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JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS				DEFENDANTS						
(b) County of Residence of First Listed Plaintiff Windham County.				Allergan, USA, Inc., LIfecell Corp., C.R. Bard, Inc., and Davnl Inc. County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)						
(c) Attomcys (Firm Name, Address, and Telephone Number) The Reardon Law Firm, P.C.160 Hempstead Street,				NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND IN VOLVED. Attorneys (If Known)						
New London, CT	06320 (860) 4	42-0444								
II. BASIS OF JURISDI	III. CI	II. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plainiff (For Diversity Cases (Only) and One Box for Defendant)								
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VI. CAUSE OF ACTION	of cause: - Personal Injury Based on Failure of Surgical Mesh									
VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS UNDER RULE 23, F.R.Cv.P.		THIS IS A CLASS ACTIO	N I	DEMAND S CHECK YES only if demanded in complaint: 3,000,000.00 JURY DEMAND: Yes No						
VIII. RELATED CAS IF ANY	E(S) (See instructio	ns): JUDGE				D●C	KET NUMBER			
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REC'EIPT # AMOUNT		APPLYING JFP		JUDGE		MAG. JUDGE				

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF CONNECTICUT

PASQUALE BERNARDO	:
Plaintiff,	:
ν.	: NO:
ALLERGAN USA, INC., LIFECELL CORP., C.R. BARD, INC., AND DAVOL INC.	: : <u>JURY TRIAL DEMANDED</u>
Defendants.	: January 6, 2022

CIVIL ACTION COMPLAINT

The Plaintiff, Pasquale Bernardo (hereinafter "Plaintiff") by and through undersigned counsel, hereby files this Complaint against the Defendants Allergan USA, Inc., Lifecell Corp., C.R. Bard, Inc., and Davol Inc. and states as follows:

PARTIES

1. At all relevant times, Plaintiff was a citizen of the state of Connecticut, County of Windham.

2. At all relevant times, Defendant Allergan USA, Inc. (hereinafter "Allergan") was a foreign corporation with its corporate headquarters located at Clonshaugh Business and Technology Park Coolock, Dublin, Ireland. Allergan's United States Administrative headquarters are located at 5 Giralda Farms, Madison, New Jersey. Allergan acquired Lifecell, Corp. on or before February 2017. Allergan is a developer, manufacturer, producer, seller, marketer, and promoter of medical Devices including Hernia Mesh Devices.

3. At all relevant times, Defendant Lifecell Corp. (hereinafter "Lifecell") was a New Jersey corporation with its corporate headquarters located at 1 Millenium Way,

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Branchburg, New Jersey. Lifecell is a subsidiary of Allergan. Lifecell is a developer, manufacturer, producer, seller, marketer, and promoter of medical Devices including Hernia Mesh Devices.

4. At all relevant times, Defendant C.R. Bard, Inc. (hereinafter "Bard") was incorporated and based in New Jersey with its corporate headquarters located at 730 Central Avenue, Murray Hill, New Jersey. Bard is the corporate parent/stockholder of Davol, Inc. Bard is a developer, manufacturer, producer, seller, marketer, and promoter of medical Devices and Devices including Hernia Mesh Devices.

5. At all relevant times, Davol Inc. (hereinafter "Davol") was incorporated in Delaware and has its principal place of business in Rhode Island. Davol is the subsidiary of Bard. Davol is a manufacturer of medical Devices, including Hernia Mesh Devices involved throughout the United States.

6. Allergan USA, Inc., Lifecell Corp., C.R. Bard, Inc., and Davol Inc. are collectively referred to hereinafter as "Defendants."

7. Defendants have derived substantial revenue related to their Hernia Mesh Devices from interstate commerce in each of the states in and territories of the United States, including the State of Connecticut.

8. Defendants are individually and jointly and severally liable to Plaintiff for damages he suffered arising from the design, manufacture, marketing, labeling, improper/inadequate warnings, distribution, sale, and placement of Defendants' Hernia Mesh Devices, effectuated directly and indirectly through Defendants' agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

9. Defendants are also vicariously liable for the acts and omissions of their employees and/or agents who were at all relevant times acting on Defendants' behalf and within the scope of their employment or agency.

JURISDICTION AND VENUE

10. Pursuant to 28 U.S.C. §1332(a), there is complete diversity among Plaintiff and the Defendants and the amount in controversy exceeds \$75,000.

11. Defendants have significant contacts with the state of Connecticut such that it is subject to the personal jurisdiction of the court.

12. A substantial part of the events and omissions giving rise to Plaintiff's causes of actions occurred in the State of Connecticut. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the United States District Court for the District of Connecticut.

