FILED
12th JUDICIAL DISTRICT COURT
Otero County
7/11/2022 10:43 AM
AUDREY HUKARI
CLERK OF THE COURT
Albert Ochoa

STATE OF NEW MEXICO
COUNTY OF OTERO
TWELFTH JUDICIAL DISTRICT

KIMBERLY DIVELBLISS
Plaintiff,

v.

BARD ACCESS SYSTEMS, INC.,
and C.R. BARD, INC.,
Defendants.

D-1215-CV-2022-00432
Bryant, Daniel A.

COMPLAINT FOR STRICT LIABILITY IN TORT,
BREACH OF STATUTORY WARRANTIES AND PUNITIVE DAMAGES

THE PLAINTIFF Kimberly Divelbliss, by and through counsel Lakins Law Firm, P.C., for her Complaint against Defendants for Strict Liability in Tort, Breach of Statutory Warranties and for Punitive Damages, states as follows:

JURISDICTION AND VENUE

1. This matter arises from the failure of a surgically-implanted medical device manufactured by Defendants sold under the trade name of Bard PowerPort® isp M.R.I Implantable Port (hereinafter "PowerPort").
2. Plaintiff Kimberly Divelbliss is a resident of Otero County, New Mexico.
3. Defendant Bard Access Systems, Inc. ("BAS") is an active foreign corporation, with its principal address in Salt Lake City, Utah, in good standing and licensed to do business in the State of New Mexico, with its principal place of business in New Mexico located in Espanola, NM. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce its medical devices, including the PowerPort. BAS is a wholly owned subsidiary of Defendant C.R. Bard.

EXHIBIT A

4. Defendant C.R. Bard, Inc. ("Bard") is a New Jersey Corporation with its principal place of business located in Murray Hill, New Jersey. Bard is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce its medical devices, including the PowerPort.

5. Venue is proper in the Twelfth Judicial District Court of New Mexico by virtue of the fact that a substantial portion of the events or omission giving rise to the claims occurred in Otero County, New Mexico, and Defendants' products are produced, sold to and consumed by individuals in the State of New Mexico.

6. This court has jurisdiction over the Defendant C.R. Bard pursuant to New Mexico's long arm statute (NMSA 1978, §38-1-16) because Defendants have and continue to conduct substantial business in the State of New Mexico and distribute vascular access products in this jurisdiction, receive substantial compensation and profits from the sale of vascular access products in this jurisdiction, and based upon the material omissions and misrepresentations and breaches of warranties in this jurisdiction as set forth herein committed a tortious act within the State of New Mexico, so as to subject Bard to the jurisdiction in this Court.

FACTS

7. The Bard PowerPort® MRI® isp Implantable Port ("PowerPort") is one of several varieties of port/catheter systems designed, manufactured, marketed, and sold by Defendants.

8. According to sales literature prepared and disseminated by Defendants, the PowerPort is a totally implantable vascular access device designed to provide repeated access to

the vascular system for delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

9. The stated intended purpose of the PowerPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

10. The PowerPort consists of two primary components: an injection port and a silicone catheter.

11. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter that is inserted into a blood vessel.

12. The PowerPort is "indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples."

13. According to BAS marketing materials, the Groshong© Catheter "[s]ilicone material offers superior biocompatibility and thromboresistance to improve indwelling catheter time."

14. The PowerPort is commonly used in patients with cancer and other illnesses requiring routine injection of medications to facilitate the administration of chemotherapy or other long-term infused medications.

15. Defendants obtained "clearance" to market these products under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

16. Unlike the rigorous pre-market approval requirements under the FDA, §510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally

marketed predicate devices without formal review for the safety or efficacy of the device. Section 510(k) reviews are completed in an average of 20 hours as compared to the 1200 hours necessary to complete a PMA review, and rarely elicit negative responses from the FDA. *See McDonald v Zimmer, Inc.,* 2020-NMCA-020, ¶ 11, 461 P.3d 930, citing to *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996) ("Whereas the premarket review process (which requires 1,200 hours to complete) is a federal safety review, the on-average 20-hour review process for devices marketed under 510k "requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.")

