STATE OF NORTH CAROLINA	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION
WAKE COUNTY	FILE NO.

STATE OF NORTH CAROLINA ex rel. JOSHUA H. STEIN, ATTORNEY GENERAL **Plaintiff,** **v.** **JOHNSON & JOHNSON** **and** **ETHICON, INC.** **Defendants.**	)	**CONSENT JUDGMENT**

THIS CAUSE came on before the undersigned Superior Court Judge for entry of a Consent Judgment between Plaintiff, State of North Carolina, by and through its Attorney General, and Defendants, Johnson & Johnson and Ethicon, Inc., a wholly-owned subsidiary of Defendant Johnson & Johnson (hereinafter, collectively referred to as "Defendants"). The Court finds that these Parties have resolved the matters in controversy between them, without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind, and have consented to the terms of this Judgment.

PARTIES

1. The North Carolina Attorney General, by and through its Consumer Protection Division is the Plaintiff in this case. The Division is charged with, among other things, the responsibility of enforcing the North Carolina Unfair and Deceptive Trade Practices Act.

2. Johnson & Johnson is a Defendant in this case and is a New Jersey company, with executive offices located at One Johnson & Johnson Plaza New Brunswick, New Jersey 08933.

3. Ethicon, Inc. is a wholly-owned subsidiary of Defendant Johnson & Johnson. Its headquarters is in New Jersey.

4. Johnson & Johnson and Ethicon, Inc. do business in the State of North Carolina and at all times relevant hereto engaged in trade affecting consumers, within the meaning of the North Carolina Unfair and Deceptive Trade Practices Act.

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 shall be governed by the laws of the State of North Carolina.

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 Defendants are 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 Defendants are 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 Defendants expressly deny. Defendants do not admit any violation of

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

the State Consumer Protection Laws set forth in footnote 4, and do 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 Defendants. 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.

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

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

1.9 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.

1.10 This Judgment (or any portion thereof) shall in no way be construed to prohibit Defendants from making representations with respect to any Ethicon products that are required under Federal law or regulations or in Food and Drug Administration ("FDA") approved or cleared Labeling.

1.11 Nothing in this Judgment shall require Defendants to:

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

(b). fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA.

II. DEFINITIONS

The following definitions shall be used in construing the Judgment:

2.1 "Covered Conduct" shall mean Ethicon's marketing and promotional practices, and dissemination of information to Health Care Providers (HCPs) and consumers, regarding Surgical Mesh products up to the Effective Date of the Judgment.

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

2.3 "Health Care Provider" or "HCP" shall mean any physician or other health care practitioner, who is licensed to provide health care services or to prescribe pharmaceutical products and/or medical devices.

2.4 "Defendants" shall mean Johnson & Johnson, Ethicon, Inc., and all of their officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, assigns and successors.

2.5 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Florida, Indiana, Maryland, Ohio, South Carolina, and Texas.

2.6 "Multistate Working Group" shall mean the Attorneys General and their staffs representing Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of

Columbia, Florida, Georgia, Hawaii[2], Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, 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, and Wisconsin.

2.7 "Parties" shall mean Defendants as defined in Section 2.4 and the Signatory Attorney General.

2.8 "Promotion," "Promotional," "Promoting," "Promote," or "Promoted" shall mean any representation made to HCPs, patients, consumers, payors or other customers, and other practices intended to increase sales or that attempt to influence prescribing practices of HCPs.

2.9 "Risks" shall mean the complications of Surgical Mesh, including complications discovered subsequent to the Effective Date, which constitute clinically significant risks material to an HCP's decision to implant Surgical Mesh. Risks shall be set forth in the Surgical Mesh Instructions-for-Use/Information-for-Use (IFU/IFUs), and include the following:

- complications that cannot be eliminated with surgical technique;
- complications that are specifically associated with the use of Surgical Mesh (as opposed to non-mesh surgery); and
- complications that are otherwise specified in this Judgment.

