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DAWNWILLIAMS and DANIEL WILLIAMS

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DAWN WILLIAMS and DANIEL WILLIAMS,

Plaintiffs,

v.

ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of ETHICON, INC; GYNECARE, a Division of ETHICON, INC; ETHICON, INC; and JOHNSON & JOHNSON,

Defendants.

CASE NO.:

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. **Strict Liability – Failure to Warn**
2. **Strict Liability – Manufacturing Defect**
3. **Negligence**
4. **Negligent Misrepresentation**
5. **Loss of Consortium**

All allegations in this Complaint are based upon information and belief except for those allegations which pertain to the Plaintiff named herein and her counsel. Each allegation in this Complaint either has evidentiary support or is likely to have evidentiary support after reasonable opportunity for further investigation and discovery. Plaintiff, for her causes of action against these Defendants, alleges as follows:

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NATURE OF CASE

1. Plaintiff Dawn Williams and her husband, Plaintiff Daniel Williams, by their undersigned counsel, brings this Complaint against Ethicon Women's Health and Urology, A Division Of Ethicon, Inc., Gynecare, A Division Of Ethicon, Inc., Ethicon, Inc., and Johnson & Johnson (collectively referred to herein as "Defendants") related to the design, manufacture, marketing, distribution and sale of Defendants' GYNECARE TVT™ Sling Retropubic System ("Retropubic Sling") implanted in Plaintiff Dawn Williams. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon her individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Defendants' actions and misconduct and alleges as follows.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. §1332(a) inasmuch as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than the Defendants.

3. Venue is proper under 28 U.S.C. §1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district.

4. Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the Northern District of California because Defendants placed a defective product in the stream of commerce, including in California, and that product caused personal injuries to Plaintiff while she resided in the State of California.

PLAINTIFFS

5. Plaintiff Dawn Williams is, and was, at all relevant times mentioned herein:

   a. A resident of the city of West Sacramento, State of California; and,

   b. Injured by Defendants' conduct in the city of Fremont, State of California.

6. Plaintiff Daniel Williams is, and was, at all relevant times mentioned herein:

   a. A resident of the city of West Sacramento, State of California; and,

   b. Injured by Defendants' conduct in the city of Fremont, State of California.

DEFENDANTS

7. Plaintiffs are informed and believe, and based upon that information and belief allege, that Defendant Ethicon Women's Health and Urology is a division of Ethicon, Inc., located at 555 US-22, Somerville, New Jersey.

8. Plaintiffs are informed and believe, and based upon that information and belief allege, that Defendant Gynecare is a division of Ethicon, Inc., located at 555 US-22, Somerville, New Jersey.

9. Plaintiffs are informed and believe, and based upon that information and belief allege, that Defendant Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson, located at 555 US-22, Somerville, New Jersey.

10. Plaintiffs are informed and believe, and based upon that information and belief allege, that Defendant, Johnson & Johnson is a corporation and, according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. (Collectively, Defendants Ethicon, Inc., Ethicon Women's Health and Urology of Ethicon, Inc., Gynecare, and Johnson & Johnson are hereinafter referred to as "Defendants.")

11. The true names and capacities, whether individual, corporate, partnership, associate, or otherwise of Defendant DOES 1 through 10, inclusive are unknown to Plaintiff who therefore sues these Defendants by such fictitious names. Plaintiff will seek leave to amend this complaint to allege Defendant DOES 1 through 10 true names and capacities when they are ascertained.

12. Plaintiffs are informed and believe, and based upon that information and belief allege, that each Defendant named in this Complaint, including DOES 1 through 10, inclusive, is responsible in some manner for one or more of the events and happenings, and proximately caused the injuries and damages, hereinafter alleged.

13. Plaintiffs are informed and believe, and based upon that information and belief allege, that each Defendant named in this Complaint, including DOES 1 through 10, inclusive, are, and at all times mentioned herein were, the agent, servant, and/or employee of each of the

other Defendants, and that each Defendant was acting within the course and scope of his, her, or its authority as the agent, servant, and/or employee of each of the other Defendants. Consequently, each Defendant is jointly and severally liable to Plaintiff for the damages sustained as a proximate result of their conduct.

14. Plaintiffs are informed and believe, and based upon that information and belief allege, that each Defendant named in this Complaint, including DOES 1 through 10, inclusive, are, and at all times mentioned herein were working jointly and in concert with one another to further their business of developing, designing, licensing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce within the United States transvaginal mesh products, specifically The Retropubic Sling Single Incision Sling System. At all times relevant hereto, each of the Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other and was acting within the scope of this respective authority by virtue of those interrelationships.

15. Plaintiffs are informed and believe, and based upon that information and belief allege, that each Defendant named in this Complaint, including DOES 1 through 10, inclusive, are, and at all times mentioned herein were individuals, sometimes referred to as detail persons, who provided instruction and guidance to Plaintiff Dawn Williams 's physicians on how to market, sell and in the method and/or manner to perform surgery utilizing Defendant's mesh products in conjunction with care and treatment provided to her.

FACTUAL BACKGROUND

16. Defendants Ethicon, Inc., Ethicon Women's Health and Urology of Ethicon, Inc., Gynecare, and Johnson & Johnson (Collectively hereinafter referred to as "Defendants") developed, designed, licensed, advertised, delivered, manufactured, packaged, labeled, marketed, sold, and distributed Retropubic Sling which was implanted in Plaintiff Dawn Williams ("Mrs. Williams").

17. In or about October 2002, Defendants began to manufacture, market, and sell a product known as Gynemesh for the treatment of medical conditions in the female pelvis,

primarily pelvic organ prolapse and stress urinary incontinence. All references herein to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

18. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' Prolene mesh hernia product and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references herein to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

19. On or about January l, 2005, without seeking clearance from the United States Food and Drug Administration (FDA), Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift System was and is offered as an anterior, posterior, or total repair system, and all references herein to the Prolift and/or Prolift System include by reference all variations thereof.

20. In or about May 2008, Defendants began to market and sell a product known as Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M System was and is offered as an anterior, posterior, or total repair system, and all references herein to the Prolift+M and/or Prolift +M System include by reference all variations thereof.

21. In or about March 2010, Defendants began to market and sell a product known as Prosima System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prosima was and is offered as an anterior, posterior, or total repair system, and all references to Prosima herein include by reference all variations thereof.

22. Defendants market and sell a product known as TVT for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple and significant variations including, but not limited to, the TVT, TVT-Obturator (TVT-O), TVTSECUR (TVT-S),

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