17. Although such devices are ordinarily required to undergo a rigorous premarket approval process, the Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (the Act), permitted devices that are "substantially equivalent" to devices already on the market to avoid the premarket approval process. *See* 21 U.S.C. § 360e(b)(1)(B) (2018). Courts have observed that this truncated route (known as the "510k process," under a prior version of the Act) is "focused on equivalence, not safety." *Medtronic, Id*, 518 U.S. at 493.

18. Once a product is cleared by the FDA under the §510(k), the manufacturer remains under an obligation to investigate and report any adverse events associated with the device and must periodically submit any new information to the FDA that may affect the agency's previous conclusions regarding safety and efficacy. This obligation extends to post-market monitoring of adverse events/complaints.

19. 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.

EXHIBIT A

20. At all times relevant hereto, Defendants misrepresented the safety of the PowerPort system, and marketed, distributed, and sold the PowerPort system as a safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions and blood products.

21. At all times relevant to hereto, Defendants knew, and had reason to know, that the PowerPort was not safe for the patients for whom they were prescribed and implanted, because once implanted, the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

22. At all times relevant hereto, Defendants knew and had reason to know that patients implanted with a PowerPort had an increased risk of suffering life threatening injuries, including but not limited to: death, hemorrhage, cardiac/pericardial tamponade, cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

23. Soon after the PowerPort was introduced to the market, and years before Plaintiff's PowerPort device was implanted, Defendants received large numbers of Adverse Event Reports (AERs) from healthcare providers, which reporting informed Defendants that the PowerPort was fracturing, migrating, and otherwise malfunctioning post-implantation, and that fractured pieces were traveling inside patient's bodies.

24. Years prior to the manufacture of the PowerPort device implanted in Plaintiff, Defendants were made aware, through the AER reports, that patients were suffering severe and life-threatening injuries, including hemorrhaging, heart attacks, sever pain, and tearing of blood vessels and organs.

25. Defendants also received large numbers of AERs reporting that PowerPort was found to have perforated internal vasculature. These failures were often associated with reports of patient injuries such as:

    a. Hemorrhage;
    b. Cardiac/pericardial tamponade;
    c. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
    d. Severe and persistent pain; and
    e. perforations of tissue, vessels and organs.

26. After becoming aware of the adverse outcomes in patients associated directly to the PowerPort device, Defendants did not warn patients, treating physicians or other healthcare providers about the risk of fracturing and migration of dislodged portions of the PowerPort device.

27. Despite knowing of a design and manufacturing defect in the PowerPort device, which created excessive risk in patients, Defendants did not change the design or manufacture of the device. Despite being aware of the significant failures of the PowerPort device through the AER reports, Defendants took no action to warn medical providers or consumers of the known flaws in the PowerPort device.

28. Rather, Defendants suggested in written warnings that accompanied the device that fracture may occur only if the physician incorrectly implanted the device in a manner that cause it to compress or "pinch off." At no time did Defendants disclose, even though they were aware, that such fracturing had already occurred in the absence of physician error.

29. There are thousands of recorded device failures and/or injuries related to the Defendants' implantable port products, including the product implanted in Plaintiff, which were

concealed from medical professionals and patients through submission to the controversial Alternative Summary Reporting ("ASR") program.

30. The FDA halted the ASR program in 2019 after its existence was exposed by a multi-part investigated piece by Christina Jewett entitled *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, in Kaiser Health News (March 2019), which prompted widespread outcry from medical professionals and patient advocacy groups.

31. Prior to the discontinuation of the ASR program, Defendants reported thousands of episodes of failures of their implanted port/catheters, including numerous incidents of device fracture and migration, under the ASR exemption, thereby concealing them from physicians and patients.

32. The Defendants improperly hid the device failures in the ASR program when the reports should have been made through the publicly searchable MAUDE database.

33. Defendants were aware or should have been aware that the PowerPort had a substantially higher failure rate than other similar products on the market, yet the Defendants failed to warn consumers of this fact.

34. Defendants were aware of a design defect of the PowerPort device and took intentional action to conceal the design defect from the FDA and consumers.

35. Defendants were also ware of a manufacturing defect of the PowerPort device and took intentional action to conceal the design defect from the FDA and consumers.

