IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA
AUGUSTA DIVISION

SHEILA SANDOVAL, Plaintiff, v. BG MEDICAL, LL; ASPIDE MEDICAL; AND DOES 1 through 10, inclusive, Defendants.	Case No. **CV 122-137** COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff SHEILA SANDOVAL ("Plaintiff"), by and through her undersigned counsel, brings this Complaint at Law against Defendants BG MEDICAL, LLC and ASPIDE MEDICAL in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' SurgimeshXB surgical mesh device ("Surgimesh", "SurgimeshXB" or "product"). As a result, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

PARTIES

2. Plaintiff Sheila Sandoval ("Plaintiff") is, and was, at all relevant times, a citizen and resident of the State of Georgia and the United States.

3. Defendant BG MEDICAL, LLC (hereinafter "BG MEDICAL), now is, and at all times relevant to this action was, a Limited Liability Company organized under the laws of Illinois and has its principal place of business and headquarters in the state of Illinois. The sole members of BG Medical are individuals by the name of John Huelskamp and Patricia Huelskamp. Both members of BG Medical are citizens of Illinois. Accordingly, BG Medical is a citizen of Illinois.

4. BG MEDICAL is the exclusive distributor for Defendant, ASPIDE MEDICAL d/b/a SURGIMESH. Dating back to at least 2009 and continuing until at least 2021, BG Medical was substantially involved in marketing, distribution, and post-market surveillance of the SurgimeshXB hernia mesh device. BG Medical independently created and maintains numerous methods to market and promote the SurgimeshXB, including multiple websites, brochures, labeling materials, testimonial pages, marketing campaigns, sales representatives, promotional activities and interactions with physician societies, and other promotional tactics. BG Medical markets itself as a "World specialist in surgical textile implants." BG Medical has also been involved in the recruitment and payment to physicians to study and promote the use of SurgimeshXB. Upon information and belief, BG Medical may also have been involved in the design of the SurgimeshXB.

5. Per BG Medical, ASPIDE MEDICAL d/b/a SURGIMESH (hereinafter "ASPIDE") designed and manufactured the SurgimeshXB implanted in Plaintiff. Plaintiff has no reason to dispute these claims at this time. Aspide is foreign (French) entity most

closely resembling a corporation, and its headquarters and principal place of business is located at 246 Allee Lavoisier, 42350 La Talaudiere, France.

6. BG Medical has advised Plaintiff's counsel that Aspide is defunct and is no longer functioning as a company. In another case filed by Plaintiff's counsel regarding the same mesh products, Aspide failed to respond to the Complaint and has taken no action to defend itself.

7. As it now stands, it does not appear that any entity, whether BG Medical or Aspide, is taking responsibility to continue to comply with Food and Drug Administration regulations requiring the post-market surveillance, adverse event investigations and reporting, and continued risk management regarding the SurgimeshXB product.

8. Does 1 through 10, are currently unknown to Plaintiff but may have liability due to involvement in the design, manufacture, promotion, labeling, post-market surveillance, or distribution of the SurgimeshXB implanted in Plaintiff, and/or are liable to Plaintiff due to fraudulent transfer of assets involving Aspide. If and when the identity and involvement of Does 1 through 10 is discovered, Plaintiff will amend the Complaint to indicate their identity, involvement, and basis for liability.

9. Hereinafter, BG MEDICAL, ASPIDE, and Does 1-10 shall collectively be referred to as "Defendants."

JURISDICTION AND VENUE

10. This Court has jurisdiction over all causes of action alleged in this

Complaint pursuant to 28 U.S.C. § 1332 (a)(1) because complete diversity exists between the Plaintiff and all Defendants, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), excluding interest and costs.

11. Venue is proper in this Court, pursuant to 28 U.S.C. § 1391 as a substantial part of the events giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this District, subjecting them to personal jurisdiction. Specifically, Plaintiff's surgeries to implant and then remove the SurgimeshXB took place in this District, Plaintiff resides in this District and receives her regular medical here.

