

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

KIMBERLY PELLEGRIN * DOCKET NO.
*
V. *
*
C.R. BARD, DAVOL, INC., *
MEDTRONIC, INC., AND *
COVIDIEN, LP *

COMPLAINT

NOW INTO COURT, through undersigned counsel, comes Plaintiff, Kimberly Pellegrin, who files this Complaint against Defendants, C.R. Bard, Davol, Inc., Medtronic, Inc., and Covidien, LP as follows:

PARTIES AND JURISDICTION

1. Plaintiff, Kimberly Pellegrin, is a person of the full age of majority, and resident of Terrebonne Parish, Louisiana;
2. Defendant, C.R. Bard, Inc. (“Bard”) is a New Jersey Corporation headquartered in Murray Hill, New Jersey;
3. Defendant, Davol, Inc., (“Davol”) is a Delaware Corporation and subsidiary of Defendant, Bard, headquartered in Warwick, Rhode Island;
4. Defendant, Medtronic, Inc. (“Medtronic”) is a Minnesota Corporation headquartered in Minneapolis, Minnesota;
5. Defendant, Covidien, LP, (“Covidien”) is a Delaware Limited Partnership and a subsidiary of Defendant, Medtronic, headquartered in Mansfield, Massachusetts.

6. Defendant Bard and Defendant Davol are hereinafter collectively referred to as “the Bard Defendants.”
7. Defendant, Medtronic, and Defendant, Covidien, are hereinafter collectively referred to as “the Medtronic Defendants.”
8. This is a lawsuit for personal injury damages in excess of \$75,000.00. There is complete diversity of citizenship between Plaintiff and all of the Defendants as the parties are citizens/entities of different states. Accordingly, subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. 1332. Further, this Court has personal jurisdiction over the Defendants because they have done business in the State of Louisiana, have committed a tort in whole or in part in the State of Louisiana, have substantial and continuing contact with the State of Louisiana, and derive substantial revenue from goods used and consumed within the State of Louisiana. The Defendants actively sell, market and promote their Parietex Mesh to physicians and consumers in this state on a regular and consistent basis.
9. Defendants are subject to *in personam* in the U.S. District Court for the Eastern District of Louisiana because they placed a defective product in the stream of commerce and that product caused personal injuries to Plaintiff (who resides in Louisiana) in Louisiana. Further, venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants conduct substantial business in this District.

ALLEGATIONS

10. The Bard Defendants design, manufacture, market, package, label and sell medical devices, including a medical device known as the Parietex Mesh, a medical device implanted to treat persons like Plaintiff for hernias (also referred to as the “Bard Product”).

11. The Medtronic Defendants design, manufacture, market, package, label and sell medical devices, including a medical device known as the Parietex Mesh, a medical device implanted to treat persons like Plaintiff for hernias (also referred to as the “Covidien Product”).
12. The Bard Product and the Medtronic Product are collectively referred to as “the Product” or “the Products”.
13. On October 23, 2014, Plaintiff presented to Terrebonne General Medical Center in Houma, Louisiana, wherein she was diagnosed with gastritis, gastroparesis and diabetes and was ultimately discharged.
14. On October 25, 2014, Plaintiff was rushed to Leonard J. Chabert Medical Center in Houma, Louisiana, wherein she was diagnosed with a perforated duodenal ulcer. Plaintiff was also suffering from tachycardia, hypotension, sepsis, acute kidney injury, abnormal coagulation profile and gastrointestinal bleeding. Plaintiff underwent an ex-lap with primary repair of duodenal perforation and omental patch. During the operation, Plaintiff was implanted with the Products and Parietex Composite Mesh (i.e., “the Product”), products designed, manufactured, marketed, packaged, labeled, sold, and placed in the stream of commerce by Defendants.
15. Due to defective design, defective manufacturing, defective construction/composition, inadequate warning, breach of express warranties, improper marketing, negligent marketing, and negligence by Defendants, the Product has caused Plaintiff severe and permanent bodily injuries, including but not limited to excruciating abdominal pain and swelling, difficulty walking, and physical pain and suffering, and economic losses.
16. Additionally, Plaintiff has undergone subsequent surgeries to remove and/or repair the damage and injuries caused by the Products