36. Despite being aware of defects in the PowerPort devices manufactured by Defendants, Defendants intentionally concealed the severity of complications caused by PowerPort and the likelihood of these events occurring from both the FDA and consumers.

37. Rather than correct the design and manufacturing process of the PowerPort or to make it safer, or adequately warn physicians of the dangers associated with the PowerPort,

Defendants continued to actively and aggressively market the PowerPort as safe, despite their knowledge of design and manufacturing defects, and despite numerous reports of catheter fracture, migration, failure and injuries to numerous patients in which the PowerPort had been installed.

38. The conduct of the Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the PowerPort System, yet consciously failed to act reasonably to:

    a. Adequately inform or warn Plaintiff, her prescribing physicians, the Food and Drug Administration, or the public at large of these dangers; and,

    b. Establish and maintain an adequate quality control procedure in the PowerPort manufacturing process; and,

    c. Establish and maintain an adequate quality and post-market quality control system to ensure the design, manufacturing and labeling deficiencies associated with the device were timely identified and corrected; and,

    d. Recall the known-defective PowerPort System from the market.

39. A Bard Groshong MRI implantable injection port ("PowerPort") was surgically placed in Plaintiff Kimberly Divelbliss on July 13, 2017. The installed port was manufactured by Bard Access Systems. It is identified as Serial Number 1778001, Lot Number REAY1729.

40. The PowerPort was correctly and properly installed by Plaintiff's surgeon, Dr. Uzodinma R. Dim, in accordance with the manufacturer's instructions.

41. The PowerPort device installed in Plaintiff was not installed in such a manner that would have caused it to compress or "pinch off."

42. Defendants, directly or through their agents, apparent agents, and employees, designed, manufactured, marketed advertised, distributed and sold the PowerPort that was implanted in Plaintiff Kimberly Divelbliss.

43. The Defendants knowingly and intentionally concealed their knowledge of the PowerPort's faulty design and manufacturing, and the unreasonably dangerous risks associated with the faulty device from Plaintiff, her physicians and the FDA.

44. On December 13, 2019 Kimberly Divelbliss underwent emergency surgery to remove the PowerPort. The polyurethane catheter had broken; a more than 7-inch section of the catheter detached and became lodged in Plaintiff's right atrium.

45. The Defendants failed to warn Plaintiff or her physicians of the true quantitative or qualitative risk of fracture, migration or dislodgement associated with the PowerPort.

46. Rather than correct the faulty design and manufacture of the PowerPort product to make it safer, or warn physicians of the known dangers associated with the PowerPort, the Defendants continued with sale and marking efforts to sell their knowingly defective product to health care providers and patients such as Plaintiff.

47. Plaintiff's physician relied upon the representations, including the instructions for use distributed with the PowerPort product implanted in the Plaintiff and the product advertising to Plaintiff's detriment.

48. At all times the PowerPort was used for its intended purpose of injecting medication into (or withdrawing blood from) Plaintiff, all medical personnel who provided treatment to Plaintiff properly followed the instructions for use of the PowerPort, including the requirement for use of certain sized needles.

49. Defendants intentionally and knowingly concealed the dangerous propensity of the PowerPort device to fracture and migrate, necessitating surgical intervention. Defendants further intentionally concealed their knowledge about the cause of these failures, and that the failures were known to cause serious injuries.

50. As a result of the intentional actions of the Defendants (including their failures to notify the FDA, the medical profession and consumers), and the Defendants' wrongful conduct in designing, manufacturing, and marketing a known defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would have been exposed to risks associated with the PowerPort and the complications Plaintiff suffered from the defective PowerPort device, and that those risks were the direct and proximate result of the Defendants' acts, omissions and intentionally and knowingly-made misrepresentations.

51. The Defendants failed to notify the FDA, the medical community and consumers of the known defects in the PowerPort device, and knowingly and intentionally withheld information about the known defects of the device, which were known to Defendants prior to the manufacture of the device that was implanted in Plaintiff.

52. While Defendants were aware prior to July 13, 2017 of design and manufacturing defects of the PowerPort device existed, and that such defects constituted extreme health risks to patients such as Plaintiff, Defendants continued to advertise the device as completely safe, and continued to distribute and sell the known-defective PowerPort.

