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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

STEVEN JOHNS, Plaintiff, vs. C.R. BARD, INC., and DAVOL, INC., Defendants.	**AMENDED COMPLAINT AND JURY DEMAND** Civil Action No. 2:18-cv-01509 Chief Judge: Edmund A. Sargus, Jr. Magistrate Judge: Kimberly A. Jolson

Plaintiff STEVEN JOHNS, by and through his undersigned attorneys, Robert J. Debry and Associates, alleges as follows:

NATURE OF THE CASE

1. This is a medical device tort action brought by Plaintiff STEVEN JOHNS ("Plaintiff") for injuries arising out of the failure of a Ventralight ST hernia mesh patch he received as part of a ventral hernia repair surgery.

2. Prior to August 2015, Defendants knew, or should have known, based on reports received from general surgeons around the U.S., that the Ventralight ST hernia mesh patch was defective and likely to fail. Defendants concealed this adverse information and continued to represent to Plaintiff, his healthcare providers, and the public that the Ventralight ST hernia mesh patch was a safe, effective medical device with a low failure rate.

3. Subsequent to implantation of the Ventralight ST hernia mesh patch, Plaintiff began to experience the painful effects of the product's defective design and manufacture. Plaintiff began suffering pain, recurrence of the hernia, and decreased mobility, which worsened over time. While Plaintiff's physicians searched for the cause of Plaintiff's pain, Plaintiff continued to endure persistent, debilitating pain. Plaintiff began suffering emotional distress as a result of the defective product. Plaintiff was required to undergo revision surgery to remove and replace the defective hernia mesh patch.

4. Revision surgery to remove the failed hernia mesh patch and replace it with a new implant is a complex, risky and painful procedure. Revision surgeries are generally more complex than the original hernia repair. Revision surgeries also are usually longer than the original hernia repair because the defective hernia mesh patch had adhered to the abdominal wall and other anatomical structure, putting the Plaintiff at a higher risk for complications.

5. After the revision surgery, Plaintiff endured a second recovery that was both physically and emotionally painful. Additionally, Plaintiff must live with a greater risk of future complications as a revised hernia presents a much higher risk of recurrence than an original repair.

PARTIES

6. At all times material hereto, Plaintiff was a resident of Davis County, State of Utah.

7. Defendant C.R. BARD, INC. is, a corporation existing under the laws of the State of New Jersey with its principal place of business located at 730 Central Ave., Murray Hill, New Jersey 07974.

8. Defendant C.R. BARD, INC. designed, manufactured, marketed, promoted and sold the Ventralight ST hernia mesh patch that is the subject of this lawsuit.

9. Defendant DAVOL, INC. is, and at all times relevant to this complaint was, a wholly owned subsidiary of Defendant C.R. BARD, INC. Defendant DAVOL, INC. is, and at

all times relevant to this complaint was, a corporation existing under the laws of the State of Delaware with its principle place of business located at 100 Crossing Blvd. Warwick, RI 02886.

10. Defendant DAVOL, INC. designed, manufactured, marketed, promoted and sold the Ventralight ST hernia mesh patch that is the subject of this lawsuit.

11. C.R BARD, INC. and DAVOL, INC. are collectively referred to hereinafter as "Defendants."

12. At all times relevant to this complaint, Defendants were the agents of each other, and in doing things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of it Co-defendants.

JURISDICTION AND VENUE

13. This court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 (a) as the parties are citizens of different states, and the amount in controversy exceeds $75,000 exclusive with interests and costs.

14. This court has supplemental jurisdiction over the remaining common law and State law claims pursuant to 28 U.S.C. §1331, *et seq.,* because a substantial part of the events, acts or omissions giving rise to Plaintiff's claim occurred in Utah and within this district.

15. Venue is proper in the United States District Court for the District of Utah pursuant to 28 U.S.C. §1331, *et seq.*, because a substantial part of the events, acts or omissions giving rise to Plaintiff's claim occurred in Utah and within this district.