17. The product has numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences including that the material in the Product abrades tissues adversely affecting patient health and regularly fail to perform the purpose of its implantation such that the patient requires repair and/or removal of the Product and repeated treatment and surgery.
18. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold the Products at issue herein without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.
19. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff, and from Plaintiff's treating/implanting physicians the true and significant risks associated with Defendants' Products at issue.
20. Prior to the time that the Product was implanted in Plaintiff, Defendants were aware of numerous defects in the Product. Despite being aware of the numerous defects and unreasonable risks in the Product, Defendants designed, manufactured, marketed, and distributed the Product with the intent they would be implanted in patients. Defendants were aware or should have been aware that implanting the Product in patients was likely to cause injury and harm to the patients into whom the Product were implanted. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Product into patients.
21. Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Products in patients was safe and would not cause harm to patients. These statements were made with the intent that medical professionals, potential patients (including plaintiff) and

members of the public would rely upon them, with the intent that potential patients and members of the public would pay for the Product and that the Product would be implanted in patients. When Defendants made these statements, Defendants knew or should have known that the statements were inaccurate.

22. Representatives of Defendants also made statements to numerous individuals, including medical professionals, that implanting the Product in patients was safe and would not cause harm to patients. When Defendants' representatives made these statements, Defendants knew that the statements were inaccurate. Alternatively, when Defendants' representatives made these statements, Defendants should have known the statements were inaccurate.

23. The Defendants owed Plaintiff, and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Product, including the duty to take all reasonable steps necessary to ensure the Product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff, Plaintiff's treating/implanting physicians, other consumers, and the medical community of the dangers associated with the Product at issue.

24. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Product at issue.

25. Defendants had a duty to disclose to potential consumers, potential patients, and to health care professionals the causal relationship or association of the Product to the development of the types of injuries sustained by Plaintiff herein.

26. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of the Product at issue, and (2) appropriate, complete, and accurate

warnings concerning the adverse effects of the Product at issue, including the injuries suffered by Plaintiff herein.

27. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold the Product at issue, Defendants knew, or in the exercise of reasonable care should have known, that the Product was defective, dangerous, and otherwise harmful to potential consumers and/or patients, including Plaintiff.
28. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of the Product at issue in interstate commerce, in that Defendants knew and had reason to know that use of the Product at issue created a significant risk of suffering unreasonably dangerous health related side effects, including the types of injuries suffered by Plaintiff herein, and failed to prevent or adequately warn of the severity of these risks and injuries.
29. Defendants were further negligent in that they manufactured and produced the defective Product - aware of the defects inherent in the Product, failed to act in a reasonably prudent manner in designing, testing, and marketing the Products, and failed to provide adequate warnings of the Product's defects and risks.
30. The Defendants' failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions: a. failing to properly and thoroughly test the Product before releasing it to market; b. failing to properly and thoroughly analyze the data resulting from the pre- marketing tests of the Product; c. failing to conduct sufficient post-market testing and surveillance of the Product; d. designing, manufacturing, marketing,

advertising, distributing, and selling the Product to consumers and/or patients, including KIMBERLY PELLEGRIN, without an adequate warning of the significant and dangerous risks of the Product and without proper instructions to avoid foreseeable harm; e. failing to accompany their Product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of the Product and the comparative severity of such adverse effects; f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks of the Product, including but not limited to the fact that the material in the Product abrades tissues adversely affecting patient health and regularly fail to perform the purpose of its implantation such that the patient requires repair and/or removal of the Product and repeated treatment and surgery; g. failing to exercise due care when advertising and promoting the Product; and h. negligently continuing to manufacture, market, advertise, and distribute the Product after the Defendants knew or should have known of its adverse effects.

31. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.
32. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff has suffered and will continue to suffer serious injuries as described herein.
33. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of the Products.