53. Due directly to the failure of the PowerPort installed in Plaintiff, Plaintiff was required to undergo extensive necessary medical treatment. This included the emergency removal of

the faulty PowerPort, as well as several subsequent heart surgeries to address the damage to her heart directly caused by the faulty device.

54. Due directly to the defective PowerPort, Plaintiff has suffered damages and continues to suffer damages including, but not limited to, undergoing multiple surgeries, medical and hospital expenses, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear of and anxiety from future injuries, including but not limited to cardiac injuries.

Count I
Strict Liability - Failure to Warn

55. Plaintiff incorporates the preceding paragraphs as if set forth herein.

56. Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the PowerPort, including the one implanted into Plaintiff into the stream of commerce (including commerce in the State of New Mexico) and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

57. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, Defendants were aware the device was defective and presented an unreasonably dangerous risk of injury to users of the product when put to its intended and reasonablyy anticipated use, namely as an implanted port/catheter system to administer the medications.

58. Defendants knew at the time they manufactured, marketed, distributed, and sold the PowerPort that was implanted into Plaintiff that the PowerPort devices were fracturing and

migrating for reasons other than "pinch-off" caused by the physician's incorrect initial placement of the device. For example, Bard knew internally long before it manufactured Plaintiff's device that these devices were fracturing due to such reason as, but not limited to, fatigue failure, flex fatigue, and chemical degradation.

59. Prior to manufacturing the PowerPort device implanted into Plaintiff, Defendants knew the PowerPort devices were fracturing and migrating and causing patient injuries at much higher reported failure rates than had ever been revealed to or expected by consumers.

60. The health risks associated with the PowerPort device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

61. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, Defendants were aware that a substantial number of PowerPort devices sold by Defendants were defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use. Despite this knowledge, Defendants failed to provide a warning (much less an adequate warning) of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

62. Defendants knew or should have known at the time they manufactured marketed, distributed, and sold the PowerPort device implanted into Plaintiff, that the PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

63. Defendants knew or should have known at the time they manufactured, marketed, distributed, and sold the PowerPort that was implanted into Plaintiff that the PowerPort devices were fracturing and migrating for reasons other than "pinch-off" caused by the

physician's incorrect initial placement of the device. For example, Bard knew internally long before it manufactured Plaintiff's device that these devices were fracturing due to such reason as, but not limited to, fatigue failure, flex fatigue, and chemical degradation.

64. Prior to manufacturing the PowerPort device implanted into Plaintiff, Defendants knew the PowerPort devices were fracturing and migrating and causing patient injuries at much higher reported failure rates than had ever been revealed to or expected by consumers.

65. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the PowerPort to medical providers and the FDA, despite having full knowledge of the failures of the PowerPort, which resulted in the device presenting an unreasonably dangerous risk of injury to patients.

66. No warning on any material published and disseminated by Defendants adequately indicated the scope of the danger.

67. The warnings, labels, and instructions provided by the Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

68. The health risks associated with the PowerPort device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

69. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, the device was defective due to inadequate warnings, labeling and/or instructions accompanying the product.

70. When the PowerPort device was implanted in Plaintiff, Defendants Bard and BAS failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, which were known to Defendants.

71. Due directly to Defendants' failure to report the known failures and medical risks associated with the PowerPort device, which were known to Defendants in July 2017, neither Plaintiff nor her health care providers had any reason to know of the substantial danger associated with the defective device.

72. Plaintiff and her health care providers used the PowerPort in a normal, customary, intended and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications into Plaintiff's bloodstream. Moreover, Plaintiff's health care providers did not place, maintain or use the device incorrectly such that it caused the device to malfunction.

73. Defendants' lack of sufficient warnings and instructions created an unreasonably dangerous risk of injury and was the direct and proximate cause of Plaintiff's serious physical injuries; if Defendants had provided adequate warnings, Plaintiff and her physicians would not have used the device, as similar competitive devices existed at the time.