16. This case is subject to transfer to the Davol, Inc./C.R. Bard, Inc. Polypropylene Hernia Mesh Products Liability Litigation (MDL 2846), in the United States District Court, Southern District of Ohio. Plaintiff does not waive any jurisdiction rights including, but not limited to, those recognized in *Lexicon, Inc. v. Milberg, Weiss, Bershad, Hynes & Lerach*, 523 US

26 (1998). Plaintiff respectfully requests that this case be transferred to the above-referenced District Court at the time of transfer for trial proceedings.

FACTUAL BACKGROUND

A. The Ventralight ST Mesh Hernia Patch Was Defective And Was Not Adequately Tested

17. A hernia occurs when an organ, intestine, or fatty tissue squeezes through a hole or a weak spot in the surrounding muscle or connective tissue. Hernias often occur at the abdominal wall. Sometimes a hernia can be visible as an external bulge particularly when straining or bearing down. Most hernias are caused by a combination of pressure and an opening or weakness of muscle or connective tissue. The pressure pushes an organ or tissue through the opening or weak spot.

18. Hernia repair refers to a surgical operation for the correction of a hernia. A ***hernioplasty*** is a specialized surgical procedure that treats a hernia by pushing the organ and/or tissue back to its original position and adding a synthetic meshwork or patch to act as support.

19. Defendants' Ventralight ST hernia mesh patch is a monofilament polypropylene mesh used in hernioplasty.

20. At all times material hereto, the Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Ventralight ST Mesh hernia patch at issue in this case. By said activities, Bard's Ventralight ST Mesh patch was placed into the stream of commerce throughout the United States, including Utah.

21. At all times material to this action, the Defendants designed, patented, manufactured, labeled, marketed, sold and distributed a line of Ventralight ST Mesh patch.

The Ventralight ST Mesh hernia patch at issue in this case was cleared for sale in the U.S. after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety of efficacy.

22. The Ventralight ST mesh suffers from a design or manufacturing defect. The Ventralight ST Mesh is co-knitted using polypropylene (PP) and polyglycolic acid (PGA) fibers to result in a two-sided mesh. On the posterior side, the mesh is coated with a barrier based on Sepra ® Technology (hereinafter "ST barrier"). This was designed to separate the mesh from the underlying tissue and organ surfaces to minimize tissue attachment to the mesh.

23. The design of the Ventralight ST mesh patch was not sufficiently tested by Defendants.

24. These manufacturing and design defects associated with the Ventralight ST Mesh were directly and proximately related to the injuries suffered by Plaintiff.

25. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of the Ventralight ST Mesh. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the Ventralight ST Mesh.

26. The Ventralight ST Mesh implanted in Plaintiff failed to reasonably perform as intended. The Ventralight ST Mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Ventralight ST Mesh was initially implanted to treat.

27. At the time the Ventralight ST Mesh was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the Ventralight

ST Mesh would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

28. On numerous occasions, Defendants met with surgeons throughout the United States to promote the Ventralight ST mesh. At all of these meetings, a representatives or representatives from Defendants were present. During these meetings, Defendants assured the surgeons, that the Ventralight ST mesh was safe, was the best product on the market, and had an excellent track record and a low and acceptable failure rate. Defendant continued to "defend" the Ventralight ST mesh even after they became aware of numerous and serious complications with the Ventralight ST mesh. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with surgeons.

B. Defendants Sold the Ventralight ST Mesh To Plaintiff After They Knew It Was Defective, That It Had Injured Others, And That It Would Injure Plaintiff

29. It wasn't long after Defendants launched the Ventralight ST mesh that reports of failures were reported to Defendants.

30. Defendants received complaints reporting that the Ventralight ST mesh had failed and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed mesh.

31. Upon information and belief, by the time Defendants sold the Ventralight ST mesh to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the Ventralight ST mesh. Consequently, Defendant was fully aware that the Ventralight ST mesh was defective and that dozens of other patients already had been injured by that defect. Based on this information, Defendants should have recalled the Ventralight ST mesh before it was sold

to Plaintiff. At minimum, Defendants should have stopped selling the defective Ventralight ST mesh when it became aware that it had catastrophically failed in several patients.

