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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA**

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AMBER NORDIN, an Individual, and

Plaintiffs,

v.

C.R. BARD, INC.; BARD
PERIPHERAL VASCULAR, INC.;
and DOES 1-100,

Defendants.

_____)
CASE NO.: 16-CV-4005

COMPLAINT AND DEMAND
FOR JURY TRIAL

1. Plaintiff, AMBER NORDIN, an Individual, brings this civil action in the District Court of South Dakota against Defendants C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., and alleges:

INTRODUCTORY ALLEGATIONS

2. Plaintiff bring this action for personal injuries damages suffered by an injured or deceased party or parties as a direct and proximate result of an injured or deceased party being implanted with a defective and unreasonably dangerous Inferior Vena Cava ("IVC") filter medical device manufactured by Bard.

3. Upon information and belief, Plaintiff received the Eclipse® model from Bard's IVC "retrievable" filter product line.

1 4. Plaintiff's claims for damages all relate to Bard's design, manufacture,
2 sale, testing, marketing, labeling, advertising, promotion, and/or distribution of
3 Bard IVC Filters.

4 5. The Bard IVC Filter that is the subject of this action reached Plaintiff
5 and her physicians without substantial change in condition from the time it left
6 Bard's possession.

7 6. Plaintiff and her physicians used the Bard IVC Filter in the manner in
8 which it was intended.

9 7. Bard is solely responsible for any alleged design, manufacture or
10 informational defect Bard IVC Filters contain.

11 8. Bard does not allege that any other person or entity is comparatively
12 at fault for any alleged design, manufacture, or informational defect Bard IVC
13 Filters contain.

14 **PARTIES**

15 9. Plaintiff AMBER NORDIN at all times relevant to this action was a
16 citizen of South Dakota and resident of Sioux Falls in Minnehaha County.

17 10. On or about October 12, 2012, Plaintiff underwent placement of a
18 Bard Eclipse® Inferior Vena Cava Filter ("G2® IVC Filter") at Sanford
19 University of South Dakota Medical Center in Sioux Falls, South Dakota.. The
20 filter subsequently failed and injured the Plaintiff in that the filter became
21 embedded within Plaintiff and cause additional complications. Thereafter, the
22 filter required open surgery to attempt removal of the device but ultimately
23 Physician's surgeon was unable to remove the filter. Plaintiff was caused to
24 undergo extensive medical treatment and care as a result of the failure of the filter
25 manufactured by Defendants. Plaintiff has suffered and will continue to suffer
26 significant medical expenses, extreme pain and suffering, mental anguish, loss of
27 enjoyment of life, disability, scarring and disfigurement, and other losses
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1 proximately caused by the device. Plaintiff will have continued risk of requiring
2 additional medical and surgical procedures, including risk of life threatening
3 complications and ongoing medical care to monitor the G2® IVC Filter to ensure
4 that it does not cause additional or further injury.

5 11. Defendant C.R. Bard, Inc. ("C.R. Bard") is a corporation duly
6 organized and existing under the laws of the state of Delaware and has its
7 principal place of business in New Jersey. Bard, at all times relevant to this action,
8 designed, set specifications for, manufactured, prepared, compounded, assembled,
9 processed, marketed, distributed, and sold the Recovery®, 02®, 02®X (02
10 Express®), Eclipse®, Meridian®, and Denali® Filter Systems to be implanted in
11 patients throughout the United States including the State of Arizona and Plaintiff's
12 states of residence and/or injury.

13 12. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly-owned
14 subsidiary corporation of Defendant C.R. Bard, with its principal place of business
15 at 1625 West Third Street, Tempe, Arizona. BPV, at all times relevant to this
16 action, designed, set specifications for, manufactured, prepared, compounded,
17 assembled, processed, marketed, distributed, and sold the Recovery®, 02®,
18 02®X(02 Express®), Eclipse®, Meridian®, and Denali® Filter Systems to be
19 implanted in patients throughout the United States, including the State of Arizona
20 and Plaintiff's states of residence and/or injury.

21 13. There exists, and at all relevant times existed, a unity of interest in
22 ownership between certain defendants and other defendants such that any
23 individuality and separateness between the certain defendants has ceased and
24 those defendants are the alter ego of the other certain defendants, and exerted
25 control over those defendants.
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1 14. Adherence to the fiction of the separate existence of these certain
2 defendants as any entity distinct from other certain defendants would permit an
3 abuse of the corporate privilege, sanction fraud, and promote injustice.

4 15. Plaintiff is informed and believe, and thereon allege, that at all times
5 herein mentioned each of the Defendants were the agent, servant, employee,
6 and/or joint venturer of the other co-defendants, and at all said times each
7 Defendant was acting in the full course, scope, and authority of said agency,
8 service, employment, and/or joint venture.

