IN THE CIRCUIT COURT OF FAULKNER COUNTY
20th JUDICIAL DISTRICT, ___ DIVISION

STATE OF ARKANSAS	)	
***ex rel.* Leslie Rutledge**	)	
Attorney General	)	
	)	**CASE NO. _____**
Plaintiff,	)	
	)	
v.	)	
	)	
JOHNSON & JOHNSON	)	
	)	
and	)	
	)	
ETHICON, INC.	)	
	)	
Defendants.	)	

COMPLAINT

1. Plaintiff State of Arkansas brings this action against Defendants Johnson & Johnson and Ethicon, Inc. for violating the Arkansas Deceptive Trade Practices Act ("ADTPA"), Ark. Code Ann. §§ 4-88-101, *et seq.*, and states as follows:

Jurisdiction and Venue

2. This action is brought for and on behalf of the State of Arkansas by Leslie Rutledge, Attorney General of the State of Arkansas pursuant to the provisions of the ADTPA.

3. This Court has jurisdiction over the Defendants pursuant to Ark. Code Ann. § 4-88-104 because the Defendants transacted business within the State of Arkansas at all times relevant to this Complaint.

4. Venue for this action properly lies in Faulkner County, Arkansas pursuant to Ark. Code Ann. § 4-88-104 and § 16-60-104(1)(B) because Defendants transact business in all counties of the State of Arkansas, including Faulkner County, or some of the transactions upon which this action is based occurred in Faulkner County.

Parties

5. Plaintiff is the State of Arkansas ("State"), by Leslie Rutledge, Attorney General of the State of Arkansas.

6. 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.

7. 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.

8. Defendant Ethicon transacts business in the State of Arkansas and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, and selling, medical devices including Surgical Mesh.

Trade and Commerce

9. Defendants were at all times relative hereto, engaged in trade or commerce in the State of Arkansas as defined in the ADTPA.

Ethicon's Conduct

10. "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").

11. 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.

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

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

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

Violation of the Arkansas Deceptive Trade Practices Act ("ADTPA"), Ark. Code Ann. § 4-88-101, *et seq.*

Count One

22. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 21.

23. 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 the ADTPA, 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 ADTPA when it misrepresented the sponsorship, approval, characteristics, benefits or qualities of their Surgical Mesh devices.

Count Two

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

25. 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 the ADTPA, 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

ADTPA when it misrepresented and failed to disclose the full range of risks and complications associated with their Surgical Mesh devices.

Prayer for Relief

WHEREFORE, the State of Arkansas respectfully request that:

a. Pursuant to Ark. Code Ann. § 4-88-113(a)(1), the Court 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. Pursuant to Ark. Code Ann. § 4-88-113(c), the Defendants be ordered to pay civil penalties in the amount of $10,000 for each and every violation of the ADTPA.

c. Pursuant to Ark. Code Ann. § 4-88-113(e), the Defendants be ordered to pay costs and reasonable attorneys' fees incurred by the Plaintiff in connection with the investigation and litigation of this matter; and

d. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of Ethicon's unlawful trade practices.

Respectfully submitted,

LESLIE RUTLEDGE
Attorney General
State of Arkansas

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