32. Upon information and belief, despite its knowledge that the Ventralight ST mesh had a defect and that it had failed, causing patients to undergo the agony of another surgery, Defendants continue to sell the defective Ventralight ST mesh. In so doing, Defendants actively concealed the known defect from doctors and patients—including Plaintiff and Plaintiff's doctor—and misrepresented that that the Ventralight ST mesh was a safe and effective medical device.

33. Upon information and belief, as numerous failures of the Ventralight ST mesh were reported to Defendants, it continued to actively promote, market and defend the defective products. For example, Defendants published marketing brochures touting the safety and durability of Ventralight ST mesh. These brochures were given to doctors, including Plaintiff's surgeon, to encourage them to use the Ventralight ST mesh.

34. Defendants did not want to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Defendants decided that it would continue to promote, market, and sell Ventralight ST mesh despite the fact that it knew the product was defective. To this day, Defendants continue to sell the Ventralight ST mesh to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff's Ventralight ST Mesh Was Defective And Failed, Forcing Plaintiff To Undergo An Additional Painful And Risky Surgery

35. Feasible and suitable alternatives to the Ventralight ST mesh have existed at all times relevant to the Plaintiff's August 7, 2015, October 4, 2016 and April 16, 2019 hernia repairs and did not present the same frequency or severity of risks as the Ventralight ST mesh.

36. The Ventralight ST mesh was at all times utilized and implanted in a manner foreseeable to and in fact intended by the Defendant, its instructions and procedures for use and its training of the health care providers.

37. The Ventralight ST mesh was implanted in Plaintiff in the same or substantially similar condition as when it left Defendant's possession.

38. Defendants failed and refused to disclose the information about adverse events to Plaintiff, his physicians, or the public. Instead, Defendants misrepresented to Plaintiff and his surgeon that the Ventralight ST Mesh was safe and effective.

39. In reliance on these representations, Plaintiff's surgeon made the decision to use the Ventralight ST Mesh. If it were not for the misrepresentations made by Defendants, Plaintiff's surgeon would not have used the Ventralight ST Mesh in Plaintiff's hernia repair surgery.

40. Defendants manufactured, sold, and/or distributed the Ventralight ST Mesh product to Plaintiff through his doctors, to be used for repair of his repair.

41. Plaintiff underwent a diastasis recti and ventral hernia repair on August 7, 2015 at Ogden Regional Medical Center, in Ogden, Utah with Joseph W. Jensen, D.O. During this procedure, Plaintiff received a Ventralight ST hernia mesh patch, Lot No. HUZD0242; Serial No. 5955680. On October 14, 2016, Plaintiff underwent a second diastasis recti ventral hernia repair at Ogden Regional Medical Center, in Ogden Utah with Joseph W. Jensen, D.O. During this procedure, the previously placed Ventralight ST hernia patch was removed; Dr. Jensen reinforced the repairs with a Ventralight ST hernia mesh patch, Lot No. HCAU1314; Serial No. 5955680. On April 15, 2019 Plaintiff underwent a third surgery to repair a recurrent diastasis recti and ventral hernia. This procedure was performed by Joseph Jensen, D.O. at Davis Medical Center, in Layton, Utah. Upon information and belief, adverse events associated with the

Ventralight ST Mesh had been filed with the FDA and Defendants knew that the product was defective.

42. After receiving the Ventralight ST Mesh, Plaintiff began to experience pain. On October 4, 2016 Plaintiff returned to surgery with Dr. Joseph W. Jensen at Ogden Regional Medical Center for removal of the previously placed Ventralight ST hernia mesh patch. Dr. Jensen noted, "lengthy arthroscopic lysis of adhesions was undertaken to all the attachments in the old surgical mesh." On April 15, 2019 Plaintiff returned to surgery with Joseph W. Jensen, D.O. at Davis Medical Center for open repair of a recurrent hernia at the site of the previously placed Ventralight ST hernia mesh patch.

43. Revision surgery is more complex than the original surgery, often because the mesh has to be dissected from surrounding tissues and/or anatomical structures. Revision surgeries also usually take longer than the original surgery and the revision surgery has a higher rate of complications.