9 16. "Bard" or "Defendants" includes any and all parent companies,
10 subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and
11 organizational units of any kind; their predecessors, successors, and assigns; their
12 officers, directors, employees, agents, representatives; and any and all other
13 persons acting on their behalf.

14 17. At all times relevant, Bard was engaged in the business of
15 researching, designing, testing, developing, manufacturing, packaging, labeling,
16 marketing, advertising, distributing, promoting, warranting, and selling in
17 interstate commerce Bard IVC Filters, either directly or indirectly through third
18 parties or related entities.

19 18. Bard develops, manufactures, sells, and distributes medical devices
20 and surgical products throughout the United States and around the world,
21 including Bard IVC Filters for use in various medical applications including
22 endovascular cardiology.

23 19. Upon information and belief, at all relevant times, Defendants
24 expected or should have expected that their acts would have consequences within
25 the United States, including in the State of South Dakota, and said Defendants
26 derived and continue to derive substantial revenue therefrom.
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1 **JURISDICTION AND VENUE**

2 20. This Court has subject matter jurisdiction under 28 U.S.C. § 1332
3 because Plaintiff and Defendants are citizens of different states, the amount in
4 controversy for each action exceeds seventy-five thousand dollars (\$75,000.00)
5 excluding interest and costs, and there is complete diversity of citizenship between
6 each Plaintiff and Defendant.

7 21. Venue is proper in this Court, as the facts and circumstances leading
8 to injuries occurred in Sioux Falls, South Dakota and the Bard Eclipse® IVC
9 Filter System that is the subject of this action was marketed, sold, purchased, and
10 implanted into Plaintiff's body and the failure of the defective Bard Eclipse® IVC
11 Filter System and resulting injuries and damages suffered by Plaintiff also
12 occurred in Sioux Falls, South Dakota. Furthermore, the Defendants herein were
13 authorized to conduct business in the State of South Dakota and did conduct
14 business in Sioux Falls, South Dakota.

15 **BACKGROUND**

16 **INFERIOR VENA CAVA FILTERS GENERALLY**

17 22. IVC filters were first made commercially available to the medical
18 community in the 1960s. Over the years, medical device manufacturers have
19 introduced several different designs of IVC filters.
20

21 23. An IVC filter is a device that is designed to filter or "catch" blood
22 clots that travel from the lower portions of the body to the heart and lungs. IVC
23 filters were originally designed to be permanently implanted in the IVC.

24 24. The IVC is a vein that returns blood to the heart from the lower
25 portions of the body. In certain people, for various reasons, blood clots travel from
26 the vessels in the legs and pelvis, through the vena cava and into the lungs.
27 Oftentimes, these blood clots develop in the deep leg veins, a condition called
28 "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are

1 considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human
2 health.

3 25. People at risk for DVT/PE can undergo medical treatment to manage
4 the risk. For example, a doctor may prescribe anticoagulant therapies such as
5 medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of
6 the blood. In some people who are at high risk for DVT/PE and who cannot
7 manage their conditions with medications, physicians may recommend surgically
8 implanting an IVC filter to prevent thromboembolic events.

9 26. As stated above, IVC filters have been on the market for decades and
10 were permanent implants. However, use of these filters was limited primarily to
11 patients who were contraindicated for anticoagulation therapy.

12 27. In order to increase sales of these devices, Bard sought to expand the
13 market for prophylactic use among nontraditional patient populations that were
14 temporarily at risk of developing blood clots.

15 28. Specifically, Bard targeted the bariatric, trauma, orthopedic and
16 cancer patient population. Expansion to these new patient groups would triple
17 sales and the first manufacturer to market would capture market share.

18 29. At the same time, Bard was aware that physicians developed interest
19 in filter devices that could be easily removed after the risk of clotting in these new
20 patient populations subsided. This too was an opportunity to gain market share in
21 the lucrative IVC filter market.

22 30. Other manufacturers also saw this opportunity, triggering a race to
23 market a device that provided physicians the option to retrieve the filter after the
24 clot risk subsided.

25 31. Bard was the first medical device manufacturer to obtain FDA
26 clearance for marketing a "retrievable" IVC filter (the Bard Recovery® filter) in
27 July 2003.
28

1 32. This "clearance" was obtained despite lack of adequate testimony on
2 the safety and efficacy of the new line of devices.

3 33. As shown below, Bard's retrievable IVC filters have been plagued
4 with problems - all created by Bard itself - most notably, the absence of any
5 evidence that the products were effective in preventing pulmonary embolism (the
6 very condition the product was indicated to prevent).

