IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CAROLINE IDELUCA	)	
	)	
Plaintiff,	)	
	)	Civil Action No.:
v.	)	
	)	
C.R. BARD, INC., and DAVOL, INC.,	)	
	)	
Defendants.	)	
	)	

COMPLAINT IN CIVIL ACTION

I. PRELIMINARY STATEMENT

1. Plaintiff brings this action against CR BARD, INC., and DAVOL, INC. (herein collectively referred to as "Defendants"), for their sale and distribution of defective hernia mesh sold under the name Marlex Mesh. Defendants' defective product was surgically implanted into the body of Plaintiff. Defendants' Marlex Mesh presents, and will continue to present a substantial risk of injury or death to the Plaintiff. As a result, Plaintiff has been injured and will need continual and ongoing medical treatment.

II. PARTIES

2. Plaintiff, Caroline Ideluca, is an adult citizen and resident of Allegheny County, Pennsylvania residing at 5448 Wolfe Drive, Pittsburgh, PA 15236. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of Marlex Mesh into her body.

3. Defendant, Davol, Inc. (hereinafter referred to as "DAVOL") is and was a wholly owned subsidiary of C.R. Bard, Inc., with its principal place of business of 100 Sockanosset Crossroads, P.O. Box 8500, Cranston, Rhode Island, 02903 in the County of Providence. At all

times material hereto, DAVOL was a corporation duly organized and existing under the laws of the State of Delaware with a registered agent at The Corporation Trust Company, 1209 Orange Street, Wilmington, DE 19801. Its principal place of business for manufacturing hernia surgical repair products is located in Cranston, Rhode Island. DAVOL designed, manufactured, tested, analyzed, distributed, recommended, merchandized, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including, but not limited to, the Commonwealth of Pennsylvania.

4. Defendant, C.R. Bard, Inc. (hereinafter referred to as "BARD"), is a New Jersey corporation with its principal place of business at 730 Central Avenue, Murray Hill, NJ 07974 in Union County. At all times material hereto, BARD designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplies and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients through the United States, including, but not limited to, the Commonwealth of Pennsylvania.

III. JURISDICTION AND VENUE

5. The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). Plaintiff is a resident of the Commonwealth of Pennsylvania, while Defendant DAVOL is a Delaware corporation and Defendant BARD is a New Jersey corporation. The amount in controversy exceeds $75,000.000, exclusive of interests and costs.

6. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(b)(2) as the events giving rise to this claim occurred within this district.

IV. STATEMENT OF CLAIM

7. Defendants design, manufacture, market, package, label and sell medical devices, including a medical device known as Marlex Mesh, which are implanted to treat certain persons like Plaintiff for hernia repair.

8. Plaintiff was implanted with Marlex Mesh which was designed, manufactured, marketed, packaged, labeled, sold and placed in the stream of commerce by Defendants. Due to defective manufacturing, defective marketing and negligence by Defendants, Marlex Mesh has caused Plaintiff severe and permanent bodily injuries and significant mental and physical pain and suffering and economic loss.

9. On or about July 14, 2003, Caroline Ideluca, underwent repair of an incisional hernia utilizing Marlex Mesh with lysis of adhesions performed by Dr. Alice Rocke. The surgery was performed at Jefferson Regional Medical Center.

10. On or about November 5, 2015, Caroline Ideluca presented to Jefferson Regional Hospital Emergency Room with complaints of severe abdominal pain, nausea and vomiting. CT Scan was completed which revealed a small bowel obstruction and bowel containing ventral hernia. Ms. Ideluca was immediately transferred to UPMC Mercy.

11. On November 6, 2015, Ms. Ideluca had a pre-operative diagnosis of incarcerated incisional hernia and small bowel obstruction. Ms. Ideluca underwent surgery performed by Dr. Matthew Neal in the nature of an exploratory laparoscopy which was converted to a laparotomy due to the large amount of adhesions and ischemic bowel. The bowel was noted to be densely adhered to the mesh. The mesh was within the hernia sac and had to be receded off of the abdominal wall. This necessitated conversion to a laparotomy. Removal of 20 cm of ischemic bowel and explant of mesh was performed. Dr. Neal performed a bowel resection and excision of

the mesh implant. Repair of the incarnated incarcerated hernia was also performed and the small bowel was resected.

