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Attorney for Plaintiffs

By: Patricia Schiripo (014441990)
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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO. _____

GURBIR S. GREWAL, Attorney General of the State of New Jersey, and PAUL R. RODRÍGUEZ, Acting Director of the New Jersey Division of Consumer Affairs,

Plaintiffs,

v.

JOHNSON & JOHNSON; ETHICON, INC.; JANE AND JOHN DOES 1-20, individually and as owners, officers, directors, shareholders, founders, members, managers, employees, servants, agents, representatives and/or independent contractors of JOHNSON & JOHNSON and/or Ethicon; and XYZ CORPORATIONS 1-20,

Defendants.

Civil Action

COMPLAINT

Plaintiffs Gurbir S. Grewal, Attorney General of the State of New Jersey ("Attorney General") with offices located at 124 Halsey Street Fifth Floor, Newark, New Jersey and Paul R. Rodríguez, Acting Director of the New Jersey Division of Consumer Affairs ("Director") with

offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs") by way of Complaint state:

PARTIES AND JURISDICTION

1. The Attorney General is charged with the responsibility of enforcing the New Jersey Consumer Fraud Act ("CFA"), N.J.S.A. 56:8-1 to -210. The Director is charged with the responsibility of administering the CFA on behalf of the Attorney General.

2. By this action, the Attorney General and Director seek injunctive relief and other relief for violations of the CFA. Plaintiffs bring this action pursuant to their authority under the CFA, specifically N.J.S.A. 56:8-8, 56:8-11, 56:8-13 and 56:8-19.

3. Venue is proper in Mercer County, pursuant to R. 4:3-2, because it is a county in which the Defendants have conducted business or in which some of the transactions upon which this action is based have occurred.

4. 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.

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

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

7. John and Jane Does 1 through 20 are fictitious individuals meant to represent the owners, officers, directors, shareholders, founders, members, managers, agents, servants,

employees, representatives and/or independent contractors of Johnson & Johnson and/or Ethicon who have been involved in the conduct that gives rise to this Complaint, but are heretofore unknown to Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

8. XYZ Corporations 1 through 20 are fictitious corporations meant to represent any additional business entities who have been involved in the conduct that gives rise to the Complaint, but are heretofore unknown to Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

9. Defendants were at all times relative hereto, engaged in the sale of merchandise, including Surgical Mesh, in New Jersey as defined in the CFA, N.J.S.A. 56:8-1.

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 transvaginal repair 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 manufactures to submit a Pre-Market Approval application to support the safety and effectiveness of Surgical Mesh for 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.

COUNT I

VIOLATION OF THE CFA

(Unconscionable Commercial Practices, Deception and Misrepresentations)

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

23. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby...

24. The CFA defines "merchandise" as including "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale." N.J.S.A. 56:8-1(c).

25. Defendants have been engaged in the marketing, promoting, advertising, offering for sale, selling, and distributing of merchandise within the meaning of N.J.S.A. 56:8-1(c), including Surgical Mesh.

26. Ethicon, in the course of marketing, promoting, advertising, offering for sale, selling, and distributing its Surgical Mesh products, has engaged in false, deceptive, unconscionable or misleading acts or practices, which are unlawful under N.J.S.A 56:8-2, including but not limited to:

a. representing that goods or services had sponsorship, approval, characteristics, benefits, or qualities that they did not have. Ethicon violated N.J.S.A. 56:8-2 when it misrepresented the sponsorship, approval, characteristics, benefits or qualities of their Surgical Mesh devices; and

b. 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 N.J.S.A. 56:8-2 when it misrepresented and failed to disclose the full range of risks and complications associated with their Surgical Mesh devices.

27. Each unconscionable commercial practice, act of deception and misrepresentation by Defendants constitutes a separate violation under the CFA, N.J.S.A. 56:8-2.

PRAYER FOR RELIEF

WHEREFORE, based upon the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendants:

(a) Finding that the acts and practices of Defendants constitute multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 to -210;

(b) Permanently enjoining Defendants and their owners, officers, directors, shareholders, founders, members, managers, agents, servants, employees, representatives, independent contractors and all other persons or entities directly under their control from engaging in, continuing to engage in or doing any acts or practices in violation of the CFA, N.J.S.A. 56:8-1 to -210, including, but not limited to, the practices alleged in this Complaint;

(c) Directing Defendants, jointly and severally, to pay restitution to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any alleged practice herein to be unlawful and found to be unlawful, as authorized by N.J.S.A. 56:8-8;

(h) Directing Defendants, jointly and severally, to disgorge to all profits unlawfully acquired or retained as authorized by the CFA, N.J.S.A. 56:8-8;

(i) Assessing the maximum statutory civil penalties against Defendants, jointly and severally for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13;

(j) Directing Defendants, jointly and severally, to pay costs and fees, including attorneys' fees, for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and

(k) Granting such other relief as the interests of justice may require.

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: October 16, 2019
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in this action involving the aforementioned violations of the CFA, N.J.S.A. 56:8-1 to -210, is not the subject of any other action pending in any other court of this State. I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution

Dated: October 16, 2019
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

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Deputy Attorney General
Consumer Fraud Prosecution Section

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Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Patricia Schiripo is hereby designated as trial counsel for the Plaintiffs in this action.

GURBIR S. GREWAL
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