34. Before Plaintiff suffered the injuries complained of herein, Defendants were on notice of numerous bodily injuries caused by the Product, and based thereon, Defendants knew or should have known that the Product caused an unreasonably high rate of infection, extrusion, perforation, chronic pain and/or abscess in people implanted with the Product.
35. Even through Defendants had known or should have known that the Product created a foreseeable, unreasonable risk of harm to those patients into whom they were implanted, Defendants continued to market the Product in the United States. Defendants have sold thousands of Product in the United States.
36. Defendants have never provided adequate warning or information to physicians who implanted the Product, to patients, or to people who may be implanted with the device, of the risks that the Product causes an unreasonably high rate of infection, extrusion, perforation, chronic pain and/or abscess.
37. The Defendants' Products used by and implanted in KIMBERLY PELLEGRIN was provided to her and her doctor in a condition substantially the same as the condition in which it was manufactured and sold.
38. KIMBERLY PELLEGRIN and KIMBERLY PELLEGRIN's treating/implanting physicians relied on claims made by Defendants that the Products were safe and effective for their intended purpose.
39. The development of Plaintiff's injuries at issue herein were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life- threatening risks, willful and wanton failure to provide adequate warnings and/or instructions, and willful misrepresentations concerning the nature and safety of their

Products at issue. This conduct and the product defects complained of herein were substantial factors in bringing about and exacerbating KIMBERLY PELLEGRIN's injuries.

40. KIMBERLY PELLEGRIN's injuries and/or her resulting damages were a reasonably foreseeable consequence of Defendants' conduct and the defects of their Products at issue herein.
41. KIMBERLY PELLEGRIN would not have used the Products at issue herein and KIMBERLY PELLEGRIN's treating/implanting physicians would not have implanted and/or used the Products at issue herein had Defendants properly disclosed and/or warned about the risks associated with the Products and/or had Defendants conformed the Products to their express warranties. Thus, had Defendants properly disclosed the risks associated with the Products at issue, KIMBERLY PELLEGRIN would have avoided the risk of developing the injuries complained of herein.
42. As a result of Defendants' actions, KIMBERLY PELLEGRIN and her treating/implanting physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that KIMBERLY PELLEGRIN would be and/or had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, negligence, omissions, and/or misrepresentations.
43. Had Defendants provided the proper warnings to KIMBERLY PELLEGRIN and her treating/implanting physicians, KIMBERLY PELLEGRIN's treating/prescribing physicians would not have used, prescribed or implanted the Products at issue, and KIMBERLY PELLEGRIN would not have been injured. Moreover, had Defendants provided the proper warnings to KIMBERLY PELLEGRIN and her treating/implanting physicians, KIMBERLY PELLEGRIN would not have sustained the injuries at issue herein.

44. As a direct and proximate result of Defendants' negligence, wrongful conduct, as well as the improper warnings and unreasonably dangerous and defective characteristics of the Products: Plaintiff KIMBERLY PELLEGRIN suffered serious physical injuries, loss of enjoyment of life, inconvenience and mental anguish, as well as incurred past medical expenses and lost wages, and will incur/sustain future medical expenses and lost wages.

**COUNT I:
CONSTRUCTION OR COMPOSITION DEFECT UNDER LA. R.S. 9:2800.55**

45. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs.
46. At all relevant times, Defendants designed, manufactured, tested, packaged, labeled, promoted, distributed and sold the Product and Plaintiff was recipient of their product.
47. The Product was expected to and did reach the usual consumers, handlers, and persons coming into contact with the Products without substantial change in the condition in which it was produced, manufactured, sold, and distributed by the Defendants.
48. At those times, the Product was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff. Plaintiff contends that the defective condition of the Product and the lack of ordinary care in manufacturing the Product is obvious and within the range of comprehension of the average juror without speculation.
49. The Product manufactured, sold, and distributed by the Defendants were defective in manufacture in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risk exceeded the benefits associated with the use of the Product.

50. The Product implanted into Plaintiff was being used in a manner reasonably anticipated at the time it was implanted in her.