2.10 "Signatory Attorney General" shall mean the Attorney General of North Carolina, or his authorized designee, who has agreed to this Judgment.

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

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

2.11 "Sponsor," "Sponsorship," or "Sponsored" shall mean 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 contributions of money, goods, or materials.

2.12 "State Consumer Protection Laws" shall mean the consumer protection laws cited in Footnote 4 under which the Attorneys General have conducted the investigation.[4]

2.13 "Surgical Mesh" shall mean any medical device (as the term "device" is defined in 21 U.S.C. § 321(h)) that contains synthetic, multi-strand, knitted or woven mesh and that is

[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.*; 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 Monopolies; Restraint of Trade, Haw. Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601 *et seq.*; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 *et seq.* and Illinois Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 *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.*; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, *et seq.*; MAINE – Maine Unfair Trade Practices Act, 5 M.R.S.A. §§ 205-A through 214; 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.*; 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 JERSEY – New Jersey Consumer Fraud Act, NJSA 56:8-1 *et seq.*; NEW MEXICO – NMSA 1978, § 57-12-1 to -26 (1967, as amended through 2019); 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.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

intended for transvaginal implantation in the pelvic floor to treat stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP).

2.14 "Valid Scientific Evidence" shall have the meaning set forth in 21 CFR § 860.7.

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

III. COMPLIANCE PROVISIONS

A. General Provision

3.1 Ethicon shall not violate the North Carolina Unfair and Deceptive Trade Practices Act in Promoting Surgical Mesh or in any material accompanying its Surgical Mesh.

B. Device Labeling: Warnings and Precautions, Adverse Reactions and Other Adverse Reactions

The following subsections of Section III shall be effective for five (5) years from the Effective Date of this Judgment.

3.2 As soon as practicable, but no later than 24 months from the Effective Date of this Judgment, Ethicon shall, in addition to disclosing the relevant hazards, contraindications, side effects, and precautions that are set forth in its IFUs as of July 30, 2018, ensure that the IFUs for its Surgical Mesh devices:

(a). Do not represent that the Surgical Mesh provides *in vivo* elasticity, including *in vivo* elasticity in both directions.

(b). Do not represent that the Surgical Mesh will remain soft, supple, or pliable after implantation.

(c). Do not represent that any inflammatory or foreign body reaction is only transient or, in all instances, minimal.

(d). Do not represent that a foreign body reaction "may occur" with implantation of the device, but instead indicate that a foreign body reaction to the device will occur, the extent of which may differ and may result in adverse reactions, which may be ongoing.

(e). State that Risks include fistula formation, inflammation, and ongoing risks of mesh extrusion, exposure, and erosion into the vagina and other structures or organs.

(f). State that Risks include temporary or permanent voiding dysfunction or obstructive voiding in addition to, and independent from, temporary or permanent lower urinary tract obstruction caused by overcorrection.

(g). State that Risks include excessive contraction or shrinkage of the tissue surrounding the mesh.

(h). State that Risks include pain with intercourse and loss of sexual function, which in some patients may not resolve.

(i). State that Risks include that one or more revision surgeries may be necessary to treat complications that result from the implantation of a Surgical Mesh device, that revision surgeries may not resolve the complications, and that revision surgeries are also associated with a risk of adverse reactions.

(j). State that Risks include urge incontinence, including de novo urge incontinence.

(k). State that Risks include a risk of infection following transvaginal implantation.

(l). State that Risks include the risk of vaginal scarring from causes which include, but are not limited to, mesh exposure.

3.3 Risk information contained in any of Ethicon's Surgical Mesh IFUs shall only be removed if such a change is supported by Valid Scientific Evidence or undertaken at the behest of the FDA.

3.4 Ethicon shall evaluate emerging Risk information for Surgical Mesh, and as soon as practicable, modify Ethicon's Surgical Mesh IFUs to include any such emerging Risk information and communicate any modification of the Risk information in the Surgical Mesh IFUs to HCPs accordingly, and to the individuals responsible for Ethicon Marketing so as to modify any Promotional communication for Surgical Mesh in accordance with any modified Risk information.

