.

3.7 BSC shall not, in any Marketing Materials, state or in any way represent that BSC Surgical Mesh remains soft, supple, or pliable, or that it continues to have bi-directional elasticity after the BSC Surgical Mesh is implanted inside the body.

3.8 BSC shall not, in any Marketing Materials, state or in any way represent that BSC Surgical Mesh does not potentiate infection or does not increase the likelihood of infection.

3.9 BSC shall not, in any Marketing Materials, state or in any way represent that BSC Surgical Mesh is superior to traditional repair unless such representations and claims are supported by Valid Scientific Evidence.

3.10 BSC shall not represent that BSC Surgical Mesh is "FDA approved" or that it has undergone the FDA's pre-market approval process, including the requirement for clinical trials, unless such is the case.

3.11 In any training provided by or on behalf of BSC to any HCPs regarding proper procedures for insertion and implantation of BSC Surgical Mesh, BSC shall ensure that such training informs the HCP about Significant Complications and Inherent Mesh Complications.

3.12 BSC shall not, in any Marketing Materials, misrepresent the complexity of BSC Surgical Mesh implantation procedure or the level of surgical skill and/or experience necessary to perform such a procedure safely.

C. Disclosures to Health Care Providers

3.13 To the extent not prohibited by federal law, BSC shall include all Significant Complications and all Inherent Mesh Complications in the DFUs for BSC Surgical Mesh products.

3.14 BSC shall inform purchasers of BSC Surgical Mesh products within the last 24 months of FDA Safety Alerts, Product Advisories, Recalls, and Public Health Notices directly relating and applicable to the safety and efficacy of BSC Surgical Mesh as soon as practicable. If BSC obtains, receives, or is aware of any new risk information that necessitates a more immediate disclosure for public health and safety purposes, BSC shall notify said purchasers of this information through other means, such as notices or letters, as appropriate given the nature of the new information.

3.15 With respect to BSC Surgical Mesh products, BSC shall comply with all FDA regulations regarding: (1) monitoring device usage and prompt revision of the warnings and precautions section of DFUs based on use experience; (2) reporting adverse events; and (3) collection and dissemination of information pertaining to product safety.

D. Conflicts of Interest

3.16 In all contracts for consulting services regarding Surgical Mesh between BSC and any HCP or other consultant, including contracts for speaking engagements or presentations relating to BSC Surgical Mesh, BSC shall include a Support disclosure provision under which the HCP or other consultant agrees that he or she shall, in terms and in a manner so as to be clearly noticed and understood by the audience, disclose in any public presentation or submission for publication relating to the contracted-for activities, BSC's Support of the contracted-for activities (including all information required by any publication's conflict disclosure requirements). Nothing in this provision is intended to change any requirement in a BSC contract that its prior written consent is required before any HCP or other consultant can present or publish in relation to BSC's contracted-for activities.

3.17 In all contracts for BSC-Sponsored studies related to BSC Surgical Mesh, BSC shall require institutions and investigators to properly acknowledge BSC in all publications or presentations resulting from the performance of the Study.

3.18 In all contracts for investigator-initiated studies related to BSC Surgical Mesh in which BSC has provided Support, BSC shall require the investigator (if a party to the agreement) and institution to comply with ethical standards concerning publications and authorship in the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals established by the International Committee of Medical Journal Editors. BSC shall further require that the institution and investigator, if a party to the agreement, properly acknowledge BSC's Support of the Study in publications.

E. Clinical Research

3.19 BSC shall present clinical information regarding BSC Surgical Mesh in a truthful, non-misleading manner and with a balanced presentation of risks in relation to benefits.

3.20 BSC shall not, when citing to any clinical study, clinical data, or preclinical data regarding Surgical Mesh, misrepresent the result or scope of the cited information.

3.21 BSC shall register all BSC-Sponsored studies regarding its BSC Surgical Mesh with ClinicalTrials.gov as required by 42 CFR Part 11.

3.22 BSC shall, when submitting a study or clinical data regarding BSC Surgical Mesh for publication, disclose BSC's role as a Sponsor and any potential conflict of interest with BSC of which BSC is aware for any author consistent with the disclosure requirements for International Committee of Medical Journal Editors ("ICMJE").

3.23 In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials, use, rely on, or cite to any clinical study, clinical data or preclinical data where it had control or possession

of underlying scientific materials, documents, or raw data on or after November 15, 2012 but does not retain the same for the three-year period following the last date such Marketing Materials are distributed by BSC. This prohibition will not apply if BSC has not retained such underlying scientific materials, documents, or raw data if (1) it was not permitted to retain the underlying scientific materials, documents, or raw data; or (2) the study/data was published in a peer-reviewed journal or has otherwise entered the public domain.