12. A pathology report reflected bowel resection with small intestine, increased fibrous and peri-intestinal soft tissue; mesh material with fibroadispose tissue with four embodied type giant cells and suture material.

13. Plaintiff was discharged from UPMC Mercy on November 15, 2015 with a discharge diagnosis of localized swelling, mass and lump, unspecified; ventral hernia without obstruction or gangrene; megacolon, not elsewhere classified.

14. On or about December 2, 2015, Plaintiff was diagnosed with wound dehiscence. It was noted that Plaintiff has been having drainage from her wound for five (5) days which had increased. There was purulent discharge. Dr. Six packed the wound daily to PID with dressing over and arranging for home health care nursing.

15. It was at the time of the November 6, 2015 explantation of her mesh that Plaintiff learned that Defendants Marlex Mesh was the cause of her continued abdominal pain, nausea and other physical manifestations.

16. At that time, Plaintiff learned that the Marlex Mesh used in the 2003 surgery was potentially defective.

17. As a result of the Defendants' Marlex Mesh being implanted into Plaintiff's body, Plaintiff was forced to undergo the aforementioned additional surgeries as a result of adhesion of the mesh to Plaintiff's bowel causing obstruction and necessitating the explanation of the mesh and also lysis of adhesions.

18. In January 2007, the FDA recalled Composix/Kugel Mesh manufactured by Defendants. This recall was expanded in January 2008 by the FDA to include specifically Marlex Mesh.

19. Defendants were aware of hundreds of reports from patients who had had Marlex Mesh implanted which subsequently caused complications and eventual excision of the Marlex Mesh in most instances.

20. The Marlex Mesh manufactured by Defendants had numerous defects which created a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to:

a. The Marlex Mesh used in the procedure failed to conform to the specifications of the product thus preventing the product from being safe for use in patients such as Plaintiff;

b. The Marlex Mesh used in the procedure migrates from the location of its implantation, adversely effecting surrounding tissues and patient health;

c. The Marlex Mesh migrates from its implant location and adheres to surrounding tissues and structures, including bowel;

d. The Marlex Mesh recedes from the abdominal wall, densely adhering to the same and incorporating itself into the bowel structure, causing ischemic bowel, necessitating bowel resection; and

e. The Marlex Mesh becomes imbedded in human tissue over time such that it needs to be removed due to its various defects as set forth above, causing damage to the organs and tissues, adversely effecting patient health.

21. Because of the numerous manufacturing and design defects, the Marlex Mesh used in Plaintiff's surgery created an unreasonable risk of injury and other adverse health consequences as aforementioned above.

22. The Marlex Mesh used in the procedure was unreasonably susceptible to contraction, shrinkage and migration inside the body.

23. The Marlex Mesh used in Plaintiff's surgery was unreasonably susceptible to deformity, elongation and migration to other organs including the bowel.

24. The Marlex Mesh implanted in Plaintiff was marketed to the medical community, including doctors who performed the surgery as safe, effective and a reliable medical device by Defendants.

25. Defendants omitted the risks, dangers, defects and disadvantages of the Marlex Mesh implanted in Plaintiff to Plaintiff's physicians and advertised, promoted, sold, marketed and distributed the Marlex Mesh as a safe medical device when Defendants knew or should have known that it was not safe for their intended purposes and that the mesh would cause serious medical complications for Plaintiff, as aforementioned above.

26. Defendants have underreported information about the propensity of Marlex Mesh, such as the defective type used in Plaintiff's implant surgery, to fail and cause injury and complications, and have made unfounded representations to medical professionals, including Plaintiff's healthcare providers, regarding the safety of Marlex Mesh.

27. The Marlex Mesh was at all times utilized and implanted in a foreseeable manner to Defendants in that Defendants generated the instructions for use and procedures for implanting the devices.

28. Defendants provided incomplete and insufficient information to Plaintiff's physicians regarding the use of Marlex Mesh and the aftercare of patients implanted with the Marlex Mesh.