12. Defendants have conducted business and derived substantial revenue from within the State of Georgia and have sufficient minimum contacts and intentionally availed themselves of the benefits of Georgia to render the exercise of jurisdiction by the Georgia courts over Defendants consistent with traditional notions of fair play and substantial justice. Specifically, BG Medical has two distribution centers located in this state: one in Savannah, Georgia, and the other in Atlanta, Georgia. Furthermore, Defendants have engaged in substantial marketing and sales activity in the state of Georgia to promote the sale of SurgimeshXB. Defendants also intentionally took actions to deliver the SurgimeshXB into the stream of commerce with the intent that it would be sold and implanted in the state of Georgia, including Plaintiff's specific device.

STATEMENT OF FACTS

13. At all relevant times, each of the Defendants designed, developed,

manufactured, licensed, marketed, distributed, sold and/or placed SurgimeshXB in the stream of commerce, deriving substantial revenue therefrom.

14. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

15. At all relevant times, upon information and belief, Defendants were and up until the time of the filing of this complaint were business entities actually doing business in the State of Georgia.

16. At all relevant times, Defendants were engaged in the business of designing, manufacturing, advertising, marketing, and selling surgical mesh products including the SurgimeshXB, and in pursuit of this business, transacted business within the State of Georgia and contracted to provide goods and services in the State of Georgia and others.

17. At all relevant times, upon information and belief, Defendant committed tortious acts inside the State of Georgia which caused injury to Plaintiff.

18. At all relevant times, upon information and belief, Defendants expected or should have reasonably expected its acts to have consequences in the State of Georgia.

19. Defendants obtained "clearance" from the Food and Drug Administration ("FDA") to market the SurgimeshXB product under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

20. Section 510(k) permits the marketing of medical devices if the device is

substantially equivalent to other legally marketed predicate devices. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacturer can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

21. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996). The Court has repeatedly held that a Section 510(k) clearance is not a determination of safety.

22. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse

associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

23. SurgimeshXB is a non-absorbable synthetic mesh, made of non-knitted, non-woven fibers of polypropylene, one surface of which is coated with silicone.

24. SurgimeshXB is marketed for use in the repair of hernias and soft tissue deficiencies, including placement next to the bowel.

25. The silicone coating is supposed to allow the mesh to be placed safely next to the bowel by preventing the mesh from adhering to the bowel, colon, or omentum.

26. Defendants falsely represented to the FDA, the public, and Plaintiff's prescribing physician that the SurgimeshXB is safer and more effective than other available hernia mesh devices due to its design.

27. Defendants' false and unsupported claims include, but are not limited to, the following:

a. SurgimeshXB provides superior patient outcomes compared to all other hernia mesh devices;

b. SurgimeshXB is the optimal hernia mesh design and allows for optimal outcomes, reduced patient complication rates, reduced recurrence rates, and has the safest track record compared to other hernia mesh devices;

c. SurgimeshXB's design would reliably prevent adhesions from forming to the device and decreased the risk of adhesions compared to other barrier mesh devices;

d. SurgimeshXB's design would lead to complete, strong, and full incorporation of the mesh into the abdominal wall, and that this would occur within 12 days;

e. SurgimeshXB's design provides superior incorporation compared to all other hernia mesh devices;

f. SurgimeshXB's design prevents shrinkage/contraction of the device after implantation unlike other hernia mesh devices.

g. SurgimeshXB's design leads to a flexible repair that prevents patient pain from the device unlike other hernia repair devices;

h. SurgimeshXB's design protects the device from infection;

i. SurgimeshXB's design limits inflammatory response to low levels and will not cause shrinkage/contraction;

j. That SurgimeshXB is a lightweight hernia mesh design and thus will not cause significant foreign body response or patient pain.

28. Defendants made these claims to the FDA, healthcare providers, including Plaintiff's prescribing physician, via promotional brochures, their marketing websites, labeling materials included with the SurgimeshXB packaging, sales calls by sales personnel, booth presentations at conferences, paid speakers at various physician group

events, sponsoring and influencing the outcome of medical studies, emails, and other ways.

