IN THE DISTRICT COURT IN AND FOR POLK COUNTY

STATE OF IOWA ex rel. Thomas J. Miller, Attorney General Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC. Defendants.	)	CASE NO.: EQCE _____ PETITION

1. Plaintiff the State of Iowa, ex rel. Thomas J. Miller, Attorney General ("Attorney General" or "State") brings this action against Defendants Johnson & Johnson and Ethicon, Inc. for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, and states as follows:

Jurisdiction and Venue

2. This action is brought for and on behalf of the State of Iowa by Thomas J. Miller, Attorney General, pursuant to the provisions of the Iowa Consumer Fraud, Iowa Code section 714.16.

3. This Court has jurisdiction over the Defendants pursuant to Iowa Code section 714.16 because the Defendants transacted business within the State of Iowa at all times relevant to this Complaint.

4. Venue for this action properly lies in Polk County, Iowa pursuant to Iowa Code section 714.16(10) because Defendants transacted business in Polk County, Iowa or some of the transactions upon which this action is based occurred in Polk County, Iowa.

Parties

5. Plaintiff the State of Iowa by Thomas J. Miller, Attorney General, is charged with enforcing the Iowa Consumer Fraud Act, Iowa Code section 714.16, which prohibits unfair or deceptive acts or practices in connection with the lease, sale, or advertisement of any merchandise. Pursuant to Iowa Code section 714.16(7), the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Iowa Consumer Fraud Act and to secure such equitable and other relief as may be appropriate in each case.

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 Iowa and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, and selling, medical devices including Surgical Mesh.

9. At all relevant times Defendants transacted business in Iowa by marketing, promoting, selling, and distributing Surgical Mesh products.

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 Iowa Code Section 714.16

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 Iowa Code section 714.16, including but not limited to representing that goods or services had sponsorship, approval, characteristics, benefits, or qualities that they did not have. Ethicon violated Iowa Code section 714.16 when it misrepresented the sponsorship, approval, characteristics, benefits or qualities of its 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 Iowa Code section 714.16, 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 Iowa Code section 714.16 when it misrepresented and failed to disclose the full range of risks and complications associated with its Surgical Mesh devices.

Prayer for Relief

26. WHEREFORE, the State of Iowa respectfully requests that the Court grant the following relief:

a. Pursuant to Iowa Code section 714.16(7), 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 Iowa Code section 714.16(7), the Defendants be ordered to pay civil penalties in the amount of $40,000 for each and every violation of the Iowa Consumer Fraud Act.

c. Pursuant to Iowa Code section 714.16(10), 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,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

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