UNITED STATES DISCTRICT COURT
FOR THE DISTRICT OF ARIZONA

JOHANNA RANDOW,

Plaintiff,

vs.

C.R. BARD, INC., a corporation; BARD ACCESS SYSTEMS, INC., a corporation; Bard Peripheral Vascular, Inc., and DOES 1 through 10 inclusive,

Defendants.

No. _____

COMPLAINT

(Jury Trial Demanded)

COMES NOW the Plaintiff, JOHANNA RANDOW, (who hereinafter shall be referred to as the "Plaintiff" or as "Randow"), by and through her undersigned counsel, and brings this Complaint against C.R. Bard, Inc.; Bard Access Systems, Inc.; Bard Peripheral Vascular, Inc., and DOES 1 through 10 (collectively, the "Defendants"), and alleges as follows:

1) This is an action for damages relating to Defendant's design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective device sold under the trade name of Bard 9.6 French Infuse-A-Port catheter (hereinafter "Infuse-A-Port" or "Defective Device").

PARTIES

2) Plaintiff, Randow, is an adult resident of the state of Maryland and claims damages as set forth below.

3) Defendant C.R. Bard, In. ("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, either directly or indirectly through third parties or related entities, its medical

devices, including the Infuse-A-Port.

4) Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located in Salt Lake City, Utah. BAS conducts business throughout the United States, including the State of Maryland, and is a wholly owned subsidiary of Bard. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Infuse-A-Port.

5) Defendant Bard Peripheral Vascular, Inc. (BPV) is an Arizona corporation as its principal place of business and state of incorporation is in Arizona. BPV is a wholly owned subsidiary corporation of Bard and is authorized to do business in and did do business in the state of Maryland. When Becton Dickinson purchased Bard in December 2017, BPV assumed responsibility for overseeing the implanted ports, including as to manufacturing, design-control, quality systems, marketing, sales and post-market surveillance.

6) Plaintiff is ignorant of the true names and capacities of defendants sued herein as DOES 1 through 10, inclusive, and therefore sues these defendants by such fictitious names. Plaintiff will amend this complaint to allege their true names and capacities when ascertained.

JURISDICTION AND VENUE

7) This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

8) Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

9) Defendants have and continue to conduct substantial business in the State of Arizona and in this District, distribute implanted port systems in this District, receive substantial compensation and

profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

PRODUCT BACKGROUND

10) The Bard Infuse-A-Port M.R.I. Implantable Port ("Infuse-A-Port") is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

11) The Infuse-A-Port is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

12) The intended purpose of the Infuse-A-Port 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.

13) The Infuse-A-Port is a system consisting of two primary components: an injection port and a silicone catheter.

14) 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.

15) The Infuse-A-Port 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."

16) According to BAS and PBV's marketing materials, the catheter has "[s]ilicone material [which] offers superior biocompatibility and thromboresistance to improve indwelling catheter time." However, Defendants have known long before Plaintiff was implanted with the device that silicone catheters are more likely to fracture, rupture or break then polyurethane catheters.

17) The Infuse-A-Port is commonly used in patients with cancer (such as Plaintiff) and rheumatoid arthritis to facilitate the administration of chemotherapy or other long-term infused

medications.

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

19) Section 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. 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 manufacture 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.

20) 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).

21) 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.

22) At all times relevant, Defendants misrepresented the safety of the Infuse-A-Port system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Infuse-A-Port system as 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.

23) At all times relevant to this action, Defendants knew and had reason to know, that the Infuse-A-Port was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was unreasonably prone to fracturing, migrating, perforating internal vasculature, causing thromboembolism and/or Pulmonary embolism, and otherwise malfunctioning and did so at rates higher than other available similar devices.

24) At all times relevant to this action, Defendants knew and had reason to know that patients implanted with Infuse-A-Ports had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); 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 or treat complications from these product failures.

25) Soon after the Infuse-A-Port was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of AERs from health care providers reporting that the Infuse-A-Port was fracturing and migrating post-implantation. Defendants also received large numbers of AERs reporting that Infuse-A-Port was found to have perforated internal vasculature or caused thromboembolism and/or pulmonary embolism. These failures were often associated with reports of severe 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;

e. and perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

26) 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.