44. As a direct and proximate result of the failure of the defective Ventralight ST Mesh and Defendants 's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000.00 jurisdictional minimum of this court.

FIRST CAUSE OF ACTION
NEGLIGENCE

45. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, alleges as follows:

46. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Ventralight hernia repair system into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

47. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the Ventralight hernia repair system into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

48. Despite the fact that Defendants knew or should have known that the Ventralight hernia repair system posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Ventralight hernia repair system for use by consumers and/or continued to fail to comply with federal requirements.

49. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

50. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

51. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Ventralight hernia repair system when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of

human life so as to warrant the imposition of punitive damages.

52. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

53. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, alleges as follows:

54. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of hernia repair mesh including the Ventralight Hernia Mesh.

55. Defendants' Ventralight ST hernia mesh patch was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Ventralight ST hernia mesh patch , there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

56. The Ventralight ST hernia mesh patch was defective when it left the Defendants control. The defects made the product unreasonably dangerous to the Plaintiff, and such defects resulted in the Plaintiff's injuries.

57. There was no substantial change in the condition of the Ventralight ST hernia mesh patch from the time it left Defendants control until the time it was implanted in the Plaintiff.

58. When affixed to the body's tissue, the impermeable coating of the Ventralight ST hernia mesh patch prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

59. The ST coating provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

60. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the Ventralight ST hernia mesh patch. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. Ventralight ST hernia mesh patch implanted with spores will eventually result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the Ventralight ST hernia mesh patch. The following non-exhaustive literature discusses the necessity of moisture during ETO sterilization:

61. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed.

> ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process.
>
> Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an

> atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.
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> Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

62. The Ventralight ST hernia mesh patch is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), which results in the inability to properly validate sterilization.

63. The coating on the Defendants' Ventralight ST hernia mesh patch is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

64. The ST coating is designed and intended to resorb in less than 30 days.

65. When the ST coating is disrupted, degrades, and/or resorbs, the "naked" polypropylene mesh and PGA is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause incarceration of organs, and fistula formation.

66. The Ventralight ST hernia mesh patch has a solid, flat, relatively smooth and continuous surface, which promotes tumor and cancer formation via the "Oppenheimer Effect." A phenomenon identified in the 1950s.

67. The solid, flat, relatively smooth and continuous surface of the Ventralight ST hernia mesh patch inhibits the body's ability to clear toxins.

68. These manufacturing and design defects associated with the Ventralight ST hernia mesh patch were directly and proximately related to the injuries suffered by Plaintiff.

69. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or

informed by Defendants of the defective and dangerous nature of the Ventralight ST hernia mesh patch. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the Ventralight ST hernia mesh patch.

70. The Ventralight ST hernia mesh patch implanted in Plaintiff failed to reasonably perform as intended. The Ventralight ST hernia mesh patch caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Ventralight ST hernia mesh patch was initially implanted to treat.

71. At the time the Ventralight ST hernia mesh patch that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the Ventralight ST hernia mesh patch would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

72. Defendants expected and intended the Ventralight ST hernia mesh patch product to reach users such as Plaintiff in the condition in which the product was sold.

73. The implantation of Ventralight ST hernia mesh patch in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

74. The risks of the Ventralight ST hernia mesh patch significantly outweigh any benefits that Defendants contend could be associated with the product. The ST coating, which is not used in any other hernia mesh product sold in the United States, incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ST coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the

body's natural immune response. This ST coating also caused immunogenic response, and was known to be cytotoxic.

75. The coating of the Ventralight ST hernia mesh patch, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh and PGA exposed to the internal viscera and tissues. Once exposed to the viscera, the polypropylene and PGA will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

76. At all relevant times, the Ventralight ST hernia mesh patch was defectively manufactured and designed by the Defendants in their design and formulation is more dangerous than an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

77. The Plaintiff and Plaintiff's surgeon expected that the Ventralight ST hernia mesh patch would not adhere to the Plaintiff's underlying organs.