FACTUAL BACKGROUND

13. At all times relevant hereto, the Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold, and otherwise engaged in activities that are part and parcel of the sale and distribution of the Hernia Mesh Devices (hereinafter "mesh," "surgical mesh," "Devices") at issue in this matter. By way of said activities, the Defendants' Hernia Mesh Devices were placed into the stream of commerce in the United States, including into the State of Connecticut.

14. At all times relevant hereto, the Defendants designed, patented, manufactured, labeled, marketed, sold, and distributed a line of Hernia Mesh Devices

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which are medical Devices generally used to repair weakened or damaged tissue, including hernias.

15. The Devices are made from porous absorbable or non-absorbable synthetic material or absorbable biologic material.

16. The Defendants' Devices at issue in this case were cleared for sale in the U.S. after Defendants made assertions the Food and Drug Administration (FDA) 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.

17. The Plaintiff was first operated on to repair a hernia, during which operation, surgical mesh manufactured, sold, and marketed by the Defendants was implanted. The Device was implanted in Plaintiff to treat his ventral hernia, the uses for which the Devices were designed, marketed, and sold.

18. The surgical mesh used in Plaintiff's first hernia repair was known as "Strattice Reconstructive Tissue Matrix" (hereinafter "Strattice" and "Strattice mesh") and was designed, manufactured, packaged, labeled, marketed, sold, and distributed by Lifecell, a subsidiary of Allergan. The implantation surgery was performed by Dr. Mark E. Tramontozzi at Backus Hospital in Norwich, CT on November 14, 2011.

19. The Strattice was made of materials which are biologically incompatible with human tissue and react negatively and sometimes dangerously with a substantial number of people on whom it is used.

20. Scientific evidence has shown that Strattice mesh causes pain, infections, hernia recurrence, adhesion, and bowel obstruction.

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21. As a result of having the Strattice mesh implanted, the Plaintiff has experienced significant mental and physical pain, and suffering and mental anguish, has sustained permanent injuries, has undergone medical treatment, underwent additional surgeries to treat the recurrent incisional hernia, and will likely undergo further treatment.

22. Defendants Allergan and Lifecell were, or should have been, aware of the dangers inherent in the Strattice mesh.

23. After the Strattice mesh was removed, Plaintiff underwent two surgeries to repair his recurrent hernia, without success.

24. Plaintiff underwent a fourth hernia repair surgery, where he was implanted with Bard's Ventralight ST surgical mesh (hereinafter "Ventralight mesh"). The Ventralight mesh was designed, manufactured, packaged, labeled, marketed, sold, and distributed by Bard and Davol. The surgery was performed by Dr. Sergio Casillas-Romero at Backus Hospital in Norwich, CT on December 14, 2015, for the purpose of repairing Plaintiff's recurrent hernia.

25. The Ventralight mesh was made of materials which are biologically incompatible with human tissue and react negatively and sometimes dangerously with a substantial number of people on whom it is used.

26. Specifically, the Ventralight mesh implanted into Plaintiff contained polypropylene which is known to cause adverse reactions and injuries in patients, including Plaintiff.

27. Adverse reactions to the polypropylene in the Devices consist of the following:

- Adhesions, injuries to nearby organs, nerves or blood vessels, and other complications including infection, pain and hernia recurrence;
- b. Degradation and/or fragmentation over time, causing inflammatory and fibrotic reactions that triggers inflammation;
- c. Shrinkage of the mesh;
- d. Wicking of fluids and bacteria, causing a build-up of bacteria; and
- e. Restriction of abdominal wall mobility and local wound disturbance.

28. Additionally, the Ventralight mesh used in the Plaintiff was a "Sepra Technology™" Device, which is denoted by the presence of the "ST" within the Device name "Ventralight ST surgical mesh." "ST" Devices utilize a biodegradable hydrogel layer which when applied to the already defective and dangerous polypropylene Hernia Mesh Devices, creates added defects and risks.

- 29. These reactions include:
 - a. A foreign body response;
 - b. Granulomatous response;
 - c. Allergic reaction;
 - d. Rejection;
 - e. Erosion;
 - f. Excessive and chronic inflammation;
 - g. Adhesions to internal organs;
 - h. Scarification;
 - i. Improper wound healing;
 - j. Infection;

- k. Seroma;
- I. Abscess;
- m. Fistula;
- n. Tissue damage and/or death;
- o. Tumor formation;
- p. Cancer;
- q. Nerve damage;
- r. Chronic pain; and
- s. Recurrence of hernia.

