COPY

OCT 17 2019

CLERK OF THE SUPERIOR COURT
B. SILVA
DEPUTY CLERK

MARK BRNOVICH
Attorney General
(Firm State Bar No. 14000)
Kaitlin Hollywood (State Bar No. 030637)
Office of the Attorney General
2005 North Central Avenue
Phoenix, AZ 85004
Telephone: (602) 542-3725
Facsimile: (602) 542-4377
Email: consumer@azag.gov
Attorneys for Plaintiff

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, *ex rel.* MARK BRNOVICH, Attorney General, Plaintiff, vs. JOHNSON & JOHNSON, a New Jersey corporation; and ETHICON, INC., a New Jersey corporation Defendants.	Case No. CV2019-013264 **COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF** (Non-classified: Consumer Fraud)

Plaintiff, State of Arizona *ex rel.* Mark Brnovich, the Attorney General (the "State"), alleges the following for its Civil Complaint (the "Complaint") against Defendants Johnson & Johnson and Ethicon, Inc. ("Defendants").

Jurisdiction and Venue

1. The State brings this action pursuant to the Arizona Consumer Fraud Act, Arizona Revised Statutes ("A.R.S.") §§ 44-1521 to 44-1534, to obtain injunctive relief to permanently enjoin and prevent the unlawful acts and practices alleged in this Complaint, and to obtain other relief, including civil penalties, and costs and attorneys' fees.

2. This Court has jurisdiction to enter appropriate orders both prior to and following a determination of liability pursuant to A.R.S. § 44-1528 because the Defendants transacted

business within Arizona at all times relevant to this Complaint.

3. Defendants caused events to occur in this state out of which the claims which are the subject of this Complaint arose.

4. Venue is proper in Maricopa County pursuant to A.R.S. § 12-401(17).

Parties

6. Plaintiff is the State of Arizona *ex rel.* Mark Brnovich, the Attorney General of Arizona, who is authorized to bring this action under the Arizona Consumer Fraud Act (the "CFA"), A.R.S. §§ 44-1521 to 44-1534.

7. 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, NJ, 08933.

8. 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.

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

Trade and Commerce

10. Defendants were at all times relative hereto, engaged in trade or commerce in the Arizona.

Ethicon's Conduct

11. "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").

12. 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.

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

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

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

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

Claims for Relief

23. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 22.

24. Ethicon, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in false, deceptive, or misleading acts or practices, that is unlawful under A.R.S. §§ 44-1521 to 44-1534, including but not limited to representing that goods or services had sponsorship, approval, characteristics, benefits, or qualities that they did not have. Ethicon violated the CFA when it misrepresented the sponsorship, approval, characteristics, benefits or qualities of its Surgical Mesh devices.

25. Ethicon, in the course of marketing, promoting, selling, and distributing its Surgical Mesh products, has engaged in false, deceptive, or misleading acts or practices that are unlawful

under A.R.S. §§ 44-1521 to 44-1534, 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 the CFA when it misrepresented and failed to disclose the full range of risks and complications associated with its Surgical Mesh devices.

Prayer for Relief

WHEREFORE, the State respectfully requests that the Court:

26. 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 pursuant to A.R.S. § 44-1528(A)(1);

27. Order Defendants to pay the State of Arizona a civil penalty of no more than $10,000 for each willful violation of the CFA pursuant to A.R.S. § 44-1528(A)(3);

28. Order Defendants to reimburse the State for its costs and attorneys' fees incurred in the investigation and prosecution of Defendants' activities alleged in this Complaint pursuant to A.R.S. § 44-1534;

29. Award the State such further relief the Court deems just and proper under the circumstances.

DATED this 17th day of October, 2019.

MARK BRNOVICH
Attorney General

By: Kaitlin Hollywood
Kaitlin Hollywood
Assistant Attorney General
Attorneys for Plaintiff