51. At all times material to this action, the Product implanted into Plaintiff was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition (which presented and constituted an unreasonable risk of danger and injury to Plaintiff) at the time it was placed in the stream of commerce in ways which include, but were not limited to, one or more of the following:

- a. The Product's manufacturing defects occurred while the product was in the possession and control of Defendants, the Product was sold in a defective condition by manufacture, and contained manufacturing defects which rendered the Product unreasonably dangerous;
- b. The Product as manufactured was unsafe for Plaintiff;
- c. The Product as manufactured was unreasonably dangerous to Plaintiff;
- d. The Product did not perform safely as an ordinary consumer/patient, like Plaintiff, would expect;
- e. The Product as manufactured was unsafe for its intended use;
- f. Defendants knew the component parts of the Product as implemented through manufacture could cause injury to the end user;
- g. The Product was not made in accordance with Defendants' specifications or performance standards; and
- h. The Product's manufacturing defects existed before it left the control of Defendants.

52. The Product manufactured and/or supplied by Defendants was defective in construction or composition in that, when it left Defendants' hands, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe, has numerous and serious side effects as outlined herein - which KIMBERLY PELLEGRIN suffered and suffers from herein. The Product was unreasonably dangerous in construction or composition as provided by La. R.S. 9:2800.55.
53. The defects in the Product were substantial factor in causing Plaintiff's injuries.
54. Defendants acted recklessly, willfully, wantonly and with a significant indifference to, and conscious disregard for the safety of others, including Plaintiff, by manufacturing and selling the dangerous and defective Products to Plaintiff. Defendants' reckless disregard for Plaintiff's safety by deliberately exposing her to the dangerous and defective Product warrant the imposition of punitive damages.
55. As a direct and proximate result of manufacturing defects in Defendants' Product, Plaintiff suffered and will continue to suffer injuries and damages.
56. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for all possible damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT II:
INADEQUATE WARNING UNDER LA. R.S. 9:2800.57**

57. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs.

58. The Product at issue was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, users and physicians/prescribers, including KIMBERLY PELLEGRIN and KIMBERLY PELLEGRIN's treating/prescribing physicians, of the dangerous risks and reactions associated with the Product, including but not limited to its propensity to cause permanent and/or severe injuries, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to La. R.S.

9:2800.57.

59. The Product developed, manufactured, marketed, distributed and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the Product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the Product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the Product could cause serious injury.

60. KIMBERLY PELLEGRIN, was prescribed, implanted with and/or used the Product for its intended purpose, and neither he nor her treating/implanting physicians could have discovered the relevant defects in the subject product through the exercise of reasonable care.

61. Defendants, as manufacturers and/or distributors of the subject Product, are held to the level of knowledge of an expert in the field.

62. Defendants had a continuing duty to warn users (including KIMBERLY PELLEGRIN) and physicians/prescribers (including KIMBERLY PELLEGRIN's treating/implanting physicians) of all of the known dangers associated with the subject product, including but not limited to the serious and permanent injuries outlined herein.
63. Plaintiff, KIMBERLY PELLEGRIN, individually and through her treating/implanting physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants, particularly as same related to the warnings regarding Defendants' Product at issue herein.
64. The warnings that were given by Defendants regarding the Product at issue were not accurate, clear, and/or were ambiguous. The warnings that were given by Defendants failed to properly warn users (including KIMBERLY PELLEGRIN) and physicians/implanters (including KIMBERLY PELLEGRIN's treating/implanting physicians) of the increased risks of permanent physical injuries as outlined herein.
65. Defendants failed to adequately warn consumers of the dangers associated with the Product and said failure caused Plaintiff's injury. If Defendants had issued a proper warning to consumers, Plaintiff would not have had the Product implanted, Plaintiff's treating/implanting physicians would not have allowed the Product to be used or implanted into Plaintiff, and Plaintiff's injuries would have been avoided.
66. The Product has numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health and consequences including that the material in the Product abrades tissues adversely affecting patient health and regularly fail to perform the purpose of its implantation such that the patient requires repair and/or removal of the Product and repeated treatment and surgery.