27) Bard's head of Quality has testified that it is understood that at most only 5 to 10% of adverse events are ever reported to Bard or the FDA.

28) The FDA halted the ASR program in 2019 after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[1]

29) Prior to the discontinuation of the ASR program, Defendants reported thousands of episodes of failures of their implanted port/catheter products –including numerous episodes of device fracture and and/or migration – under the ASR exemption, thereby concealing them from physicians and patients.

30) Defendants also improperly hid substantial numbers of device failure in the ASR program when these reports should have been made to the publicly searchable MAUDE database.

31) Defendants were aware or should have been aware that the Infuse-A-Port had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

32) Defendants also intentionally concealed the likelihood and severity of complications caused by the Infuse-A-Port and the likelihood of these events occurring.

33) Rather than alter the design of the Infuse-A-Port to make it safer or adequately warn physicians of the dangers associated with the Infuse-A-Port, Defendants continued to actively and aggressively market the Infuse-A-Port as safe, despite their knowledge of numerous reports of catheter failure, including fracture, migration, perforation and associated injuries.

[1] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

34) Indeed, Defendants sought to mislead physicians and patients in marketing and labeling materials by suggesting that catheter portion of the device can only fracture from physician error in placement of the device leading to "pinch-off." However, Defendants knew internally that these devices were actually fracturing from other causes such as degradation and fatigue failure. Defendants knowingly concealed the true cause of these failures and the likelihood and severity of these failures in order to induce physicians and patients to continue to use the devices.

35) Numerous reports of Infuse-A-Port catheter fractures and migration or dislodgment in the absence of physician error or pinch-off were recorded and reported to BAS prior to prior to the implantation of the Infuse-A-Port in Plaintiff.

36) Defendants also knowingly used materials in the construction of these devices that were never indicated for long term implantation in humans despite knowing there was no time limitation on the implantation of these devices and that the devices were often left implanted for many years. However, Defendants again knowingly concealed this information from physicians and patients.

37) However, Defendants continued to actively and aggressively market the Infuse-A-Port as safe, despite knowledge of numerous reports of catheter migration or dislodgment. Defendants utilized marketing communications, including the Instruction for Use, and direct communications from sales representatives to Plaintiff's health care providers to intentionally misled her health care providers into believing these failures were caused by physician error.

38) The conduct of 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 Infuse-A-Port System, yet consciously failed to act reasonably to:

a. Adequately Inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;
b. Establish and maintain an adequate quality and post-market surveillance system to ensure the design, manufacturing and labeling deficiencies associated with the device were timely identified and corrected; or
c. Recall and/or retrofit the Infuse-A-Port System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO JOHANNA RANDOW

39) On or about April 27, 2018, Plaintiff underwent placement of the Bard Infuse-A-Port, reference number 1809601, lot number RECP1112. The device was implanted by Dr. Micah Girotti at University of Maryland Upper Chesapeake Medical Center, Maryland. The purpose of the device was to facilitate chemotherapy treatment.

40) Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the Infuse-A-Port system that was implanted in Plaintiff.

41) On July 19, 2019, Plaintiff underwent removal of the Infuse-A-Port system because the device was no longer functioning. Plaintiff developed a pulmonary embolism in November 2021. Echocardiogram examinations in March and June 2022 and June 2023 show a fragmented portion of catheter in Plaintiff's heart.

42) Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of fracture, migration, perforation, thromboembolism or dislodgment associated with the Infuse-A-Port system. Rather than alter the design of their product to make it safer or warn physicians of the dangers associated with the Infuse-A-Port, the Defendants chose to continue their efforts to promote their defective product.

43) As a result of the failure of the Defendants' Infuse-A-Port and the Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions and misrepresentations.

44) Plaintiff's physicians relied upon the representations, including the instructions for use distributed with the product implanted in Plaintiff, and advertisements to Plaintiff's detriment.