3.5 Ethicon shall ensure that the language within each of its Surgical Mesh IFUs is internally consistent and that the language addressing Risks within a Surgical Mesh IFU is in no way contradicted by, or in any way conflicts with, other language within the IFU.

C. Promotion

3.6 Ethicon shall not make any representations in its Promotion for Surgical Mesh that contradict or are inconsistent with information, including Risk information, contained in the Surgical Mesh IFU or IFUs for the product or products addressed in the Promotion, including as such IFUs are amended pursuant to this Judgment, nor make any representations in its Promotion regarding Surgical Mesh that Ethicon has removed from any of its IFUs pursuant to this Judgment/Order.

3.7 Ethicon shall not, in any Promotion for Surgical Mesh, represent or imply that Risks associated with Surgical Mesh can be eliminated with surgical experience or technique alone unless such claim is supported by Valid Scientific Evidence.

3.8 Ethicon shall not, in any Promotion for Surgical Mesh, misrepresent the extent to which Risks associated with Surgical Mesh are common to pelvic floor or other surgeries.

3.9 Ethicon shall not make any claim comparing the safety or efficacy of the use of Surgical Mesh to any non-mesh procedure unless the claim is supported by Valid Scientific Evidence.

3.10 Ethicon shall not represent in any Promotion for Surgical Mesh that Surgical Mesh is "FDA approved" or that it has undergone the FDA's Premarket Approval (PMA) process, including any requirement for clinical trials, unless such is the case. Ethicon shall train each sales representative who promotes or sells any of Ethicon's Surgical Mesh products on the accurate FDA approval or clearance status of each Surgical Mesh product that the sales representative promotes or sells in advance of any such promotion or sale.

3.11 Ethicon shall not, in any Promotion for Surgical Mesh, misrepresent FDA update(s) or communication(s) regarding Surgical Mesh.

3.12 In any written or electronic Promotion that is intended to reach patients, consumers, or Health Care Providers, Ethicon shall include a complete description of Risks set forth in the respective IFU for the Surgical Mesh Product, but in written or electronic Promotion intended for patients or other non-Health Care Providers, in language that is understandable for the consumer or patient.

3.13 In any Promotion that is intended to reach HCPs that addresses any particular aspect of Surgical Mesh which is specifically addressed in the IFU for that Surgical Mesh device, Ethicon shall provide a complete description of the Risks set forth in the respective IFU for the Surgical Mesh Product which the Promotion addresses.

D. Health Care Provider Training

3.14 In any training that Ethicon Sponsors and/or undertakes to provide to any HCP regarding its Surgical Mesh, Ethicon shall ensure that such training informs the HCP about all Risks included in the applicable IFU. In addition, such training must otherwise comply with the requirements of Subsection C, above.

E. Sponsorship

3.15 By the following means, Ethicon shall ensure that its Sponsorship of any professional event, training material, clinical program, research, grant, or publication concerning Surgical Mesh is disclosed:

(a). When submitting a clinical study, clinical data, or pre-clinical data regarding Surgical Mesh for publication, Ethicon shall adhere to the most recent Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals developed by the International Committee of Medical Journal Editors (ICMJE) guidelines for the naming of authors.

(b). In all contracts for consulting services regarding Surgical Mesh between Ethicon and any HCP or other author/consultant (hereinafter "HCP Contract"), Ethicon shall include a sponsorship disclosure provision under which the HCP or other author/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 Ethicon's Sponsorship of the contracted-for activities (including all Sponsorship information required by any publication's conflict disclosure requirements). Ethicon shall also include a disclosure clause in any HCP Contract under which the HCP or other author/consultant acknowledges that Ethicon may publicly report Ethicon's value transfers to him or her.

3.16 In all Ethicon-sponsored manuscripts, publications, or presentations reporting the results of an Ethicon-sponsored study, Ethicon shall disclose Ethicon's role as a Sponsor, and any author's potential conflict of interest, consistent with the conflict of interest disclosure requirements of the ICMJE.