30. The Ventralight mesh was defective due to its high rate of failure, injury, complications, failure to perform as intended, the requirement of frequent and often debilitating re-operations and its cause of severe and irreversible injuries to numerous patients, including Plaintiff.

31. As a result of having the Ventralight mesh implanted, the Plaintiff has experienced significant mental and physical pain, and suffering and mental anguish, has sustained permanent injuries, has undergone medical treatment, and will likely undergo further treatment.

32. Defendants Davol and Bard were, or should have been, aware of the dangers inherent in the Ventralight mesh.

33. Defendants Lifecell, Allergan, Bard and Davol, knew or should have known that their Hernia Mesh Devices were unreasonably harmful, but failed in numerous ways to protect Plaintiff, other patients, and the general public from the harm caused by their Devices.

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34. The Hernia Mesh Devices were at all times utilized and implanted in manner foreseeable to and in fact intended by the Defendants.

35. The Hernia Mesh Devices were implanted in the Plaintiff in the same or substantially same condition as when they left the Defendants' possession.

36. Despite diligent investigation by Plaintiff into the cause of his injuries including consultations with his medical providers, and their relationship to the Defendants' Hernia Mesh Devices, the cause was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims.

37. As a result of having the Hernia Mesh Devices implanted, the Plaintiff has experienced significant mental and physical pain and suffering and mental anguish, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial and economic loss and other damages.

CAUSES OF ACTION AGAINST ALL DEFENDANTS COUNT I: NEGLIGENCE

38. Plaintiff incorporates by reference paragraphs 1-37 of this Complaint as if fully set forth herein.

39. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, selling, and creating instructions and warnings for, their Hernia Mesh Devices.

40. Defendants breached their duty by:

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- Failing to design the Hernia Mesh Devices so as to avoid an unreasonable risk of harm to people in whom the mesh Devices were implanted, including Plaintiff;
- b. Failing to manufacture the Hernia Mesh Devices so as to avoid unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- c. Failing to use reasonable care in the testing of the Hernia Mesh Devices so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- d. Failing to respond promptly and appropriately their own and other testing and information regarding their Hernia Mesh Devices;
- e. Failing to use reasonable care in inspecting the Hernia Mesh Devices so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- f. Failing to warn or instruct the Plaintiff and/or his healthcare providers of the full extent of the risks and hazards known to exist with the use of the mesh in a manner commensurate with the exercise of reasonable care;
- g. Failing to warn the Plaintiff and/or his healthcare providers of the severity and duration of such adverse effects;
- h. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of implanting the Hernia Mesh Devices, which were knowingly false and misleading, in order to influence patients' health care providers to implant the Devices;

- Aggressively promoting, marketing, advertising and/or selling their Hernia Mesh Devices despite their knowledge and experience of the Devices' dangers and risks;
- j. Promoting the hernia mesh advertisements, websites and other modes of communication aimed at creating or increasing the rate and frequency of implantation of the Devices, without regard to the dangers and risks associated with their implantation;
- k. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Hernia Mesh Devices.

41. As a direct and proximate result of the Defendants' negligence, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injuries and has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial and economic loss, including but not limited to, obligations for medical services and expenses, lost income, and other damages.

42. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence.

COUNT II: STRICT PRODUCT LIABILTY, DESIGN DEFECT

43. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

44. At the time the Hernia Mesh Devices were implanted in Plaintiff, the Devices were defectively designed. As described in the Complaint, there was an

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unreasonable risk that the Devices would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the risks.

45. The Defendants' Hernia Mesh Devices were defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce.

46. The Hernia Mesh Devices in question were improperly designed in that they were:

a. Not designed to remain in the human body indefinitely;

b. Not designed to remain in place and not migrate;

c. Designed in such a way that could cause infection;

d. Designed in such a way that the mesh could grow into the patient's

skin, causing scar tissue and becoming unremovable; and

e. Safer alternative designs were available at the time of sale.

47. The Hernia Mesh Devices reached Plaintiff's implanting surgeon without substantial change in the condition in which they were sold.

48. The Hernia Mesh Devices were unreasonably dangerous, taking into consideration the utility of said Devices and the risks involved in their use.

49. The defective and unreasonably dangerous condition of the mesh Devices was the proximate cause of the damages and injuries to Plaintiff.

50. When the Hernia Mesh Devices at issue were implanted into Plaintiff, there existed safer alternative designs for Hernia Mesh Devices, which were

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economically and technologically feasible at the time the Devices left Defendants' control.