74. Plaintiff has suffered damages due directly to Defendants' failure to warn.

Count II
Strict Liability - Design Defect

75. Plaintiff incorporates the preceding paragraphs as if set forth herein.

76. Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the PowerPort, including the one implanted into Plaintiff into the stream of commerce (including commerce in the State of New Mexico) and in the course of same, directly

advertised and marketed the device to consumers or persons responsible for consumers, and therefore are strictly liable for distributing a defectively designed product.

77. The PowerPort implanted in Plaintiff was defective in its design and unreasonably dangerous at the time it left the control of Defendants and entered the stream of commerce; it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable, and because the foreseeable risks of the device devices exceeded any benefits associated with its use.

78. At the time PowerPort implanted in Plaintiff was manufactured, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

79. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, Defendants were aware the design of the device was defective and presented a substantial danger to users of the product when put to its intended and reasonablyy anticipated use.

80. Plaintiff and her health care providers used the PowerPort in a manner that was reasonably foreseeable to Defendants and in the manner it was intended to be used.

81. Neither Plaintiff nor her health care providers could have by the exercise of reasonable care discovered the defective condition or perceived the unreasonable dangers with the PowerPort prior to the device being implanted into Plaintiff.

82. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing and selling the defectively designed PowerPort implanted in Plaintiff.

83. The design defect of the PowerPort implanted into Plaintiff created an unreasonably dangerous risk of injury and was a direct and proximate cause of Plaintiff's serious physical injuries, and Plaintiff has suffered damages due directly to the design defect.

Count III
Strict Liability - Manufacturing Defect

84. Plaintiff incorporates the preceding paragraphs as if set forth herein.

85. Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the PowerPort, including the one implanted into Plaintiff into the stream of commerce (including commerce in the State of New Mexico) and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore are strictly liable for manufacturing a defective product.

86. Upon information and belief, the defective and dangerous condition of the device implanted into Plaintiff existed at the time it was manufactured by Defendants.

87. Based on information and belief, Defendants operated under design and manufacturing specifications for the PowerPort, which included appropriate material content, strength, size, durability appearance, resistance levels, and the devices were not to be distributed if they exhibited excessive surface damage. The manufacturing process was intended to identify any end-product products that did not meet design specifications, so that those devices would not be placed into the stream of commerce.

88. Based upon information and belief, The PowerPort implanted in Plaintiff contained manufacturing defects when it left Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical units of the same product line.

89. Upon information and belief, the PowerPort implanted in Plaintiff varied from its intended specifications in that the device did not have the specified material content, strength, size, durability, strength, and contained surface damage, pitting, or cracking on the exterior of the device which increased the risk of fracture and migration.

90. The device implanted in Plaintiff was in the same condition as when it was manufactured distributed and sold by Defendants.

91. The PowerPort device implanted into Plaintiff, which Defendants manufactured, marketed, distributed, and sold into the stream of commerce was defective at the time of its release into the stream of commerce.

92. Plaintiff and her health care providers used the PowerPort in a way that was reasonably foreseeable to Defendants.

93. The device's manufacturing defect created an unreasonably dangerous risk of injury and was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages.

Count IV
Breach of Implied Warranties

94. Plaintiff incorporates the preceding paragraphs as if set forth herein.

95. Under New Mexico's Uniform Commercial Code (NMSA 1978, §55-2-314), an implied warranty of merchantability is created in a contract for the sale of their goods if the seller is a merchant with respect to goods of that kind.

96. Under New Mexico's Uniform Commercial Code (NMSA 1978, §55-2-315), "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section [55-2-316 NMSA 1978] an implied warranty that the goods shall be fit for such purpose."

97. Defendants impliedly warranted that the PowerPort was merchantable and fit for the ordinary purposes for which it was intended.

98. The PowerPort was sold to the Plaintiff's health care providers for implantation in patients, such as the Plaintiff.

99. When the PowerPort was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

100. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' statements and representations in consenting to have the PowerPort implanted in her.

101. Defendants breached the implied warranties of merchantability because the PowerPort implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted.