F. Clinical Research

3.17 Ethicon shall, when citing to any clinical study, clinical data, or preclinical data in any Promotion, present a fair balance of that clinical study, clinical data, or preclinical data and disclose any role as a Sponsor.

3.18 Ethicon shall not use any Promotion that references clinical or preclinical data relating to any of its Surgical Mesh devices over which it has had possession, custody, or control unless Ethicon has retained possession, custody, or control over such clinical data or preclinical data.

G. Monitoring and Compliance

3.19 Ethicon shall be responsible for ensuring monitoring and compliance with the provisions of this Judgment.

IV. PAYMENT

4.1 No Later than 30 days after the Effective Date of this Judgment, Defendants shall pay a total amount of One Hundred Sixteen Million Eight Hundred and Sixty Thousand Dollars ($116,860,000.00) to be divided and paid collectively by Defendants 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]. North Carolina's portion of said payment shall be used by the State of North Carolina as and for attorneys' fees and other costs of investigation and litigation, or be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation, or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of the North Carolina Attorney General. The Parties

[5] The payment to the North Carolina Attorney General under this paragraph shall be $3,348,052.63.

acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

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 Ethicon has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date, then such Attorney General shall notify Ethicon in writing of the specific objection, identify with particularity the provision of this Judgment that the practice appears to violate, and give Ethicon 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, Ethicon shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Ethicon believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Ethicon intends to remedy the alleged breach. Nothing in this Section shall be interpreted to limit the State of North Carolina's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and Defendants reserve all of their rights in responding to a CID or investigative subpoena issued pursuant to such authority.

5.2 Upon giving Ethicon 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 Ethicon that relate to Ethicon'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 Ethicon.

5.3 The Signatory Attorney General may assert any claim that Ethicon 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 Ethicon 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 North Carolina releases and forever discharges Defendants and their past and present officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, predecessors, assigns and successors (collectively, the "Releasees") from the following: all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the North Carolina Attorney General has asserted or could have asserted against the Releasees under the State Consumer Protection Statutes resulting from the Covered Conduct up to and including the Effective Date.

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

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

(b). Any civil or administrative liability that any person and/or entity, including

Releasees, has or may have to the State of North Carolina not expressly covered by the release in Subsection 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 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 North Carolina arising from the purchase of Surgical Mesh.

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

6.3 Nothing contained in this Judgment shall relieve Defendants of the obligations they maintain under any other Judgment or agreement relating to any product.

VII. ADDITIONAL PROVISIONS

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

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

7.3 The Defendants shall not cause or encourage third parties, nor knowingly permit third parties acting on the behalf of either Defendant, to engage in practices from which either Defendant is prohibited by this Judgment.

7.4 The acceptance of this Judgment by North Carolina shall not be deemed approval by North Carolina of any of Defendants' past, present, or future advertising or business practices. Further, neither Defendants nor anyone acting on their behalf shall state or imply, or cause to be stated or implied, that North Carolina or any other governmental unit of North Carolina has approved, sanctioned or authorized any past, present, or future practice, act, advertisement, or conduct of either Defendant.

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

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

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

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

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

Defendants:
William Craco and Shelly Goldklang
Johnson & Johnson Law Department
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
wcraco@its.jnj.com
SGoldkla@its.jnj.com

Copy to Defendants' attorneys at
O'Melveny & Myers LLP and Covington & Burling LLP
via electronic mail sent to:
Steve Brody (sbrody@omm.com)
Carolyn Kubota (ckubota@cov.com)

Signatory Attorney General:
Kim D'Arruda, Special Deputy Attorney General
North Carolina Department of Justice
Consumer Protection Division
114 West Edenton Street
Raleigh, NC 27603
kdarruda@ncdoj.gov

7.10 To the extent that any provision of this Judgment obligates Defendants to change any policy(ies) or procedure(s) and to the extent not already accomplished, Defendants 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, unless another period for compliance is specified herein.