29. Defendants knew these statements were untrue at the time they were made, including long before Plaintiff's device was distributed, based on information gained in the pre-market design process and real-world post-market adverse events that were reported to and investigated by them.

30. Many years before Plaintiff's SurgimeshXB was manufactured and distributed by Defendants, they knew that the SurgimeshXB's design was not reasonably safe for its intended and reasonably foreseeable use (hernia repair via intraperitoneal mesh placement) and was certainly not the "optimal design" that improved patient safety and reduced the risk of complications when compared to all other hernia mesh devices. In fact, Defendants knew and had reason to know that the complications rates associated with the SurgimeshXB actually far exceeded those of other available hernia mesh devices, including for: mesh adherence to bowel, colon, and omentum; organ perforation; infection; chronic pain; recurrence; mesh shrinkage/contracture; severe inflammatory response or foreign body reaction; migration; mesh rupture; bowel obstruction; never injury; seroma; abscess; sexual dysfunction; biofilms; and wound dehiscence.

31. Contrary to the Defendants marketing claims, Defendants knew the SurgimeshXB is a heavyweight mesh that induces a strong foreign body and inflammatory response, which can and does lead to a serious patient complications including, among others, infection, contraction/shrinkage, chronic pain, adhesions, bowel

perforation, fistula, rupture and recurrence. As recognized in the literature, heavyweight mesh devices like the SurgimeshXB lead to a more significant foreign body reaction, inflammatory response and patient pain.

32. The polypropylene material used in the manufacture of the SurgimeshXB is not inert. Once implanted in the body, the polypropylene begins to degrade leading to severe inflammatory response and continuing cycle of degradation and inflammation. Surface degradation also causes flaking of the polypropylene, which increases the surface area of host tissue exposed to the biomaterial and, in turn, increasing the host Foreign Body Response ("FBR") and accelerating the material degradation. Additionally, the degradation of the polypropylene in the SurgimeshXB causes microscopic fissures to form on the surfaces of the polypropylene filaments, creating a nidus for infection and biofilm. This risk can be and is mitigated by other manufacturers by using antioxidants in the manufacturing process to limit the amount of degradation that occurs once implanted. However, Defendants chose not employ this safety step in the manufacturing process. Thus, the SurgimeshXB exposes patients to an unnecessary and greater risk of degradation than other manufacturers.

33. Contrary to Defendants' claims otherwise, Defendants knew or should have known that SurgimeshXB can and often does exhibit substantial contraction/shrinkage once implanted in the body. Defendants knew and should have known that this often causes severe patient injuries including, chronic pain, adhesions to the mesh, perforation and erosion of the bowel or colon, fistulas, device migration, recurrence, meshoma and

need for corrective surgery. Further, Defendants knew that it's claims that the SurgimeshXB exhibits substantially less contraction than other available hernia mesh devices was and is untrue.

34. The SurgimeshXB design is also problematic in that the use of silicone in the mesh exacerbates the development of biofilms by creating an additional impediment to the human body's defenses to infection. Biomaterials research predating the manufacture and distribution of Plaintiff's device, clearly document concerns that permanently implanted products incorporating silicone-coated polypropylene increase the risk for erosion and wound dehiscence.

35. Contrary to Defendants' marketing claims, Defendants knew or should have known that the design of the SurgimeshXB would not reliably or reasonably prevent the SurgimeshXB from becoming adhered to, or eroding or perforating into the bowel, colon, or omentum. Defendants knew such events can and were causing severe patient injuries such as bowel perforation, bowel blockage, chronic pain, infection, sepsis, fistulas, corrective surgeries, and patient death.

36. Contrary to Defendants' claims otherwise, Defendants knew the SurgimeshXB was more likely to cause adhesions than other available hernia mesh devices.