45) Had adequate warnings been provided, Plaintiff's prescribing physician would not have used the device or would have passed this information on to Plaintiff in the informed consent process and Plaintiff would have declined the use of the device.

46) As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of

the Infuse-A-Port, which has caused and will continue to cause Plaintiff's various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

47) Upon information and belief, one or more fragments of the Infuse-A-Port remain in or around Plaintiff's heart. As a result, Plaintiff is exposed to substantial risk of future injury including cardiac injuries, vasculature perforation, and thromboembolism or pulmonary emboli. Plaintiff will also worry every day of the rest of her life if today is the day that a catheter fragment causes additional injury.

FIRST CAUSE OF ACTION
NEGLIGENCE

(Against All Defendants)

48) Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

49) The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the Infuse-A-Port.

50) The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

(a) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

(b) Failing to use reasonable care in manufacturing the product and producing a product that differed from their design specifications or from other typical units from the same production line;

(c) Manufacturing a product using materials that were not cleared for long term use in the human body;

(d) Designing a product that lacked sufficient design elements to withstand foreseeable in vivo forces and conditions without suffering fracture and migration from things such as fatigue failure, chemical degradation, and flex fatigue;

(e) Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's physicians, or

the general health care community about the products substantially dangerous condition or about facts making the product likely to be dangerous;

(f) Failing to perform reasonable pre- and post-market testing of the product to determine whether or not the product was safe for its intended use;

(g) Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the product;

(h) Advertising, marketing and recommending the use of the product, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the device;

(i) Representing that the product was safe for its intended use when in fact, the Defendants knew and should have known the product was not safe for its intended purpose;

(j) Continuing the manufacture and sale of the product with the knowledge that said product was dangerous and not reasonably safe;

(k) Failing to use reasonable and prudent care in the design, research, manufacture, and development of the product so as to avoid the risk of serious harm associated with the use of the device;

(l) Failing to establish and maintain an adequate quality assurance program used in the manufacturing of the product;

(m) Failing to establish and maintain and adequate post-market surveillance program to ensure deficiencies in the design, manufacturing process, and labeling were timely and adequately identified and corrected.

(n) Making changes to the design of the product and or its predecessor products on which it obtained FDA clearance without notifying and obtaining clearance from the FDA to make these design changes.

(o) Failing to timely and adequately recall or retrofit the product; and

(p) Failing to issue any safety or warning letters to doctors correcting false marketing claims made in marketing materials or by sales representatives or providing notice of updated labeling.

51) A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

52) As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice, so as to justify an award of punitive and/or exemplary damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All Defendants)

53) Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

54) Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Infuse-A-Port, including the one implanted into Plaintiff, into the stream of commerce 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.

55) At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn 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.

56) Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Infuse-A-Port that was implanted into Plaintiff that the Infuse-A-Port posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

57) Defendants further knew that these 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 fatigue failure, flex fatigue, and chemical degradation. Prior to manufacturing, Plaintiff's product, Defendants also knew that these 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.

58) Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Infuse-A-Port; neither Plaintiff's health care providers or Plaintiff would have used the device in the manner directed, had these facts been made known to them.

59) 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.

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

61) The device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

62) When Plaintiff was implanted with the device, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

63) Defendants intentionally underreported the number and nature of adverse events associated with dislodgement and migration of the devices to Plaintiff's health care providers, as well as the FDA. Moreover, Defendants abused the ASR program to ensure that consumers would not discover thousands

of reported device failures and patient injuries from these products.

64) Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

65) Plaintiff and her health care providers used Infuse-A-Port in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to malfunction.

66) The defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. The device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

67) Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the device.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against All Defendants)

68) Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

69) Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Infuse-A-Port that was implanted into Plaintiff.

70) Based on information and belief, Defendants operated under design and manufacturing

specifications for the Infuse-A-Port, 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 Defendants' specifications, so that those devices would not be placed into the stream of commerce.

71) Based on information and belief, The Infuse-A-Port 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 unites of the same product line.

72) Upon information and belief, the Infuse-A-Port implanted in Plaintiff varied from its intended specifications in that the device in that it 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 acted to increase the risk of fracture and migration.