SO ORDERED, ADJUDGED AND DECREED.

_____
Date

_____
Presiding Judge

Approved:

FOR PLAINTIFF STATE OF NORTH CAROLINA

JOSHUA H. STEIN
North Carolina Attorney General

By: _____ Date: 10-17-19

KIMBERLEY A. D'ARRUDA
Special Deputy Attorney General
N.C. Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629
(919) 716-6013
kdarruda@ncdoj.gov
State Bar No. 25271

Defendants

Johnson & Johnson

Date: 10/15/19

By: _____
Tina French
Assistant Corporate Secretary

Ethicon, Inc.

Date: 10/15/19

By: _____
Tina French
Assistant Corporate Secretary

Approved as to form:

Date:

By: _____
Stephen D. Brody
O'Melveny & Myers
Counsel for Defendants

Approved by Local Counsel

Date:

By: _____
[Name]
[Firm]
Local Counsel for Defendants

Defendants

Johnson & Johnson

Date:

By:_____
Tina French
Assistance Corporate Secretary

Ethicon, Inc.

Date:

By:_____
Tina French
Assistant Corporate Secretary

Approved as to form:

Date:

By:_____
Stephen D. Brody
O'Melveny & Myers
Counsel for Defendants

Approved by Local Counsel

Date:

By:_____
David R. Fitzgerald
N.C. Bar Number: 49205
O'Melveny & Myers
Local Counsel for Defendants

Defendants

Johnson & Johnson

Date:

By:_____
Tina French
Assistance Corporate Secretary

Ethicon, Inc.

Date:

By:_____
Tina French
Assistant Corporate Secretary

Approved as to form:

Date:

By:_____
Stephen D. Brody
O'Melveny & Myers
Counsel for Defendants

Approved by Local Counsel

Date:

By:_____
[Name]
[Firm]
Local Counsel for Defendants

19 CV 014357

STATE OF NORTH CAROLINA

WAKE COUNTY

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
19 CVS _____

STATE OF NORTH CAROLINA *ex rel.* JOSHUA H. STEIN, ATTORNEY GENERAL,

Plaintiff,

v.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

COMPLAINT

INTRODUCTION

Plaintiff State of North Carolina, by and through its Attorney General, brings this action against Defendants JOHNSON & JOHNSON and ETHICON, INC. pursuant to North Carolina's Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq.* Plaintiff seeks a permanent injunction, statutory civil penalties, costs, and other appropriate relief.

PLAINTIFF COMPLAINS OF DEFENDANTS AND ALLEGES AND SAYS AS FOLLOWS:

PARTIES

1. Plaintiff is the State of North Carolina acting on relation of its Attorney General, Joshua H. Stein, who brings this action pursuant to authority found in Chapters 75 and 114 of the North Carolina General Statutes.

2. Defendant Johnson & Johnson is a New Jersey company and its principal place of business and executive offices are located at One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933.

3. Defendant Ethicon, Inc. ("Ethicon") is a business corporation organized under the laws of the State of New Jersey with its principal place of business at U.S. Route 22, Somerville, New Jersey, 08876, and is a wholly owned subsidiary of Defendant Johnson & Johnson.

4. Defendant Ethicon transacts business in North Carolina and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, and selling, medical devices including Surgical Mesh.

COMMERCE

5. Defendants were at all times relative hereto, engaged in trade or commerce in the State of North Carolina as defined in North Carolina's Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq.*

ETHICON'S CONDUCT

6. "Surgical Mesh" is any synthetic, multi-strand, knitted or woven mesh device that is intended for transvaginal implantation in the pelvic floor to treat stress urinary incontinence ("SUI") and/or pelvic organ prolapse ("POP").

7. SUI and POP are conditions that pose lifestyle limitations, such as involuntary urine leakage during daily activities, discomfort, or mild pain, and are not life threatening.