3.24 In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials, use, rely on, or cite to any clinical study, clinical data, preclinical data, research, or article, (1) for which BSC has not complied with the disclosure requirements in paragraph 3.22, unless BSC provides the disclosure detailed in paragraph 3.22 in the Marketing Material that uses, relies on, or cites such clinical study, clinical data, preclinical data, research, or article, (2) Sponsored by BSC for which the institution or investigator has not complied with the disclosure requirements set forth in paragraph 3.17, unless BSC provides the disclosure detailed in paragraph 3.17 in the Marketing Material that uses, relies on, or cites such clinical study, clinical data, preclinical data, research, or article, or (3) Supported by BSC for which any author/consultant/investigator has not complied with the disclosure requirements set forth in paragraphs 3.16 or 3.18, unless BSC discloses the conflict, consistent with the conflict of interest disclosure requirements of the ICMJE, in the Marketing Material that uses, relies on, or cites such clinical study, clinical data, preclinical data, research, or article.

F. Policies and Training

3.25 BSC shall maintain policies requiring that its independent contractors, agents, and employees who sell, market, or promote BSC Surgical Mesh or otherwise communicate with

HCPs, nurses, physician's assistants, and other medical professionals, regarding BSC Surgical Mesh, are adequately trained to report patient complaints and/or adverse events to BSC.

3.26 BSC shall ensure that its responses to requests for medical information regarding BSC Surgical Mesh and complications associated with BSC Surgical Mesh are accurate and truthful.

G. Monitoring and Compliance

3.27 BSC shall be responsible for monitoring and compliance with the provisions of this Judgment/Order.

IV. MONETARY RELIEF

4.1 No Later than 30 days after the Effective Date of this Judgment, BSC shall pay a total amount of One Hundred Eighty-Eight Million, Six Hundred Fifty-Five Thousand, Sixty-Seven Dollars ($188,655,067). This amount shall be divided and paid by BSC to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee.[5] The Parties acknowledge that no portion of the payment is a fine or penalty. The states may use the payment in any of the following ways: (1) to pay for attorney's fees and other costs of investigation and litigation; (2) to place in, or apply to, consumer protection enforcement, including future consumer protection enforcement, consumer education, litigation, or local consumer aid or revolving funds; (3) to defray the costs of the inquiry leading to this final Judgment/Order; and/or (4) for any lawful purpose, at the sole discretion of each Signatory Attorney General.

[5] The payment to the State of Tennessee under this paragraph shall be $4,900,958.00.

V. 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 BSC has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date, then such Attorney General shall notify BSC in writing of the specific objection, identify with particularity the provision of this Judgment that the practice appears to violate, and give BSC 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. Upon receipt of written notice, BSC shall provide a good-faith written response to the Signatory Attorney General's notification, containing either a statement explaining why BSC believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how BSC intends to remedy the alleged violation. The Attorney General may agree, in writing, to provide BSC with additional time beyond the thirty (30) days to respond to a notice. Nothing in this section shall be interpreted to limit the State of Tennessee's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law. BSC reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

5.2 Upon giving BSC 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 BSC that relate to BSC'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 will provide a list of those documents to BSC.

5.3 The State may assert any claim that BSC 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 BSC 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.

VI. RELEASE

6.1 Released Claims. By its execution of this Judgment, the State of Tennessee releases and forever discharges BSC and its past and present officers, directors, shareholders, employees, representatives, agents, affiliates, parents, subsidiaries, predecessors, attorneys, assigns and successors (collectively, the "Releasees") from the following: all civil causes of action, claims, damages, restitution, fines, costs, attorney's fees, remedies or penalties that the Tennessee Attorney General has asserted or could have asserted against the Released Parties under the State Consumer Protection Statutes resulting from the Covered Conduct up to and including the Effective Date except as set forth in paragraph 6.2 below.

6.2 Claims Not Covered. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims in Paragraph 6.1 as to any entity or person, including Releasees, are any and all of the following, to which BSC expressly reserves each and every available defense:

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

(b) Any civil or administrative liability that any person or entity, including Releasees, has or may have to the State of Tennessee not expressly covered by the release in Paragraph 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 device 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 State of Tennessee arising from the purchase of BSC Surgical Mesh.

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

6.3 Nothing contained in this Judgment shall relieve BSC of the obligations it maintains under any other Judgment or agreement relating to any of BSC's products.

VII. ADDITIONAL PROVISIONS

7.1 If, subsequent to the Effective Date of this Judgment, the federal government, the FDA, or any state, or any state agency, enacts legislation, regulation, policy or guidance with respect to matters governed by this Judgment that creates a conflict with any provision of the Judgment, and such conflict makes it impossible for BSC to comply with both the newly enacted

legislation, regulation, policy, or guidance and the provision of the Judgment that BSC claims is the subject of the conflict, BSC shall provide the Attorney General with notice of the impossible conflict, which shall include an explanation as to how the newly enacted legislation, regulations, policies or guidance creates a conflict and makes it impossible for BSC to comply with the subject provision of the Judgment. The Attorney General shall have thirty (30) days from receipt of the notice to either notify BSC that it agrees to a modification of the Judgment to address the conflict BSC raised, or notify BSC that the Attorney General does not agree that a conflict exists that makes it impossible for BSC to comply with both the legislation, regulation, policy, or guidance and the subject provision of the Judgment, in which case BSC, subject to an Order to the contrary from this Court, must comply with both the newly enacted legislation, regulations, policies or guidance and the provision of the Judgment.