51. The hernia mesh Devices implanted into Plaintiff failed to reasonably perform as intended and resulted in complications. In many cases, including the Plaintiff's, these complications necessitated further surgery to repair the injuries caused by the defective Devices, and to repair the very issue the Devices were intended to repair. Thus, the Devices provided no benefit to Plaintiff.

52. Defendants' Hernia Mesh Devices failed consumer safety expectations, as they did not perform safely when used in an intended or reasonably foreseeable manner, as an ordinary consumer would have expected.

53. Defendants' Hernia Mesh Devices injured Plaintiff.

54. Defendants are strictly liable to Plaintiff for designing defective Devices.

55. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence in all states and territories of the United States, including the State of Connecticut.

56. As a direct and proximate result of the mesh Device's aforementioned defects, Plaintiff was caused and, in the future, will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial and economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

57. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively designed Hernia Mesh Devices.

COUNT III: STRICT PRODUCT LIABILITY, FAILURE TO WARN

58. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

59. The Defendants' Devices were inherently dangerous.

60. The use of any of the Defendants' Hernia Mesh Devices in a reasonably foreseeable manner involves a substantial danger that a user would not readily recognize.

61. Defendants knew or should have known of these dangers, given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution of their Hernia Mesh Devices.

62. Defendants failed to provide adequate warning of the dangers created by the reasonably foreseeable use of their Devices.

63. At the time the Devices were implanted in Plaintiff, the Defendants' warnings and instructions for them were inadequate and defective. As described in this Complaint, there was an unreasonable risk that any Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

64. Defendants failed to properly and adequately warn and instruct Plaintiff and his health care providers concerning the risks of Hernia Mesh Devices, given Plaintiff's conditions and need for that information.

65. Defendants also failed to properly and adequately warn and instruct Plaintiff and his health care providers concerning the inadequate research and

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testing of Hernia Mesh Devices and the complete lack of a safe, effective procedure for removal of the Devices.

66. Defendants expected and intended the Hernia Mesh Devices to reach Plaintiff, his health care providers, and other consumers in the condition in which their Devices were sold.

67. Plaintiff and his health care providers were unaware of the defects and dangers of Hernia Mesh Devices and were further unaware of the frequency, severity and duration of the defects and risks associated with the Devices.

68. Defendants' instructions for use for the Devices expressly understated, misstated, or concealed the risks Defendants knew or should have known were associated specifically with them, as described in this Complaint.

69. Defendants' instructions for use for the Hernia Mesh Devices failed to adequately warn Plaintiff or his health care providers of numerous risks Defendants knew or should have known were associated with the Devices.

70. Defendants failed to adequately train or warn Plaintiff or his health care providers about the necessity for surgical intervention in the event of complications or how to properly treat such complications associated with the Hernia Mesh Devices when they occurred.

71. Defendants failed to adequately warn Plaintiff, his health care providers, and the general public, that the necessary surgical removal of a hernia mesh Device in the event of complications would leave the hernia unrepaired and would necessitate a further attempt to repair the same hernia that the failed Device was intended to treat.

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72. The Defendants provided inadequate or no information regarding the complications, frequency, severity, and duration, even though the complications were more frequent and more severe and lasted longer than those associated with safer feasible alternative hernia repair treatments.

73. If Plaintiff or his health care providers had been properly warned of the defects and dangers of Hernia Mesh Devices and of the frequency, severity and duration of the risks associated with the Devices, Plaintiff would not have consented to allow the Devices to be implanted, nor would his health care providers have implanted them.

74. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct, including their failure to warn or provide adequate instructions regarding Hernia Mesh Devices. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states, including Connecticut General Statutes § 52-572q.

75. As a direct and proximate result of the mesh Device's aforementioned defects, Plaintiff was caused and, in the future, will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial and economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

76. Plaintiff's injuries were a reasonably foreseeable result of Defendants' failure to provide adequate warnings and instructions.

77. As a result of Defendants' failure to warn or to provide adequate warnings, Plaintiff and his health care providers were unaware, and could not have known or

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learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and/or omissions.

78. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' failure to provide adequate warnings and instructions on the risks and dangers associated with their Hernia Mesh Devices.

COUNT IV: STRICT PRODUCT LIABILITY, MANUFACTURING DEFECT

79. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

80. Defendants' Hernia Mesh Devices were not reasonably safe for their intended use and were defective with respect to their manufacture, in that they deviated materially from Defendants' manufacturing and/or design specifications, and thus posed unreasonable risks of serious bodily harm to Plaintiff.

81. Defendants' Hernia Mesh Devices were unreasonably dangerous as a result of malfunction, failure to properly manufacture to specifications as intended, improper assembly, and/or improperly broken or damaged packaging.