29. The Marlex Mesh implanted into Plaintiff was the same or in a substantially similar condition as it was when it left Defendants' possession, and in the condition directed and expected by Defendants.

30. Patients receiving Marlex Mesh implants have been forced to undergo extensive medical treatment, including but not limited to, surgeries to locate and remove the mesh, repair of abdominal tissue and nerve damage as well as the use of pain and other medications as well as operations to remove portions of organs and other tissues.

31. Marlex Mesh as manufactured, distributed, sold and/are supplied by Defendants was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing of which Defendants had knowledge.

32. As a result of having Marlex Mesh implanted in her, Plaintiff has experienced significant physical pain and suffering, mental anguish, has sustained permanent injury and has undergone medical treatment and will likely have to undergo additional surgeries.

COUNT I

STRICT LIABILITY – MANUFACTURING DEFECT

33. Plaintiff incorporates by reference Paragraphs 1 through 32 above of the within Complaint as though set forth at length.

34. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Marlex Mesh.

35. At all times material to this action, Marlex Mesh was expected to reach, and did reach, consumers in the State of Pennsylvania and throughout the United States, including Plaintiff herein without substantial change in the condition in which it was sold.

36. At all times material to this action, Marlex Mesh was developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of

commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Marlex Mesh contained manufacturing defects which rendered Marlex Mesh unreasonably dangerous;

b. Marlex Mesh's manufacturing defects occurred while the product was in the possession and control of the Defendant;

c. Marlex Mesh's manufacturing defects existed before it left the control of the Defendants.

37. As a direct and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff sustained significant and permanent injuries. In addition, Plaintiff required and will continue to require health care and services.

38. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include case for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

39. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers and Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT II

NEGLIGENCE – DEFECTIVE DESIGN

40. Plaintiff incorporates by reference Paragraphs 1 through 39 above of the within Complaint as though set forth at length.

41. At all times relevant, Defendants were engaged in the design, formulation, production, construction, creation, making, assembly, testing, marketing, sale, distribution, packaging, promotion, advertising and/or providing warnings and/or instruction for the Marlex Mesh.

42. When the Marlex Mesh left the control of Defendants, the mesh was defectively designed because the foreseeable risks associated with its design or formulation exceeded the benefits of that design or formulation, and because the mesh was more dangerous than a reasonably prudent consumer would expect.

43. Defendants designed the mesh implanted on July 14, 2003 with an inherent and unreasonable propensity for the mesh to migrate from the location of its implantation and adhere to surround tissues and structures, including bowel; the mesh recedes from the abdominal wall incorporating itself into the bowel structure; the mesh becomes imbedded in human tissue over time such that it needs to be removed due to its various defects set forth above, causing damage to the organs and tissues and the mesh is unreasonable susceptible to contraction, shrinkage, deformity, elongation and migration inside the body to other organs including the bowel.

44. At all times relevant, Defendants had a duty to exercise reasonable care in the preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the Marlex Mesh, including a duty to ensure that users would not suffer from unreasonable, dangerous and/or adverse side effects therefrom.

45. Defendants deviated from their duty to exercise reasonable care and were negligent, careless and/or reckless in failing to design the Marlex Mesh and in failing to use proper materials in the design and manufacture of the mesh such that the mesh would not contract, shrink, become deformed and/or elongate and migrate to other organs including bowel.

46. Further, Defendants failed to take appropriate action to correct the design of the mesh when Defendants knew or should have known that the mesh was defectively designed as set forth above.

47. Defendants failed to conduct adequate clinical trials, testing and studies regarding the adequately of the design of the mesh.

48. As a direct and proximate result of Defendants' negligence, carelessness and recklessness, the Marlex Mesh migrated to the bowel and hernia sac causing the aforementioned complications requiring Plaintiff to undergo an open laparotomy surgery as described above.

49. Plaintiff sustained significant and permanent injuries as a result of the defective mesh and will continue to require healthcare and services.

50. As a direct and proximate result of Defendants' negligence, carelessness and recklessness, Plaintiff suffered permanent injuries which have caused and will in the future cause pain, suffering, mental anguish and permanent disability.