37. Contrary to Defendants marketing claims otherwise, Defendants' knew that the SurgimeshXB's design was such that it would often not adequately incorporate into the abdominal wall. Defendants knew such failures could and often did lead to severe

complications including, but not limited to, recurrence, migration, adhesions, perforation/erosion, infection, and chronic pain. Further contrary to Defendants' claims otherwise, the SurgimeshXB's design does not provide for superior incorporation compared to all other hernia mesh devices.

38. Contrary to Defendants' marketing claims to the contrary, Defendants knew or should have known that the SurgimeshXB caused consumers chronic and substantial pain once implanted. Moreover, Defendants knew or should have known that their claims that the SurgimeshXB was substantially less likely to cause chronic pain was untrue.

39. Contrary to Defendants' marketing claims otherwise, Defendants knew or should have known that the SurgimeshXB's design does not prevent mesh infection or colonization by microbes, nor does it reduce the risk of such adverse events compared to the other hernia mesh devices.

40. Contrary to Defendants' marketing claims otherwise, Defendants knew or should have known that the SurgimeshXB was not the "optimal" hernia mesh design and that it did not in fact have lower complication rates compared to other available hernia mesh devices. In fact, Defendants knew or should have known that the complication rates associated with the SurgimeshXB, including for recurrence, were substantially higher than other available hernia mesh devices.

41. Long before Plaintiff's SurgimeshXB was distributed by Defendants, Defendants knew, or in the exercise of reasonable care should have known, that the SurgimeshXB mesh was not properly manufactured, tested, inspected, packaged, labeled,

distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the products' users.

42. Defendants ignored reports from patients and health care providers throughout the United States of the SurgimeshXB mesh's failure to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out the SurgimeshXB product's design as the cause of the injuries, Defendants continued to market SurgimeshXB mesh as a safer and more effective medical device compared to other available alternative treatment for hernias.

43. Despite having made the many above described false and unsupported statements regarding the SurgimeshXB being safe and effective, being the best possible design of all hernia mesh devices, and having substantially lower complication rates than other hernia mesh devices, Defendants failed to ever take any action to inform the public, the FDA, or Plaintiff's prescribing physician that these statements were not actually true, including the actual severity and frequency of adverse events association with SurgimeshXB were or what the comparative safety data actually showed. Instead, Defendants, knowingly and intentionally concealed from the Plaintiff and her health providers the true and significant risk associated with the SurgimeshXB mesh.

44. On or about December 17, 2018, Plaintiff was implanted with a SurgimeshXB product (Ref# TINTRACK7, Lot# F14531A) to repair an incisional ventral hernia.

45. The SurgimeshXB product implanted in Plaintiff was designed, manufactured, distributed, and/or sold by Defendants. The product was intended to be used by surgeons for hernia repair surgeries.

46. Defendants represented the product to be appropriate and suitable for such purposes.

47. Subsequently, as a direct result of the implanted SurgimeshXB product, Plaintiff experienced, among other ailments, an infection of the abdominal wall and incision drainage for more than a year due to the chronically infected mesh.

48. On or about November 13, 2020, Plaintiff underwent surgery to have the SurgimeshXB removed. The mesh had not incorporated into her abdominal wall and was explanted in its entirety.

49. Had Defendants adequately warned Plaintiff's prescribing physician of the above-described information, said prescribing physician would not have used the SurgimeshXB mesh. Alternatively, said prescribing physician at minimum would have disclosed this information to Plaintiff in order to obtain informed consent and Plaintiff would not have agreed to implantation of the SurgimeshXB.

50. Plaintiff and Plaintiff's physicians used the SurgimeshXB in a manner that was both intended by and foreseeable to Defendants.

51. The Defendants' SurgimeshXB mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants. Plaintiff and Plaintiff's health care providers did not alter the SurgimeshXB in any way that was not intended by and reasonably foreseeable to Defendants.

52. At the time the SurgimeshXB implanted in Plaintiff was distributed by Defendants, feasible and safer alternative designs existed. Such designed included substantially more effective barrier technology and lighter weight mesh designs.