82. At the time the Hernia Mesh Devices were implanted, the Devices were defective with respect to their manufacture, in that the Defendants deviated materially from their manufacturing and/or design specifications and thus posed an unreasonable risk of harm to Plaintiff in whom the Hernia Mesh Devices were implanted.

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83. The manufacturing defects associated with the Hernia Mesh Devices were not known, knowable or readily visible to the Plaintiff's healthcare providers or the Plaintiff, nor were they discoverable upon reasonable examination. The Hernia Mesh Devices were used and implanted in the very manner in which they were intended to be used and implanted, in accordance with Defendants' instructions for use and marketing materials.

84. The Hernia Mesh Devices implanted in Plaintiff were different from their intended design and failed to perform as safely as Devices manufactured in accordance with the intended design would have performed.

85. As a direct and proximate result of the mesh Device's aforementioned defects, Plaintiff was caused and, in the future, will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial and economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

86. Defendants' defective manufacture of Hernia Mesh Devices was a proximate cause of the damages and injuries Plaintiff suffered.

87. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states, including the State of Connecticut.

88. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages under law for injuries sustained as a result of Defendants' defectively manufactured Hernia Mesh Devices.

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COUNT V: VIOLATION OF THE CONNECTICUT PRODUCT LIABILITY ACT

89. Plaintiff realleges and incorporates by reference every all paragraphs in this Complaint.

90. Plaintiff brings this claim pursuant to the Connecticut Product Liability Act, Connecticut General Statute § 52-572m.

91. The applicable statutes and regulations were aimed at preserving the health and safety of Plaintiff and the general public.

92. Plaintiff is among the class of individuals that the statutes and regulations were meant to protect.

93. Plaintiff's injuries are among the type that the statutes and regulations were intended to prevent.

94. As a result of the acts and omissions described in this Complaint, Plaintiff was caused to suffer serious injuries as described in this Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

95. Defendants' violation of the Connecticut Product Liability Act proximately caused the damages and injuries to the Plaintiff.

96. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' violation.

COUNT VI: NEGLIGENCE PER SE

97. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

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98. Defendants' actions also constitute negligence per se under the applicable health and safety statutes and regulations of all states, including the State of Connecticut, as well as federal law.

99. The applicable statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

100. Plaintiff is among the class of individuals that the statutes and regulations were meant to protect.

101. As a result of the acts and omissions described in this Complaint, Plaintiff was caused to suffer serious injuries as described in this Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

102. Defendants' negligence per se proximately caused the damages and injuries to Plaintiff.

103. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence per se.

<u>COUNT VII: VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT</u> (CUTPA)

104. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

105. Plaintiff purchased and used Defendants' Hernia Mesh Devices primarily for personal use. Therefore, Plaintiff suffered ascertainable losses as a result of the Defendants' actions in violation of the Connecticut Unfair Trade Practices Act General States Section 42-110a, et seq. ("CUTPA").

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106. Had Defendants properly advised Plaintiff, or his health care providers of the defects and risks associated with the Hernia Mesh Devices, including the frequency, severity and duration of those risks, Plaintiff would not have purchased or paid for the Devices, would not have consented to the Devices being implanted, and would not have suffered injuries and incurred related medical costs.

107. Defendants engaged in wrongful conduct, while at the same time obtaining under false pretenses, monies from Plaintiff for Hernia Mesh Devices for which Plaintiff would not have paid had Defendants not engaged in unfair and deceptive conduct.

108. Deceptive acts or practices prescribed by law include the following:

- Representing that good or services have characteristics, ingredients, uses, benefits or quantities that they do not have;
- 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 or misunderstanding.

109. The cumulative effect of Defendants' conduct directed at Plaintiff his health care providers, and the general public, was to create demand for and sell Hernia Mesh Devices. Each aspect of Defendants' conduct combined to artificially create sales of their Devices.

110. Plaintiff was injured by the cumulative nature of Defendants' conduct.

111. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and

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sale of their Hernia Mesh Devices throughout all states, including the State of Connecticut.

112. Defendants' deceptive, unconscionable, or fraudulent representations, or material omissions to Plaintiff, his health care providers, and the general public, constituted unfair and deceptive acts and trade practices in violation of the consumer protection statutes of all states, including the State of Connecticut.

113. Defendants' actions constitute unfair, unconscionable, deceptive, or fraudulent acts and trade practices in violation of the consumer protection statutes and regulations in states where the purchases and/or implantation of the Hernia Mesh Devices occurred.