67. The warnings provided to Plaintiff's healthcare providers in their capacities as learned intermediaries were improper because they did not reflect the full extent of the potential health complications associated with using the Products.
68. Had Defendants adequately warned Plaintiff's healthcare providers of the risks associated with the Product, the healthcare providers, acting as reasonably prudent healthcare providers, would have elected not to use the Product to repair Plaintiff's inguinal hernias and/or umbilical hernia.
69. Defendants acted recklessly, willfully, wantonly and with a significant indifference to, and conscious disregard for the safety of others, including Plaintiff, through their negligent failure to adequately warn Plaintiff to the dangerous and defective nature of the Product. Defendants' reckless disregard for Plaintiff's safety through their inadequate warnings and/or negligent failure to adequately warn her of the dangerous and defective nature of the Product warrants the imposition of punitive damages.
70. As a direct and proximate result of the Defendants' inadequate warnings and/or negligent failure to warn, Plaintiff suffered and will continue to suffer injuries and damages.
71. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for all possible damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT III:
DESIGN DEFECT UNDER LA. R.S. 9:2800.56**

72. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs.
73. The Product is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated

with its design and formulation. The Product was unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

74. At all times material to this action, the Product was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including KIMBERLY PELLEGRIN, without substantial change in the condition in which it was sold.

75. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in the preparation of the Product for use in repairing inguinal hernias.

76. The Product has numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences including that the material in the Product abrades tissues adversely affecting patient health and regularly fail to perform the purpose of its implantation such as the patient requires repair and/or removal of the Product and repeated treatment and surgery.

77. At all times material to this action, the Product was designed, 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:

- a. When placed in the stream of commerce, the Product contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting KIMBERLY PELLEGRIN, to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries and adverse side effects as outlined herein;
- b. When placed in the stream of commerce, the Product was defective in design and formulation, making the use of the Product more dangerous than an ordinary

consumer would expect, and more dangerous than other risks associated with the other similar products on the market;

- c. The design defects of the Product existed before it left the control of Defendants;
- d. The Product was insufficiently and inadequately tested;
- e. The Product caused harmful side effects that outweighed any potential utility; and;
- f. The Product was not accompanied by adequate instructions and/or warnings to fully apprise users, consumers, physicians and/or implanters, including KIMBERLY PELLEGRIN and KIMBERLY PELLEGRIN's treating/implanting physicians, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

78. Defendants were negligent in designing and/or preparing the Product for use in repairing inguinal and/or umbilical hernias. The Product was designed and manufactured improperly. The Defendants have breached their duty to design and manufacture the Product line without any defects.

79. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of KIMBERLY PELLEGRIN's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented KIMBERLY PELLEGRIN's injuries without substantially impairing the product's utility.

80. Defendants acted recklessly, willfully, and wantonly and with significant indifference to, and conscious disregard for the safety of others, including Plaintiff, through their negligent

design and manufacture of the Product, a dangerous and defective product. Defendant's reckless disregard for Plaintiff's safety through their defective design and manufacture of the Products warrants the imposition of punitive damages.

81. As a direct and proximate result of the Defendants' defective design of their Product, Plaintiff suffered and will continue to suffer injuries and damages as outlined herein.

82. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for all possible damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT IV:
BREACH OF EXPRESS WARRANTY UNDER LA. R.S. 9:2800.58**

83. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs.

84. Defendants expressly represented to KIMBERLY PELLEGRIN, KIMBERLY PELLEGRIN's treating/implanting physicians, other consumers, and the medical community that the Product was safe and fit for its intended purposes, was of merchantable quality, had been adequately tested, and did not produce dangerous side effects which it actually does produce (e.g., the Product abrades tissues adversely affecting patient health and regularly fails to perform the purpose of its implantation such that the patient requires repair and/or removal of the Product and repeated treatment and surgery).