53. Defendants advertised, promoted, marketed, sold, and distributed the SurgimeshXB mesh as a safe and effective medical device when Defendants knew or should have known the SurgimeshXB mesh was not safe for its intended purposes and that the SurgimeshXB was failing and causing serious complications at rates substantially higher than other available mesh designs.

54. Defendants had sole access to material facts concerning the defective nature of the Surgimesh mesh and its propensity to cause serious and dangerous side effects.

55. Defendants failed to report information regarding the propensity of the SurgimeshXB to fail and cause injury and have made unfounded representations regarding the efficacy and safety of the SurgimeshXB.

56. In reliance on Defendants' representations, Plaintiff s doctors were induced to and did use the Defendants' SurgimeshXB.

57. As a result of Defendants' conduct, Plaintiff incurred and will continue to incur medical costs related to the SurgimeshXB product.

58. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' conduct.

59. As a direct result of being implanted with SurgimeshXB, Plaintiff has been permanently and severely injured.

60. Plaintiff requires and will in the future require ongoing medical care and treatment, including the possibility of further surgeries.

61. Plaintiff, as a direct and proximate result of the SurgimeshXB, suffered severe physical pain and suffering, including distress, and has and will continue to sustain permanent injuries and emotional distress, along with various economic losses due to her injuries.

FIRST CAUSE OF ACTION: NEGLIGENCE

62. Plaintiff re-alleges 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, allege as follows:

63. At the time, Defendants designed, manufactured, promoted, and distributed the SurgimeshXB implanted in Plaintiff, Defendants were engaged in the business of selling such hernia mesh devices. The device was expected to and did reach Plaintiff's

prescribing physician and plaintiff without substantial change in condition from when it was sold and distributed.

64. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, distribution and post-market surveillance of the SurgimeshXB product.

65. Defendants breached the duty of care to the Plaintiff in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and post-market surveillance of the device.

66. Defendants breached their duty of care to Plaintiff by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the SurgimeshXB product.

67. Defendants breached their duty of care to Plaintiff because the SurgimeshXB was not fit for the ordinary purposes for which it was intended, hernia repair with intraperitoneal placement, and did not meet the reasonable expectation of an ordinary consumer as to its safety at the time it was manufactured and distributed.

68. Additionally, at the time the SurgimeshXB implanted in Plaintiff was manufactured and distributed, there were safer, practical, alternative designs available, the utility of which outweighed the utility of the SurgimeshXB. For example, there are other hernia mesh designs that employ far more effective barrier designs to prevent the type of injuries experienced by Plaintiff.

69. As a direct and proximate result of the duties breached, the SurgimeshXB failed, causing Plaintiff pain and suffering, along with mental anguish, doctor visits, subsequent procedures, and substantial medical bills.

70. As a direct and proximate result of Defendants' negligence, Plaintiff suffered severe pain, injuries and damages.

71. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and will continue to suffer severe pain and mental anguish.

72. Defendants' conduct in continuing to market, sell and distribute the SurgimeshXB after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

73. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the SurgimeshXB would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with SurgimeshXB.

74. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the SurgimeshXB, Plaintiff has

been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

75. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SECOND CAUSE OF ACTION: STRICT PRODUCTS LIABILITY - DESIGN DEFECT

76. Plaintiff re-alleges 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, allege as follows:

77. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SurgimeshXB implanted into Plaintiff. The product was defective in its design in that when it left the hands of Defendant, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant. A reasonably prudent medical device manufacturer would not have placed the SurgimeshXB with its defective design into the stream of commerce.

78. The SurgimeshXB was defectively designed when Defendants supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff.

79. The SurgimeshXB was unreasonably dangerous because the foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physician would expect when the product was used for its normal and intended purpose.