114. Under CUTPA, protecting consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants are the developers, suppliers, manufacturers, advertisers, and sellers, making them subject to liability under such act for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

115. Defendants violated CUTPA because the purchase and/or implantation of Hernia Mesh Devices occurred in Connecticut. CUTPA was enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising. Defendants' violations occurred by their knowledge occurred by their knowingly false representation that the Hernia Mesh Devices were fit for the purpose for which the Devices were intended, when in fact they were defective and dangerous; and by other acts alleged in this Complaint.

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116. Defendants breached and/or violated CUTPA in that their misconduct as alleged in this Complaint constituted unfair acts or practices in the conduct of its trade and commerce which caused substantial injury to the Plaintiff as a consumer of their Hernia Mesh Devices.

117. Defendants' acts and omissions are uncured or incurable deceptive acts under all state laws enacted to protect consumers, including Plaintiff, against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising. Defendants had actual knowledge of the defective and dangerous conditions of their Hernia Mesh Devices but failed to take any action to cure such defective and dangerous conditions.

118. Plaintiff, his health care providers, and the general public, relied upon Defendants' misrepresentations and omissions in determining to use the Hernia Mesh Devices or in allowing the Devices to be implanted.

119. As a direct and proximate result of the Defendants' violations of CUTPA, the Plaintiff has been injured and undergone medical treatment, and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss, and damages, including medical expenses, lost income, and other damages.

120. As a direct and proximate result of the Defendants' violations of CUTPA, Plaintiff has sustained economic losses, injuries, and other damages, and is entitled to statutory and compensatory damages in an amount to be proven at trial.

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121. The Plaintiff has provided notice of this action to the Attorney General of the State of Connecticut and Commission of Consumer Protection, pursuant to Connecticut General Statutes § 42-110c.

COUNT VIII: BREACH OF IMPLIED WARRANTY

122. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

123. Defendants sold the Hernia Mesh Devices implanted in Plaintiff.

124. Defendants knew or reasonably should have known at the time of sale that each Hernia Mesh Device was intended to be used for the purpose of hernia repair through surgical implantation in the human body.

125. Defendants warranted to Plaintiff, his health care providers, and other consumers that the Devices were of merchantable quality, and safe for the use for which they were intended.

126. Plaintiff and their health care providers reasonably relied on Defendants' judgment, indications, and statements that Hernia Mesh Devices were fit for such use. Because of that reliance, Defendants' Hernia Mesh Devices were implanted in Plaintiff.

127. Defendants distributed into the stream of commerce and sold Hernia Mesh Devices that were unsafe for their intended use, and not of merchantable quality as warranted by Defendants, in that the Devices had dangerous propensities when used as intended and implanted.

128. As a result of Defendants' conduct, Plaintiff suffered injuries and damages, making Defendants liable for breaching their implied warranties.

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129. As a direct and proximate result of Defendants' breach of the implied warranties associated with their Hernia Mesh Devices, Plaintiff has been injured an undergone medical treatment, and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain and suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expense, lost income, and other damages.

COUNT IX: BREACH OF EXPRESS WARRANTY

130. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

131. Defendants warranted and represented to Plaintiff, his health care providers, and other consumers, that their Hernia Mesh Devices were safe and reasonably fit for their intended purposes.

132. Plaintiff and his health care providers chose Hernia Mesh Devices based upon Defendants' warranties and representations regarding the safety and fitness of their Devices, as described in this Complaint.

133. Plaintiff and his health care providers reasonably relied upon Defendants' express warranties and guarantees that the Devices were safe, merchantable, and reasonably fit for their intended purposes.

134. Defendants breached these express warranties because their Hernia Mesh Devices were unreasonably dangerous and defective, and not as Defendants had represented them to be.

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135. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective Hernia Mesh Devices in Plaintiff, placing his health and safety in jeopardy.

136. As a direct and proximate result of Defendants' breach of the express warranties associated with Hernia Mesh Devices, Plaintiff has been injured and undergone medical treatment, and will likely undergo future medical treatment. He has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, and other damages.

COUNT X: FRAUD AND FRAUDULENT MISREPRESENTATION

137. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

138. Defendants designed, manufactured, marketed, and sold their Hernia Mesh Devices, and provided inadequate warnings and information about the Devices.

139. When Plaintiff or his healthcare providers received the inadequate information and warnings, the Devices were defective and unreasonably dangerous for their intended and reasonably foreseeable use.

140. Further, Defendants fraudulently represented to Plaintiff, his health care providers, and the general public, that their Hernia Mesh Devices were safe and effective permanent implants. Additionally, even though Defendants were fully aware of the dangerous and defective nature of the Devices, which could and did cause

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injuries such as those that Plaintiff suffered, Defendants intentionally concealed the defects in the Devices from Plaintiff.