8. Ethicon has marketed and sold Surgical Mesh devices for the treatment of SUI and POP for more than ten (10) years.

9. Prior to the introduction of Surgical Mesh, the treatments for POP and SUI included surgical repair with a woman's own tissue and non-surgical treatments including behavioral modifications such as exercises to strengthen the pelvic floor and pessaries.

10. Ethicon did not conduct human trials prior to the initial sale of its Surgical Mesh devices, which were cleared through the FDA's 510(k) process based upon substantial equivalence to a legally marketed predicate device.

11. Ethicon marketed its Surgical Mesh to doctors and patients as minimally invasive with minimal risk, and as superior to traditional methods of treatment. In marketing its Surgical Mesh devices, Ethicon misrepresented and failed to disclose the full range of risks and complications associated with the devices, as well as the frequency and severity of those risks and complications, including misrepresenting the risks of Surgical Mesh as compared with native tissue repair and other surgeries including pelvic floor surgeries.

12. Ethicon misrepresented the safety and efficacy of its Surgical Mesh by failing to adequately disclose serious risks and complications, including the following:

a. a lifelong risk of erosion;

b. chronic pain;

c. distortion of the vagina;

d. sexual dysfunction;

e. chronic foreign body reaction;

f. tissue contraction;

g. urge and de novo incontinence;

h. infection; and

i. vaginal scarring.

13. Ethicon misrepresented, and failed to disclose, to doctors and patients that Surgical Mesh complications may be irreversible. Ethicon's Surgical Mesh products are intended to be permanent implants and were designed for integration into the body and tissue ingrowth, making

them difficult, if not impossible, to surgically remove. Ethicon misrepresented and failed to disclose that removal of its Surgical Mesh devices may be difficult if not impossible, and that removal procedures present additional risks and complications.

14. As misrepresented and undisclosed risks and complications of Surgical Mesh became apparent to doctors and patients, Ethicon continued to misrepresent risks and complications it knew to be inherent in the devices as caused by physician error.

15. In 2012, the FDA ordered post-market surveillance studies by manufacturers of Surgical Mesh to address specific safety and effectiveness concerns related to mini-sling devices for SUI (one category of SUI Surgical Mesh) and Surgical Mesh used for the transvaginal repair of POP. Subsequently, in 2012, Ethicon announced the removal of its mini-sling and POP Surgical Mesh products from the market. 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 Pre-Market Approval application to support the safety and effectiveness of Surgical Mesh for the transvaginal repair of POP in order to continue marketing the devices.

16. In 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (POP) to stop distributing and selling their products due to safety concerns.

17. Ethicon continues to sell its SUI Surgical Mesh products.

VIOLATIONS OF LAW - COUNT I

18. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 17.

19. Ethicon, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in a course of trade or commerce which constitutes false, deceptive,

or misleading acts or practices, and is therefore unlawful under N.C.G.S. § 75-1.1, including but not limited to representing that goods or services had sponsorship, approval, characteristics, benefits, or qualities that they did not have. Ethicon violated N.C.G.S. § 75-1.1 when it misrepresented the sponsorship, approval, characteristics, benefits or qualities of their Surgical Mesh devices.

VIOLATIONS OF LAW - COUNT II

20. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 17.

21. Ethicon, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices and is therefore unlawful under N.C.G.S. § 75-1.1, including but not limited to misrepresenting and failing to disclose the full range of risks and complications associated with Surgical Mesh, as well as their frequency and severity. Ethicon violated N.C.G.S. § 75-1.1 when it misrepresented and failed to disclose the full range of risks and complications associated with their Surgical Mesh devices.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

A. That this Court, pursuant to N.C.G.S. § 75-1.1, permanently enjoin and restrain Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in false, misleading, or deceptive practices in the marketing, promotion, selling, and distributing of their Surgical Mesh devices;

B. That this Court fashion equitable relief to cure Defendants' deceptive practices;

C. That this Court order Defendants to pay all costs for the prosecution and investigation of this action, as provided by N.C.G.S. § 75-16.1; and

D. That this Court grant such other and further relief as the Court deems just and proper.

This the 17th day of October, 2019.

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