85. The Product at issue does not conform to its/Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to: the Product abrades tissues adversely affecting patient health and regularly fails to perform the purpose of its implantation such that the

patient requires repair and/or removal of the Product and repeated treatment and surgery, as well as other serious injuries and side effects.

86. At the time of the making of the express warranties regarding the Product, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the Product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of Defendants as provided by La. R.S. 9:2800.58.

87. At the time of the making of the express warranties regarding the Product, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the Product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

88. At all relevant times the Product did not perform as safely as an ordinary consumer (including Plaintiff and Plaintiff's treating physicians) would expect, when used as intended or in a reasonably foreseeable manner.

89. KIMBERLY PELLEGRIN, KIMBERLY PELLEGRIN's treating/implanting physicians, other consumers, and the medical community relied upon the Product's/Defendants' express warranties and/or representations. KIMBERLY PELLEGRIN purchased and/or allowed the Product to be used/implanted as a result of its/Defendants' express warranties and/or representations, and KIMBERLY PELLEGRIN's treating/implanting physicians used, prescribed and/or implanted the Product (relative to Plaintiff) as a result of its/Defendants' express warranties and/or representations. Moreover, because the Product did not conform to its/Defendants' express

warranties and/or representations, KIMBERLY PELLEGRIN sustained significant injuries and damages as outlined herein.

90. As a direct and proximate result of the Defendants' breach of express warranty relative to the Product, Plaintiff suffered and will continue to suffer injuries and damages as outlined herein.

91. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for all possible damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT V:
REDHIBITION**

92. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs.

93. The Product contains a vice or defect which renders it useless or its use so dangerous that buyers, including KIMBERLY PELLEGRIN, would not have purchased it had she been aware of same.

94. Defendants sold and promoted the Product, which Defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The Product sold and promoted by Defendants possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the Product useless or so inconvenient that it must be presumed that a buyer would not have bought the Product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the Product.

95. The Product alternatively possesses a redhibitory defect because the Product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the Product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction of the purchase price.
96. Defendants are liable as a bad faith seller for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff for the price of the Product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the Product and attorneys' fees. As the manufacturer of the Product, under Louisiana law, Defendants are deemed to know that Product possessed a redhibitory defect. La. C.C. art. 2545.
97. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for all possible damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

OTHER/ALTERNATIVE COUNTS

98. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs.
99. In the instance that Louisiana's Product Liability Law is deemed inapplicable to the instance matter and/or if another State's law is deemed applicable, Plaintiff makes the following common law and/or other claims against all defendants— using the same operative facts as outlined herein.
100. Breach of Warranty of Fitness for Ordinary Use.
101. Negligence.

102. Breach of Implied Warranty.
103. Negligent Misrepresentation.
104. Negligent Design.
105. Attorney Fees. As a result of Defendants wrongful acts as set forth above, Plaintiff has been compelled to retain The Andry Law Group, LLC to pursue this action. Plaintiff should be awarded attorney fees and costs pursuant to applicable law.

DAMAGES

106. Plaintiff KIMBERLY PELLEGRIN was seriously injured as a result of the actions/inactions of the Defendants and/or as a result of using the Product of Defendants.
107. Plaintiff KIMBERLY PELLEGRIN suffered unnecessarily as a result of the actions/inactions of the Defendants and/or as a result of using the Product of Defendant.
108. As a result of the actions/inactions of the Defendants and/or as a result of using the Product of Defendants, Plaintiff KIMBERLY PELLEGRIN has suffered and/or incurred and will suffer and/or incur damages, including but not limited to: past and future physical pain and suffering, past and future mental anguish, past and future loss of enjoyment of life, past and future inconvenience, past and future medical expenses, past and future lost wages, permanent injury, permanent scarring and/or disfigurement, and other damages which will be proven at the trial of this matter.

WHEREFORE, Plaintiff requests that the Court grant relief against the Defendants and hereby demands a trial by jury as to all issues set forth in this Complaint.

Signed, this 14th day of November, 2017.

Respectfully Submitted,

By: /s/ Jonathan B. Andry
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