141. Defendants fraudulently represented to Plaintiff, his health care providers, and the general public that their Hernia Mesh Devices had been adequately tested, were safe for the repair of hernias, and were accompanied by adequate warnings.

142. Defendants widely advertised, marketed, and promoted their Hernia Mesh Devices as safe and effective for permanent implantation in the human body, and for the repair of hernias.

143. Defendants made these representations with the intent of deceiving Plaintiff, his health care providers, and other potential consumers; and with the intent of inducing the implantation of their Hernia Mesh Devices, under circumstances that Defendants knew were dangerous and unsafe, and created a high risk of harm.

144. Defendants also made material representations that were false. Further, Defendants knew that they were false when made, or willfully, wantonly, and recklessly disregarded whether the representations were true or false. Defendants intended that Plaintiff, his health care providers, and other potential consumers would rely and act upon the false representations.

145. Plaintiff and/or his health care providers relied upon Defendants' fraudulent misrepresentations in allowing the defective Hernia Mesh Devices to be implanted. Plaintiff thus sustained severe and permanent personal injuries, and/or was at an increased risk of sustaining severe and permanent personal injuries in the future.

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146. Defendants knew or should have known that their Hernia Mesh Devices had not been sufficiently tested, were defective in nature and/or lacked adequate warnings and information.

147. Defendants' actions constituted common law fraud and/or fraudulent misrepresentation in all states, including the State of Connecticut.

148. As a direct and proximate result of Defendants' fraud or fraudulent misrepresentation, Plaintiff has been injured and undergone medical treatment and will likely undergo further medical treatment and procedures. He has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, and other damages.

COUNT XI: FRAUDULENT CONCEALMENT

149. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

150. Before Defendants' Hernia Mesh Devices were implanted in Plaintiff, Defendants fraudulently concealed material information regarding adverse events, pre-marketing and post-marketing injuries, and literature indicating unreasonable risks associated with the implantation of the Hernia Mesh Devices.

151. Although Defendants were aware of the dangerous and defective condition of the Hernia Mesh Devices, they intentionally concealed such information from Plaintiff, his health care providers, and the general public. The significant dangers Defendants concealed included a warning that the material was not suited

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for permanent human implantation. Further, the dangers were not readily obvious to the ordinary user of the Devices, even after post-implant complications had arisen.

152. Defendants made these omissions with the intent of defrauding and deceiving Plaintiff and his health care providers specifically, and other consumers generally; and with the further intent of specifically inducing health care providers to recommend implantation of the Hernia Mesh Devices. All such acts and omissions evinced Defendants' callous, reckless, willful, depraved indifference to the health, safety, and welfare of Plaintiff.

153. When Defendants made the foregoing partial disclosures and fraudulent omissions, and at the time Plaintiff was implanted with the Hernia Mesh Devices, Plaintiff and/or his health care providers were unaware of their falsity and reasonably believed the misrepresentations and omissions to be true.

154. Defendants fraudulently concealed the safety issues associated with the implantation of their Hernia Mesh Devices, to induce health care providers to recommend implanting the Devices in patients like Plaintiff, and to induce Plaintiff to consent to the implantation of the Devices.

155. Plaintiff's health care providers reasonably relied on Defendants' omissions when they recommended implantation of the Hernia Mesh Devices in Plaintiff, thereby causing him to sustain severe and permanent personal injuries. Defendants knew, or should have known, that their Hernia Mesh Devices had not been sufficiently tested and were defective in nature and/or that their Hernia Mesh Devices lacked adequate warnings.

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156. Defendants also knew or should have known that their Hernia Mesh Devices had a potential to, and would, cause severe injury to those implanted with their Devices, and that the Devices were inherently dangerous in a manner exceeding any purported warnings.

157. Defendants had a duty to provide Plaintiff, his health care providers, and the general public with full, complete, accurate and truthful information concerning their Hernia Mesh Devices.

158. By virtue of Defendants' omissions and partial disclosures about the Hernia Mesh Devices, in which Defendants touted their Devices as a safe and effective for implantation in patients, Defendants had a duty to disclose all facts about the risks associated with the Devices, including the risks described in this Complaint.

159. Plaintiff's health care providers reasonably relied on these material and fraudulent omissions when recommending implantation of the Devices in Plaintiff, and Plaintiff reasonably relied on the material and fraudulent omissions when consenting to have the Devices implanted.

160. Defendants did not provide Plaintiff's health care providers with the information necessary to adequately warn Plaintiff.