80. The SurgimeshXB reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

81. The SurgimeshXB failed to perform as safely as an ordinary consumer and/or her physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the SurgimeshXB outweigh its benefits. The design defects in the SurgimeshXB were not known, knowable and/or reasonably apparent to Plaintiff and/or her physician or discoverable upon any reasonable examination. The SurgimeshXB was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

82. The defective and unreasonably dangerous condition of the SurgimeshXB was the proximate cause of the damages and injuries sustained by Plaintiff.

83. As a direct and proximate result of the SurgimeshXB's aforementioned design defects, Plaintiff has suffered and will continue to suffer severe personal injuries, severe emotional distress, pain and suffering, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

84. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

THIRD CAUSE OF ACTION: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

85. Plaintiff re-alleges 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, allege as follows:

86. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SurgimeshXB implanted in Plaintiff. The SurgimeshXB was defective in its manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

87. The SurgimeshXB as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger, and harm to Plaintiff.

88. The SurgimeshXB was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, supplied, distributed sold and/or otherwise placed in the stream of commerce.

89. The manufacturing defect in the SurgimeshXB implanted in Plaintiff was not known, knowable or readily apparent to Plaintiff's physician or to Plaintiff. Nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The SurgimeshXB was used and implanted in the manner it was intended by Defendant to be used and implanted per the instructions for use and specifications provided by Defendants.

90. The SurgimeshXB implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

91. The defective and unreasonably dangerous condition of the SurgimeshXB product was a proximate cause of damages and injuries suffered by Plaintiff.

92. As a direct and proximate result of the SurgimeshXB's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or

economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

93. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION: FAILURE TO WARN

94. 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, allege as follows:

95. Defendants manufactured, designed, marketed, sold and/or otherwise placed their SurgimeshXB product into the stream of commerce.

96. Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that SurgimeshXB was not safe and effective for its intended and reasonably foreseeable use or of the severity and likelihood of injury it posed to consumers that Defendants knew or should have known at the time the SurgimeshXB implanted in Plaintiff was manufactured and distributed.

97. Defendants also failed to warn or disclose that its many marketing claims regarding the safety and efficacy of the SurgimeshXB were not in fact true, including that the device was the optimal design, would reliably and consistently prevent adhesions to

bowel and omentum, would fully incorporate, had lower complications and better outcomes than all other hernia mesh designs, would not cause chronic pain, would not shrink or contract, would prevent infection.

98. While Defendants Instruction for use provide some general warnings of "possible" complication associated with any hernia mesh device, those warnings offer not indication that Defendants knew these events were in fact occurring and how often, and do nothing to correct the many false and deceptive claims made in the marketing and labeling materials. There is also no warning of dense adhesions to bowel or omentum, erosion or perforation of internal organs, no warning of chronic pain, and no warning of bowel obstruction.

99. Indeed, the Instructions For Use actually downplay the risk posed by adhesions by not including it as a "main risk" but rather only as a "possible risk" and then only noting "visceral attachment."

100. The reality is that Defendants knew the silicone adhesion barrier designed to prevent the mesh from adhering to the bowel, colon and omentum did not work, yet did nothing to warn plaintiff's prescribing physician of this issue.

101. Defendants further failed to inform and further warn Plaintiff and her prescribing physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive SurgimeshXB.

102. The Defendants also failed to properly and adequately warn and instruct Plaintiff and her prescribing physician that inadequate research and testing of the

SurgimeshXB was done prior to Surgimesh being placed on the market and in the stream of commerce, and that Defendants lacked a safe, effective procedure for removal of the Surgimesh once complications from same arise.

103. The Defendant intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of SurgimeshXB, understating the risks and exaggerating the benefits in order to advance their own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

104. The dangerous and defective conditions in the SurgimeshXB existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff had her implant surgery, the Surgimesh was in the same condition as when manufactured, distributed and sold.

105. Neither Plaintiff or her prescribing physician knew at the time of surgery that the SurgimeshXB placed during Plaintiff's surgery or at any time prior thereto, of the existence of the defects or dangerous propensities in the SurgimeshXB.