73) Plaintiff and her health care providers used the Infuse-A-Port in a way that was reasonably foreseeable to Defendants.

74) The device's manufacturing defect was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against All Defendants)

75) Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

76) The Infuse-A-Port 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, because 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.

77) At the time Infuse-A-Port implanted in Plaintiff was manufactured, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

78) Plaintiff and her health care providers used the Infuse-A-Port in a manner that was reasonably foreseeable to Defendants and in the manner it was intended to be used.

79) 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 Infuse-A-Port prior to Plaintiff's implantation with the device.

80) Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling the defectively designed Infuse-A-Port implanted in Plaintiff.

81) As a direct and proximate result of the Infuse-A-Port's aforementioned defects, the Plaintiff was caused and/or 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.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

(Against All Defendants)

82) Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

83) Defendants impliedly warranted that the Infuse-A-Port was merchantable and fit for the ordinary purposes for which it was intended.

84) When the Infuse-A-Port was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

85) The Plaintiff, individually and/or by and through her physician, relied upon Defendants'

implied warranties of merchantability in consenting to have the Infuse-A-Port implanted in him.

86) Defendants breached these implied warranties of merchantability because the Infuse-A-Port implanted in the Plaintiff was neither merchantable nor suited for its intended uses as warranted.

87) Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective Infuse-A-Port in the Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

88) The Infuse-A-Port was sold to the Plaintiff's health care providers for implantation in patients, such as the Plaintiff.

89) As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, the Plaintiff was caused and/or 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.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

(Against All Defendants)

90) Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

91) Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Infuse-A-Port 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.

92) The Infuse-A-Port does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

93) At all relevant times, the Infuse-A-Port did not perform as safely as an ordinary consumer

would expect, when used as intended or in a reasonably foreseeable manner.

94) Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the Infuse-A-Port.

95) At all relevant times, the Infuse-A-Port was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

96) Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

97) As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

SEVENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

(Against All Defendants)

98) Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

99) Defendants fraudulently concealed information with respect to the Infuse-A-Port in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Infuse-A-Port was safe and fraudulently withheld and concealed information about the substantial risks of using the Infuse-A-Port;

b. Defendants represented that the Infuse-A-Port was safer than other alternative systems and

fraudulently concealed information which demonstrated that the Infuse-A-Port was not safer than alternatives available on the market;

c. Defendants concealed that it knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and that frequency of these failures and the severity of injuries were substantially worse than had been reported.

100) The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Infuse-A-Port.

101) The concealment of information by the Defendants about the risks of the Infuse-A-Port was intentional, and the representations made by Defendants were known by Defendants to be false.

102) The concealment of information and the misrepresentations about the Infuse-A-Port was made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely upon them.

103) Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the Infuse-A-Port which the Defendants concealed from the public, including Plaintiff and her physicians.

104) As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

105) The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

106) Had Defendants not concealed this information, neither Plaintiff nor her health care providers would have consented to using the device in Plaintiff.

Wherefore, Plaintiff sues the Defendants for damages in a sum to confer jurisdiction upon this

Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

PUNITIVE DAMAGES

107) Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Infuse-A-Port. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and her health care providers, regarding the cause of dislodgement and migration failures of the device.

108) Defendants had knowledge of, and were in possession of evidence demonstrating that, the Infuse-A-Port caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the Infuse-A-Port, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the Infuse-A-Port and consumers from agreeing to being implanted with the Infuse-A-Port, thus depriving physicians and consumers from weighing the true risks against the benefits of

prescribing and implanting the Infuse-A-Port.

109) As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered, and will continue to suffer, the injuries and damages described in this complaint.

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

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgement be entered against all Defendant on all causes of action of this Complaint;
b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;
c. Plaintiff be awarded general damages according to proof at the time of trial;
d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;
e. Plaintiff be awarded punitive damages according to proof at the time of trial;
f. Awarding pre-judgment and post-judgment interest to the Plaintiff;
g. Awarding the costs and the expenses of this litigation to the Plaintiff.
h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: September 19, 2023

BEN MARTIN LAW GROUP

By */s/ Ben C. Martin*

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