161. The Hernia Mesh Devices were improperly marketed to Plaintiff and his health care providers because Defendants did not provide proper instructions on how to implant the Devices and did not adequately warn about the risks associated with implantation.

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162. Plaintiff could not know in the exercise of reasonable diligence that Defendants' statements concerning their Hernia Mesh Devices were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to Plaintiff of their health care providers that would have been material to the choice of treatment.

163. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and/or his health care providers, Defendants caused or contributed to Plaintiff's injuries.

164. Had Plaintiff's health care providers been aware of the hazards associated with the implantation of Defendants' Hernia Mesh Devices, they would have used safer alternative Devices for the repair of Plaintiff's hernias.

165. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested reckless indifference for the safety and well-being of Plaintiff and other consumers.

166. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from Plaintiff and/or his health care providers, Defendants caused, and increased the risk of harm of the injuries and damages Plaintiff suffered after having been implanted with Defendants' Hernia Mesh Devices.

167. Had Plaintiff been aware of the hazards associated with the implantation of the Hernia Mesh Devices, he would not have consented to their implantation.

168. Defendants' actively and fraudulently concealed information in their exclusive possession regarding the hazards associated with the implantation of their

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Hernia Mesh Devices, for the purpose of preventing Plaintiff and his health care providers from discovering these hazards.

169. Defendants' conduct was outrageous and shocked the conscience, and they knowingly and intentionally placed considerations of financial gain, revenues and profits, market share, and marketing advantage over patient safety and wellbeing.

170. As a result of the foregoing material and fraudulent omissions, Plaintiff was caused to suffer serious injuries as described in this Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

171. Defendants' conduct, as described in this Complaint, was extreme and outrageous. Defendants risked the lives of Plaintiff and other consumer and users of their Devices. Although Defendants had knowledge of the safety and efficacy problems with their Devices, they concealed this knowledge from Plaintiff, his health care providers, and the general public. Further, Defendants made conscious decision onto to redesign, re-label, and/or warn unsuspecting consumers. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XII: PUNITIVE DAMAGES

172. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

173. Defendants sold Hernia Mesh Devices to health care providers throughout the United States, without conducting adequate testing to ensure that the Devices were reasonably safe for implantation.

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174. Defendants knew their Devices posed unreasonable risks, including degradation excessive and chronic inflammation, inadequate or complete failure to incorporate in tissue, adhesion, migration, infection, erosion, abscess, fistula formation, nerve damage, excessive scarification, contracture, shrinkage, breakage, and other harm-causing defects.

175. Defendants sold their Hernia Mesh Devices to health care providers throughout the United States, despite knowing of these unreasonable risks.

176. At all material times, Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of their Hernia Mesh Devices, including adverse data and information from studies and testing conducted with respect to the Devices, which showed that the risks and dangers associated with the Devices were unreasonable.

177. Defendants' misrepresentations, omissions, and partial disclosures, included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' Hernia Mesh Devices.

178. At all material times, Defendants knew and intentionally and/or recklessly disregarded the fact that their Hernia Mesh Devices caused severe and potentially permanent complications with greater frequency and feasible alternative Devices or treatment.

179. Notwithstanding that knowledge, Defendants continued to market their Hernia Mesh Devices to consumers without disclosing the true risk of side effects and complications, or the frequency, severity, and duration of those risks.

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180. Defendants knew of their Devices defective and unreasonably dangerous nature. But they continued to manufacture, produce, assemble, market, distribute, and sell the Devices, and failed to include adequate warnings about them. Defendants' acts and omissions were taken with reckless disregard of the foreseeable harm caused by the Hernia Mesh Devices, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

181. Defendants' conduct described in this Complaint shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences. Therefore, an award of punitive damages is justified.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands a trial by jury and judgment against Defendants Allergan, Inc., Lifecell, Corp., C.R. Bard, Inc., and Davol, Inc., jointly and severally, on each of the above claims or causes of actions, as follows:

- a. Compensatory damages in excess of \$75,000.00, including, but not limited to damages for pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial;
- Economic damages in the form of medical expenses, out-of-pocket expenses, lost earnings and other economic damages, in an amount to be determined at trial;
- c. Punitive damages for Defendant's wanton, willful, fraudulent, and reckless acts, established by their demonstration of complete disregard and reckless indifference for the safety and welfare of Plaintiff and the general public, in an amount sufficient to punish Defendants an deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. An award of reasonable attorney's fees;
- g. Costs of these proceedings;
- h. And further relief this Court deems just and proper.

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JURY DEMAND

Plaintiff demands a trial by jury as to all issues triable by jury.

Dated: January 6, 2022

Respectfully,

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