106. Had Defendants provided adequately warnings regarding the severity and likelihood of risks posed by the SurgimeshXB, Plaintiff's prescribing physician would not have used the device. Alternatively, said prescribing physician would have disclosed these warnings to Plaintiff and Plaintiff would not have consented to the use of the device.

107. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the SurgimeshXB, Plaintiff has been injured and

sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

108. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

FIFTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

109. Plaintiff re-alleges 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, allege as follows:

110. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce the SurgimeshXB product.

111. In advertising, marketing and otherwise promoting SurgimeshXB to physicians, hospitals and other healthcare providers, including Plaintiff's treating physician, Defendants' expressly warranted that their SurgimeshXB was safe and effective for use; was the best and safest design available, would reliably and consistently prevent adhesions to bowel and omentum, would fully incorporate, had lower complications and better outcomes than all other hernia mesh designs, would not cause chronic pain, would not shrink or contract, and would prevent infection. In advertising,

marketing and otherwise promoting SurgimeshXB, Defendant intended physicians, hospitals and other healthcare providers rely upon their representations to induce them to use SurgimeshXB for their patients.

112. The Plaintiff was a person whom Defendants could reasonably have expected to use, consume, or be affected by its SurgimeshXB product, as the Defendant specifically designed the SurgimeshXB for implantation in patients requiring reinforcement of abdominal wall defects such as Plaintiff.

113. With respect to Plaintiff, Defendant intended that SurgimeshXB be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants as her prescribing physician stands in her shoes.

114. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the SurgimeshXB implanted in Plaintiff including the following particulars:

a) Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' SurgimeshXB was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SurgimeshXB;

b) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SurgimeshXB was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that SurgimeshXB was not safer than alternative therapies and products available on the market; and

c) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SurgimeshXB was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SurgimeshXB.

115. At the time of making such express warranties, Defendants knew or should have known that Defendants' SurgimeshXB does not conform to the express warranties, and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

116. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FIFTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY OF MERCHANTIBILITY

117. 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, allege as follows:

118. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' SurgimeshXB.

119. At all relevant times, Defendants intended that SurgimeshXB be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it in accordance with the instructions for use and product specifications provided by Defendants and Defendants impliedly warranted that their SurgimeshXB was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

120. When the SurgimeshXB was distributed into the stream of commerce and sold by Defendants, they were unsafe for their intended use, and not of merchantable quality, as warranted by Defendants, in that they had very dangerous propensities when used as intended and implanted into a patient's body and, as a result, could cause serious injury of harm or death to the end user.

121. Plaintiff is a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' surgical mesh product, as the Defendants specifically designed the SurgimeshXB for implantation in patients requiring reinforcement of abdominal wall defects such as Plaintiff.

122. Defendants were aware that consumers such as Plaintiff would be implanted with SurgimeshXB by their treating physicians in accordance with the instructions for use and product specifications provided by Defendants to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' SurgimeshXB, and plaintiff was in privity with Defendants.

123. Defendants breached implied warranties with respect to the SurgimeshXB including the following particulars:

a. Defendants represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' SurgimeshXB was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SurgimeshXB;

b. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' SurgimeshXB was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants

fraudulently concealed information, which demonstrated that the SurgimeshXB was not safe, as safe as or safer than alternatives and other products available on the market; and

c. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' SurgimeshXB were more efficacious than other alternative procedures and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SurgimeshXB.

124. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used SurgimeshXB to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions.

125. Defendants breached their implied warranty to Plaintiff in that the Defendants' SurgimeshXB was not of merchantable quality, safe and fit for its intended use, nor was it adequately tested prior to being placed in the stream of commerce.

126. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendant. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

127. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused

to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SIXTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION

128. 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, allege as follows:

129. At all times relevant to this cause, Defendants negligently provided Plaintiff, her medical care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose materials information concerning the SurgimeshXB including but not limited to:

a. the safety of the SurgimeshXB;

b. the efficacy of the SurgimeshXB;

c. the rate of failure of the SurgimeshXB;

d. the likelihood of complications developing for patients implanted with a SurgimeshXB such as chronic infection, chronic pain, chronic inflammation.