102. Defendants' breaches of the implied warranties resulted in the implantation of unreasonably dangerous and defective PowerPort in Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

103. In accordance with NMSA 1978, §55-2-607(3)(a), on December 14, 2020, counsel for Plaintiff sent to each of the Defendants a "Notice of Breach Under New Mexico Uniform Commercial Code," which stated:

> A Bard Groshong MRI implantable injection port ("PowerPort") was surgically placed in Ms. Divelbliss on 7/13/2017. The installed port was manufactured by Bard Access Systems. It is identified as Serial Number 1778001, Lot Number REAY1729.
>
> On December 13, 2019 Ms. Divelbliss underwent surgery to remove the PowerPort. The polyurethane catheter had broken; a more than 7-inch section of the catheter detached and became lodged in her right atrium. Due directly to the failure of the port, Ms. Divelbliss has been required to undergo extensive necessary medical treatment. This has been for the emergency removal of the faulty port, as well as several subsequent heart surgeries to address the damage to her heart directly caused by the faulty device.
>
> Under New Mexico's Uniform Commercial Code, an express warranty is created based upon the description that the goods sold shall conform to the description, upon which the buyer relies as the basis of the bargain. (NMSA 1978, § 55-2-313). Under NMSA § 55-2-314, an implied warrant of merchantability is also created. NMSA § 55-2-315

further creates an implied warranty of fitness for a particular purpose. All of these statutorily-created warranties have been breached. This letter serves as Notice of Breach of the warranties created under New Mexico's Uniform Commercial Code, required under NMSA 1978, Section 55-2-607(3)(a).

104. On December 28, 2020, counsel for Defendants, David J. Cooner of McCarter & English, LLP, acknowledged via e-mail receipt of Plaintiff's counsel's December 14, 2020 Notice of Breach letter.

105. Due directly to Defendants' breaches of their implied warranties Plaintiff has suffered and will continue to suffer significant physical injuries and damages.

Count IV
Breach of Express Warranty

106. Plaintiff incorporates the preceding paragraphs as if set forth herein.

107. Under New Mexico's Uniform Commercial Code, express warranties are created by the seller under the following conditions:

a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise;

(b) any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description;.

NMSA 1978, § 55-2-313.

108. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use

109. The PowerPort implanted in Plaintiff did not conform to the Defendants' express representations because it was not reasonably safe, had numerous serious side effects, and caused severe and permanent injuries to Plaintiff.

110. At all relevant times, the PowerPort did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

111. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the PowerPort.

112. At all relevant times, the PowerPort was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

113. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breach of warranty and realized the danger of implanting the PowerPort into Plaintiff.

114. As a direct and proximate result of Defendants' breach of the statutory express warranty, Plaintiff has suffered, and will continue to suffer, suffered significant physical injuries and damages.

Count V
Punitive Damages

115. Plaintiff incorporates the preceding paragraphs as if set forth herein.

116. Not only did Defendants intentionally fail to issue any warning regarding the known hazardous condition of the PowerPort device to the FDA, to the medical community and to patients, Defendants knowingly, intentionally and with conscious disregard for the health and safety of patients, including Plaintiff, concealed the defects of the device that were known to Defendants from the FDA, from the medical community and from patients such as Plaintiff.

117. The conduct of the Defendants was malicious, reckless, wanton and/or in bad faith.

118. Punitive damages should be awarded against Defendants.

Jury Demand

119. Plaintiff demands a jury on all issues triable by jury.

WHEREFORE, Plaintiff Kimberly Divelbliss respectfully requests that the Court:

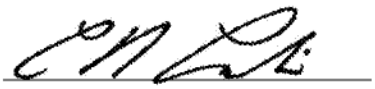
A. Award Plaintiff compensatory damages, including for pain & suffering, emotional damages, loss of consortium and all other allowable damages, for each of her claims against Defendants, in an amount to be proven at trial; and,

B. Award appropriate punitive damages against Defendants; and,

C. Award Plaintiff her reasonable attorneys fees and costs incurred as permitted under New Mexico law; and,

D. Enter such further relief as the Court deems just and appropriate.

Respectfully Submitted,
Lakins Law Firm, P.C.



Charles N. Lakins, Esq.
PO Box 91357
Albuquerque, NM 87199
(505) 404-9377

EXHIBIT A

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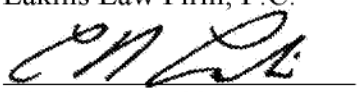
Bryant, Daniel A.