78. The Ventralight ST hernia mesh patch malfunctioned, in that the Plaintiff's abdominal wall adhered to the mesh.

79. The polypropylene mesh within the defective coating of the Ventralight ST hernia mesh patch was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Ventralight ST hernia mesh patch. The particular polypropylene material used in the Ventralight ST hernia mesh patch was substandard, adulterated and non-medical grade,

and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the ST coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for Ventralight ST hernia mesh patch, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

80. The appropriate treatment for complications associated with Ventralight ST hernia mesh patch involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

81. The Ventralight ST hernia mesh patch was designed and intended for intraperitoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

82. At the time the Ventralight ST hernia mesh patch was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products, including but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

83. The Ventralight ST hernia mesh patch product cost significantly more than competitive products because of its unique ST coating, even though the ST coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

84. The Ventralight ST hernia mesh patch has a solid, flat, relatively smooth and continuous surface. Medical devices which utilize this design greatly increase the risk of tumor and cancer formation:

85. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the

Presarcomatous Stage was published in the Journal of Cancer.

> **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not a present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**
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> Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presarcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

86. The Ventralight ST hernia mesh patch implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

87. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

88. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

89. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Ventralight ST hernia mesh patch.

90. Defendants expected and intended the Ventralight ST hernia mesh patch product to

reach users such as Plaintiff in the condition in which the product was sold.

91. The implantation of Ventralight ST hernia mesh patch in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured, and sold the product.

92. The Ventralight ST hernia mesh patch manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

93. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Ventralight ST hernia mesh patch implanted in Plaintiff. The Ventralight ST hernia mesh patch implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

94. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ST coating on their finished Ventralight ST hernia mesh patches, which deviated from Defendants' material and supply specifications.

95. As a direct and proximate result of the Plaintiff's use of Defendants' Ventralight ST hernia mesh patch as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

96. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

97. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

98. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

99. Defendants, as manufacturers and/or distributors of the Ventralight ST hernia mesh patch are held to the level of knowledge of an expert in the field.

100. Defendants had a duty to test the Ventralight ST hernia mesh patch.

101. Defendants had a duty to keep abreast of scientific knowledge, discoveries, and advances related to the Ventralight ST hernia mesh patch, hernia mesh in general, and hernia repairs.

102. Defendants must have known, or through the exercise of reasonable care would have been able to discover the defects of the Ventralight ST hernia mesh patch.

103. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

104. Plaintiff, individually and through his physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

105. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

106. At the time the Ventralight ST hernia mesh patch was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the Ventralight ST hernia mesh patch

were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

107. Defendants expected and intended the Ventralight ST hernia mesh patch to reach users such as Plaintiff in the condition in which the product was sold.

108. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of Ventralight ST hernia mesh patch, and were unaware of the frequency, severity and duration of the risks associated with the Ventralight ST hernia mesh patch.

109. The Defendants' Instructions for Use provided with the Ventralight ST hernia mesh patch expressly understates and misstates the risks known to be associated specifically with the Ventralight ST hernia mesh patch by representing that the complications, such as inflammation, associated with the Ventralight ST hernia mesh patch are "possible complications." The Ventralight ST hernia mesh patch will incite severe inflammation once implanted. The inflammation caused by the Ventralight ST hernia mesh patch is chronic in nature and systemic, not acute localized inflammation. No other surgical mesh sold in the United States has the dangerous and defective ST coating, which itself causes or increases the risks of numerous complications, including increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Ventralight ST hernia mesh patch.

110. The Defendants' Instructions for Use for the Ventralight ST hernia mesh patch failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or

should have known were associated with the Ventralight ST hernia mesh patch, including the risks of the product's immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

111. Defendants failed to adequately train or warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

112. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the Ventralight ST hernia mesh patch in the event of complications would leave the hernia unrepaired, the resulting hernia would be much larger than the original, and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed Ventralight ST hernia mesh patch was intended to treat.