130. The foregoing misrepresentations were contained in information distributed by Defendants to the public, medical community, and Plaintiff's health care providers in the form of reports, press releases, advertising, labeling materials, print advertisements, Instructions for Use included with the product, commercial media containing material representations.

131. Plaintiff and Plaintiff's medical care providers were foreseeable users of Defendants' SurgimeshXB who reasonably relied on Defendant's misrepresentations about the safety and efficacy of the SurgimeshXB product when they chose this product to implant in Plaintiff instead of other similar but safer and more effective products.

132. The foregoing misrepresentations were in fact false. The SurgimeshXB is not safe, fit, or effective for human use in its intended and reasonably foreseeable manner. The use of the SurgimeshXB is hazardous to the user's health and has a propensity to cause serious injury, including but not limited to Plaintiff's injuries.

133. As a direct result of their reliance on Defendant's misrepresentations, Plaintiff and her treating doctors implanted the SurgimeshXB in Plaintiff, which caused Plaintiff to suffer injuries.

PUNITIVE DAMAGES ALLEGATIONS

134. 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, allege as follows:

135. Defendants sold their products to healthcare providers throughout the United States without doing adequate testing to ensure that the products were reasonably safe for their intended use.

136. Despite knowing the SurgimeshXB had higher reported rates of recurrence, other complications, and patient injury than other devices indicate for hernia repair, Defendants falsely represented the SurgimeshXB was safer and more effective than other repair options.

137. Despite knowing the SurgimeshXB had no safety mechanism designed into the device to prevent severe adhesions to the bowel, Defendants marketed the device as being safe and effective for intrabdominal placement.

138. Even as Defendants became aware of ever-growing evidence that the SurgimeshXB was not safe for intrabdominal placement given the high risk of bowel injury posed by the design of the mesh as the device has no barrier designed to prevent adhesions, Defendants continued to market the SurgimeshXB for intrabdominal placement.

139. Defendants ignored reports from patients and healthcare providers throughout the United States and elsewhere of the products' failures to perform as intended, which lead to the injuries suffered by Plaintiff. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the products' designs or the processes by which the products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and see the products as safe and effective.

140. Defendants knew the products were unreasonably dangerous in light of their risks of failure resulting in pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the products, as well as other severe injuries which are permanent and lasting in nature.

141. Defendants withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the product.

142. Defendants knew and recklessly disregarded the fact that the products caused debilitating and potentially life-altering complications with greater frequency than feasible alternative methods and/or products.

143. Defendants misstated and misrepresented data, and continue to misrepresent data, to minimize the perceived risk of injuries caused by the products.

144. Notwithstanding the foregoing, Defendants continue to aggressively market the products to consumers, without disclosing the true risks associated with the products.

145. Defendants knew of the products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the products to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

146. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the products, to ensure continued and increased sales.

147. Defendants conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

VICARIOUS LIABILITY

148. Whenever in this complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATION

149. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Surgimesh.

150. As a result of the Defendants' actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through

reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

151. Furthermore, Defendants are estopped from relying on any statute of limitations defense because of their fraudulent concealment of the truth regarding the quality and nature of Surgimesh. Defendants had a duty to disclose the true character, quality and nature of Surgimesh because this was non-public information over which Defendants had and continued to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to health facilities. Defendants is estopped from relying on any statute of limitation because of their intentional concealment of these facts.

152. Plaintiff had no knowledge that Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing until less than the applicable limitations period prior to the filing of this action.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, emotional distress and anxiety, loss of enjoyment of life,

past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Reasonable attorneys' fees to the extent allowed by law;

iii. The costs of these proceedings, including past a future cost of the suit incurred herein;

iv. Prejudgment interest on all damages as is allowed by law;

v. Punitive Damages as to all Counts except Breach of Express and Implied Warranties.

vi. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Respectfully Submitted,

DATED: October 31, 2022

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