51. As a direct and proximate result of the conduct of Defendants, Plaintiff has suffered and will continue to suffer diminished capacity for enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions and activation of latent conditions and other losses and damages.

52. Plaintiff's direct medical losses and costs include costs of hospitalization, physician care, monitoring, treatment, medications and supplies.

53. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and earnings capacity.

54. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers and Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT III

NEGLIGENT MANUFACTURING

55. Plaintiff incorporates by reference Paragraphs 1 through 54 above of the within Complaint as though set forth at length.

56. Defendants had a duty to Plaintiff to exercise reasonable care in manufacturing Marlex Mesh used in the Plaintiff's Procedure, including a duty to assure that this Marlex Mesh would not cause Plaintiff to suffer unreasonable, dangerous side effects.

57. More specifically, Defendant failed to conform this Marlex Mesh, used by Plaintiff's medical providers in the Procedure to product specifications, including among information and belief the:

a. Failure to manufacture the mesh in sterile fashion;

b. Failure to manufacture the mesh in accordance with product specifications;

c. Failure to manufacture the mesh consistent with product design; and

d. In placing in the stream of commerce, Marlex Mesh continued manufacturing defects rendering the product unreasonably dangerous.

COUNT IV

NEGLIGENCE – FAILURE TO WARN

58. Plaintiff incorporates by reference Paragraphs 1 through 57 above of the within Complaint as though set forth at length.

59. Defendants failed to exercise ordinary and reasonable care by failing to provide adequate warnings and instructions to Plaintiff's physicians regarding the Marlex Mesh.

60. Plaintiff's suffered injuries as the above-described defects in the product were well known to each of the Defendants. Despite such knowledge, Defendants failed to properly warn Plaintiff's medical providers of such defects.

61. Defendants, in wanton, reckless, grossly negligent and indefensible disregard of Plaintiff's safety, failed to adequately and appropriately to warn Plaintiff's medical provider of substantial risk posed by Marlex Mesh.

62. Upon information and belief, Defendants failed to warn Plaintiff's medical provider of the defects and attendant risks in Marled Mesh, including, but not limited to:

a. The Marlex Mesh's propensity to contract, retract and/or shrink inside the body resulting in migration to other tissues and structures;
b. The Mesh's propensities for degradation, fragmentation and/creep;
c. The Mesh's inelasticity preventing proper mating with the human tissues;
d. The rate and manner of Mesh erosion;
e. The risk of chronic inflammation resulting from the Marlex Mesh;
f. The risk of chronic infections resulting from the Marlex Mesh;
g. The risk of permanent scarring as a result of the Marlex Mesh;
h. The risk of recurrent, intractable pain and other pain resulting from the Marlexd Mesh;
i. The need for corrective or revision surgery to adjust or remove the Marlex Mesh;
j. The severity of complications that could arise as a result of implantation of the Marlex Mesh;
k. The hazards associated with the Marlex Mesh;
l. The Marlex Mesh's defects described herein;
m. Treatment of hernia repair with the Marlex Mesh exposes patients to greater risk than feasible available alternatives;

n. Treatment of hernia repair with the Marlex Mesh makes future surgical repair more difficult than feasible average alternatives;
o. Use of the Marlex Mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
p. Removal of Marlex Mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
q. Complete removal of the Marlex Mesh may not be possible and may not result in complete resolution of the complications, including pain.

63. Defendants' failure to warn and advise Plaintiff's medical providers of the danger of Marlex Mesh was the direct and proximate cause of Plaintiff's injuries as described above, as Defendants' failure to warn, Plaintiff's medical professionals would not have used the Marlex Mesh in Plaintiff's implant surgery.

64. As a direct and proximate result of the negligence of Plaintiffs, Plaintiffs have suffered serious bodily injury, mental and physical pain and suffering and has incurred economic losses.

WHEREFORE, Plaintiff demands a jury trial against Defendants for compensatory and punitive damages as well as costs, attorneys fees, interest and such other relief, monetary of equitable, which the Court deems appropriate.

Date: October 18, 2017

JURY TRIAL DEMANDED

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