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

7.3 Modification: The Judgment may be modified by a stipulation of the Parties, once it is approved by and becomes a judgment of the Court, or by court proceedings resulting in a modified Judgment of the Court.

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

7.5 The Attorney General may, at his or her sole discretion, agree in writing to provide BSC with additional time to perform any act required by this Judgment.

7.6 The acceptance of this Judgment by Tennessee shall not be deemed approval by Tennessee of any of BSC's advertising or business practices. Further, neither BSC nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that Tennessee or any

other governmental unit of Tennessee has approved, sanctioned or authorized any practice, act, advertisement, or conduct of BSC.

7.7 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.

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

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

7.10 Notice: All Notices under this Judgment/Order shall be provided to the following via email and Overnight Mail:

BSC:

Eileen M. Hunter
Vice President
Head of Global Litigation
Head of Legal Operations
4100 Hamline Ave N,
St. Paul, MN 55112
eileen.hunter@bsci.com

CC: Boston Scientific Corporation's attorneys:

Joseph Rebein
Shook, Hardy & Bacon, L.L.P.
2555 Grand Blvd.
Kansas City, MO 64018
jrebein@shb.com

Amy R. Fiterman
Faegre Drinker Biddle & Reath LLP
2200 Wells Fargo Center
90 S. Seventh Street
Minneapolis, MN 55402
amy.fiterman@faegredrinker.com

Signatory Attorney General:

Deputy Attorney General
Consumer Protection Division
P.O. Box 20207
Nashville, TN 37202-027
Jeff.hill@ag.tn.gov

7.10 To the extent that any provision of this Judgment obligates BSC to change any policy(ies) or procedure(s) and to the extent not already accomplished, BSC 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.

7.11 Court costs are hereby taxed to Defendant, for which execution may issue of necessary.

BSC will revise its current BSC Surgical Mesh DFUs (the "Current DFUs") to comply with the terms of this Judgment, including by, among other things, listing all Significant Complications and Inherent Mesh Complications and ensuring the revised DFU (the "Updated DFU") conforms with the provisions of Section III.B, as soon as reasonably practicable, but no later than 18 months from the Effective Date of this Judgment.

Once there is an Updated DFU available for a product, BSC shall cease packaging that product with the Current DFU.

BSC will make reasonable efforts to deliver Updated DFUs to all HCPs known to implant BSC Surgical Mesh as soon as reasonably practicable after Updated DFUs are available, but no later than 18 months after the Effective Date of this Judgment.

This Judgment does not require BSC to collect or remove pre-existing materials from the public domain. However, BSC shall remove materials available that are inconsistent with this Judgment over which it has control such as materials posted on websites controlled by BSC.

APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this _____ day of _____, 2021.

_____
Judge

For Defendant Boston Scientific Corporation

By:_____ _____
Eileen M. Hunter Date
Vice President
Head of Global Litigation
Head of Legal Operations

Local Counsel for Boston Scientific Corporation

By:_____ 3/17/21
Stacey L. Smiricky Date
Tennessee Bar No. 035524
Faegre Drinker Biddle & Reath LLP
311 S. Wacker Drive, Suite 4300
Chicago, IL 60606
stacey.smiricky@faegredrinker.com

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APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this _____ day of _____, 2021.

_____
Judge

For Defendant Boston Scientific Corporation

By: _____ 3-17-21
Eileen M. Hunter
Vice President
Head of Global Litigation
Head of Legal Operations

Date

Local Counsel for Boston Scientific Corporation

By: _____
Stacey L. Smiricky
Tennessee Bar No. 035524
Faegre Drinker Biddle & Reath LLP
311 S. Wacker Drive, Suite 4300
Chicago, IL 60606
stacey.smiricky@faegredrinker.com

Date

Approved:

For Defendant Boston Scientific Corporation

By:_____ _____

Eileen M. Hunter
Vice President
Head of Global Litigation
Head of Legal Operations

Date

Local Counsel for Boston Scientific Corporation

By:_____ _____

Stacey L. Smiricky
Tennessee Bar No. 035524
Faegre Drinker Biddle & Reath LLP
311 S. Wacker Drive, Suite 4300
Chicago, IL 60606
stacey.smiricky@faegredrinker.com

Date

For Plaintiff State of Tennessee

Herbert H. Slatery III 3/22/2021

HERBERT H. SLATERY III
Tennessee Attorney General and Reporter
B.P.R. 009077

Date

3/22/2021

MARGARET ROWLAND
Assistant Attorney General
B.P.R. 033513
Office of the Tennessee Attorney General
Public Protection Section
Consumer Protection Division
P.O. Box 20207
Nashville, TN 37202-0207
(615)741-5857

Date