113. Defendants represented to physicians, including Plaintiff's physician, that the ST coating would prevent or reduce adhesions, and expressly intended for the Ventralight ST hernia mesh patch to be implanted in contact with the bowel and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the ST coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

114. Defendants marketed and continue to market the Ventralight ST hernia mesh patch in brochures and online without disclosing or making evident that PGA is utilized in the Ventralight ST hernia mesh patch.

115. With respect to the complications that were listed in the Defendants' warnings,

Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Ventralight ST hernia mesh patch were more frequent, more severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

116. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of Ventralight ST hernia mesh patch, and of the frequency, severity and duration of the risks associated with the Ventralight ST hernia mesh patch, Plaintiff would not have consented to allow the Ventralight ST hernia mesh patch to be implanted, and Plaintiff's physicians would not have implanted the Ventralight ST hernia mesh patch in Plaintiff.

117. Defendants had a continuing duty to warn consumers and the public, including Plaintiff, of the dangers associated with the Ventralight ST hernia mesh patch, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

118. As a direct and proximate result of the Plaintiff's use of the Ventralight ST hernia mesh patch, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the Ventralight hernia repair system and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

119. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

120. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief

as the Court deems proper.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

121. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

122. Defendants expressly warranted that the Ventralight ST hernia mesh patch was a safe and effective device for those patients requiring hernia repair.

123. The Ventralight ST hernia mesh patch manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed.

124. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

125. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Ventralight hernia repair system when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

126. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

127. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, alleges as follows:

128. Defendant impliedly warranted that the subject mesh was merchantable and was fit for the ordinary purposes for which it was intended.

129. When the mesh was implanted in the Plaintiff to treat a hernia, the product was being used for the ordinary purpose for which it was intended.

130. Plaintiff, individually and/or by and through his providers, relied upon Defendant's implied warranties of merchantability in consenting to have the subject mesh implanted.

131. The Defendant breached these implied warranties of merchantability because the Product implanted in Plaintiff was neither merchantable nor suited for their intended uses as warranted, including the following:

a. Defendants represented to Plaintiff and his physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

b. Defendants represented to Plaintiff and his physicians and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time, they fraudulently concealed information demonstrating that the product was not safer than alternatives

available on the market; and

c. Defendants represented to Plaintiff and his physicians and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Ventralight ST hernia mesh patch.

132. Defendant's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product which placed Plaintiff's health and safety in jeopardy.

133. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.

134. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Ventralight hernia repair system when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

135. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

136. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, alleges as follows:

137. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Ventralight ST hernia mesh patch.

138. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Ventralight ST hernia mesh patch, Defendants knew the use for which the Ventralight ST hernia mesh patch was intended, and impliedly warranted the Ventralight ST hernia mesh patch to be safe for such use.

139. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Ventralight ST hernia mesh patch was safe for its intended use.

140. Contrary to Defendants' implied warranties, the Ventralight ST hernia mesh patch was not safe for its intended use or fit for the particular purpose for which it was designed, manufactured, tested, distributed or sold – for use and implantation as a hernia repair system, because the Ventralight ST hernia mesh patch was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

141. Defendants' actions, representations, and/or omissions violate Utah Code Ann. § 70A-2-314.

142. As a direct and proximate result of Defendants' breach of implied warranty of merchantability regarding the safety and effectiveness of the Ventralight ST hernia mesh patch, Plaintiff experienced and/or will experience significant damages, including but not limited to

physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

143. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Ventralight ST hernia mesh patch. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
VIOLATION OF CONSUMER PROTECTION LAWS

144. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

145. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Ventralight hernia mesh patch as a high-quality, safe and effective hernia repair system to Plaintiff and Plaintiff's physicians.

146. Before they advertised, marketed, sold and represented the Ventralight hernia mesh patch that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks posed by the Ventralight hernia repair system posed to patients like Plaintiff.

147. Plaintiff purchased and used the Ventralight hernia mesh patch for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer

protection laws.

148. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Ventralight hernia repair system, and would not have incurred related medical costs and injury.

149. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Ventralight hernia mesh patch that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

150. Unfair methods of competition or deceptive acts or practices that were prescribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

151. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Ventralight hernia repair system. Each aspect of Defendants' conduct combined to artificially create sales of the Ventralight hernia repair system.

152. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Ventralight hernia repair system.

153. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Ventralight hernia repair system, and would not have incurred related medical costs.

154. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

155. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

156. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of Utah Consumer Protection Act, §13-11-1, *et seq.*

157. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

158. Defendants violated the statutes that were enacted by the State of Utah to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Ventralight hernia mesh patch was fit to be used for the purpose for which it was intended, when in fact the device was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

159. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted by the State of Utah to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

160. Defendants had actual knowledge of the defective and dangerous condition of the Ventralight hernia mesh patch and failed to take any action to cure such defective and dangerous conditions.

161. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which mesh implant device to use and recommend.

162. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

163. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

164. As specifically described in detail above, Defendants knew that the Ventralight hernia mesh patch subjected patients to early failure, is incompatible with human tissue, can trigger an immune response and/or other painful and harmful physical reactions to Ventralight hernia mesh patch, which can bring about a need to explant the hernia mesh patch via revision surgery.

165. As a direct and proximate result of Defendants' representations, Plaintiff has experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for revision surgery to repair the physical damage to Plaintiff caused by the Ventralight hernia repair system.

166. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety

and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Ventralight hernia repair system. Defendants' outrageous conduct warrants an award of punitive damages.

NINTH CAUSE OF ACTION
Negligent Misrepresentation and/or Fraud

167. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

168. Defendants knowingly and intentionally made material, false and misleading representations to Plaintiff, his physicians, and to the public that the Defendants' Ventralight ST hernia mesh patch had been adequately tested and was safe and effective.

169. Defendants' representations were in fact false, as Defendants' Ventralight ST hernia mesh patch had not been adequately tested and was not safe and effective.

170. Defendants knew, or should have known, that Ventralight ST hernia mesh patch created an unreasonable risk of serious bodily injury or death to consumers.

171. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff Steven Johns, and the public in general, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense, and/or purchase the subject product, all of which is evidence of callous, reckless, and willful disregard for the health, safety, and welfare of Plaintiff Steven Johns.

172. At the time said representations were made by Defendants, and at the time Plaintiff Steven Johns used the subject products, Plaintiff and/or his medical providers were unaware of the falsity of said representations and reasonably believed them to be true.

173. In justifiable reliance upon said representations, Plaintiff and/or his medical providers were induced to and did have implanted the Ventralight ST hernia mesh patch for use as a hernia mesh implant, thereby causing Plaintiff to suffer severe personal injuries.

174. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentations, Plaintiff Steven Johns suffered harm, damages, and economic loss.

175. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, willfully, wantonly, fraudulently, and/or with reckless indifference and disregard toward the safety and rights of others, so as to warrant the imposition of punitive damages.

TENTH CAUSE OF ACTION
Punitive Damages

176. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

177. Plaintiff alleges Defendants C.R. Bard, Inc. and Davol, Inc. engaged in intentional, willful, wanton, and reckless conduct with conscious disregard for the safety of consumers including Plaintiff Steven Johns.

178. Based on information and belief, C.R. Bard, Inc. and Davol, Inc. actually knew the Ventralight ST hernia mesh patch's defective nature but continued to design, manufacture, market and sell the Ventralight ST hernia mesh patch so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Ventralight ST hernia mesh patch.

179. C.R. Bard, Inc. and Davol, Inc.'s conduct entitles Plaintiff to punitive damages in an amount appropriate to punish and set an example of C.R. Bard, Inc. and Davol, Inc.

WHEREFORE, Plaintiff demands judgment for damages from the Defendant for an

amount in excess of Seventy-five Thousand Dollars ($75,000.00) together with interest and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with the interest and costs as provided by the law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff attorney's fees;

4. Awarding Plaintiff the costs of the proceedings; and

5. Such other and further relief as this Court deem just and proper.

REQUEST FOR JURY TRIAL

The Plaintiff herein requests trial by jury of all issues triable by right.

DATED: June 19, 2019.

By: /s/ Nancy A. Mismash
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