BARD ACCESS SYSTEMS, INC.,
and C.R. BARD, INC.,
Defendants.

JURY DEMAND

THE PLAINTIFF Kimberly Divelbliss, by and through counsel of record, pursuant to NMRA Rule 1-038, hereby submits her demand for a six (6) person jury in the trial of the above-captioned matter.

Respectfully Submitted,
Lakins Law Firm, P.C.



Charles N. Lakins, Esq.
PO Box 91357
Albuquerque, NM 87199
(505) 404-9377

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IN THE DISTRICT COURT
TWELFTH JUDICIAL DISTRICT
STATE OF NEW MEXICO
COUNTY OF OTERO

Kimberly Divelbliss

Plaintiff(s),

vs.

No. CV- D-1215-CV-2022-00432

Judge Daniel A. Bryant
Division III

Bard Access Systems, Inc., et. al.

Defendant(s).

ORDER REQUIRING COMPLETION OF SCHEDULING FORM

IT IS ORDERED:

A. Plaintiff shall serve a copy of this order on each defendant with the summons and complaint and file a certificate of such service. Rule 1-005.

B. Within ninety (90) days after service of the complaint is completed, the parties shall confer and are encouraged to file a Joint Scheduling Form.

c. Parties of record shall complete and file the scheduling conference form (attached) and submit a copy to the assigned judge. If the parties cannot agree on the scheduling deadlines, counsel of record shall request a Rule 1-016(B) scheduling conference.

D. The Court will draft a Scheduling Order from the stipulated scheduling form and/or after the Rule 1-016(B) scheduling conference hearing.

E. Any party who enters the case after the scheduling order has been filed and cannot abide by the scheduling deadlines, shall contact counsel/parties of record and either submit an amended scheduling order or request a Rule 1-016(B) scheduling conference hearing.

Daniel A. Bryant

DANIEL A. BRYANT
DISTRICT JUDGE, DIVISION III

Delivered to Plaintiff this 11 day of July, 20 22.

By: /s/ Albert Ochoa
Court Clerk

SCHEDULING CONFERENCE FORM

_____

Plaintiff(s),

vs.

Cause No. CV-[redacted]
Judge Daniel A. Bryant
Division III

_____

Defendant(s).

Date of discussions:

_____

Counsel for Plaintiff(s):

_____

Counsel for Defendants(s):

_____

Joinder of parties and amendment of pleadings: Deadline _____

___ There is no need to join additional parties.

There is no need for further amendment of the pleadings.

___

___ Motions addressed to the pleadings: Deadline _____

*Plaintiffs lay witness list shall be exchanged: Deadline _____

*Defendant's lay witness list shall be exchanged: Deadline _____

*Plaintiffs expert witness list shall be exchanged: Deadline _____

*Defendant's expert witness list shall be exchanged: Deadline _____

Discovery will be complete by: Deadline _____

___ Discovery is complete.

All motions, except for motions in limine, shall be filed by: Deadline _____

There is no need for further Motions.

Parties will conduct a Settlement Conference on the following date:

_____

A settlement facilitator is (requested) (not requested).

__

Name of settlement facilitator

_____

*Exhibit list shall be filed by: Deadline_____

*Specific objections to other parties's proposed exhibits by: Deadline

_____

Plaintiffs shall submit their portions of a pretrial order to defendants by: Deadline _____Defendants shall file the proposed final pretrial order with the court by: Deadline_____

Parties shall file a final witness list by: Deadline_____
Final witness list shall list "will call" and "may call"

Pre-Trial Conference needed: Yes No_____

Proposed Jury Instructions shall be due to the Court by: Deadline_____

Proposed Findings of Fact and Conclusions of Law by: Deadline_____

Motions in limine shall be filed by: Deadline_____
Amount of time needed for Trial on the Merits: _____days

__Non-Jury 6 Person Jury 12 Person Jury

_____ _____

Counsel for Plaintiff(s) Counsel for Defendant(s)

Dates contained in paragraphs of this form marked with an asterisk (*) may be modified by written agreement of all parties, without court approval. Only the court, for good cause, may change other dates.

EXHIBIT A