7 34. Years after the implantation of retrievable filters into the bodies of
8 patients, scientists began to study the effectiveness of the retrievable filters -
9 studies that Bard itself had never done before placing the product on the market.
10 As recently as October 2015, an expansive article published in the *Annals of*
11 *Surgery* concerning trauma patients inserted with IVC filters concluded that IVC
12 filters were not effective in preventing pulmonary emboli, and instead actually
13 caused thrombi to occur.

14 35. Comparing the results of over 30,000 trauma patients who had not
15 received IVC filters with those who had received them, the *Annals of Surgery*
16 study published its alarming results:

- 17 a. Almost twice the percentage of patients with IVC filters in the
18 study died compared to those that had not received them.
- 19 b. Over five times the relative number of patients with IVC filters
20 developed DVTs.
- 21 c. Over four times the relative percentage of patients with filters
22 developed thromboemboli.
- 23 d. Over twice the percentage of patients developed a pulmonary
24 embolus – the very condition Bard told the FDA, physicians,
25 and the public that its IVC Filters were designed to prevent.
- 26

27 36. This *Annals of Surgery* study - and many others referenced by it -
28 now shows without any question that IVC filters are not only utterly ineffective

1 but that they are themselves a health hazard.

2 **THE RECOVERY® FILTER**

3 **A. Development and Regulatory Clearance of the Recovery® Filter**

4 37. Bard has distributed and marketed the Simon Nitinol Filter ("SNF")
5 device since 1992. The SNF is a permanent filter with no option to retrieve it after
6 implantation.

7 38. The SNF was initially manufactured by a company known as Nitinol
8 Medical Technologies. In late 1999, Bard worked with Nitinol on the redesign of
9 the SNF in order to make it retrievable. On October 19, 2001, Bard purchased the
10 rights to manufacture, market, and sell this new, redesigned product in
11 development at the time. This product ultimately became the Recovery® filter.

12 39. Bard's purpose for making a retrievable IVC filter was to increase
13 profits by expanding the overall IVC filter market and, in turn, Bard's percentage
14 share of that market.

15 40. Bard engaged in an aggressive marketing campaign for the filter,
16 despite negative clinical data.

17 41. On November 27, 2002, Bard bypassed the more onerous Food and
18 Drug Administration's ("FDA's") approval process for new devices and obtained
19 "clearance" under Section 510(k) of the Medical Device Amendments to the Food,
20 Drug, and Cosmetic Act to market the Recovery® filter as a *permanent* filter by
21 claiming it was substantially similar in respect to safety, efficacy, design, and
22 materials as the SNF.

23 42. Section 510(k) permits the marketing of medical devices if the device
24 is substantially equivalent to other legally marketed predicate devices without
25 formal review for the safety or efficacy of the said device. The FDA explained the
26 difference between the 510(k) process and the more rigorous "premarket approval"
27 (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
28

1 Corp., which the court quoted from:

2 A manufacturer can obtain an FDA finding of 'substantial equivalence' by
3 submitting a premarket notification to the agency in accordance with section
4 510(k) of the [Food Drug and Cosmetic Act]. 21 U.S.C. § 360(k). A device
5 found to be 'substantially equivalent' to a predicate device is said to be
6 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA. *A*
7 *pre-market notification submitted under 510(k) is thus entirely different*
8 *from a PMA which must include data sufficient to demonstrate that the IVC*
9 *Filters is safe and effective.*

10 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

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

13 If the FDA concludes on the basis of the [manufacturer's] § 510(k)
14 notification that the device is "substantially equivalent" to a pre-existing
15 device, it can be marketed without further regulatory analysis. . . . The §
16 510(k) notification process is by no means comparable to the PMA process;
17 in contrast to the 1,200 hours necessary to complete a PMA review, the §
18 510(k) review is completed in average of 20 hours. . . . As one commentator
19 noted: "The attraction of substantial equivalence to manufacturers is clear.
20 Section 510(k) notification requires little information, rarely elicits a
21 negatIVC response from the FDA, and gets processed quickly."

22 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device*
23 *Amendments: A Step in the Right Direction Needs Another Step in the Right*
24 *Direction*, 43 Food Drug Cosmo LJ. 511,516 (1988)).

25 44. Pursuant to *Wyeth V. Levine*, 555 U.S. 555 (2009), once a product is
26 cleared "the manufacturer remains under an obligation to investigate and report
27 any adverse events associated with the drug ... and must periodically submit any
28 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.

45. In July 2003, through this 510(k) process, Bard obtained clearance

1 from the FDA to market the Recovery® filter for optional retrieval.

2 46. Although Bard began aggressively marketing the Recovery® filter in
3 2003, full market release did not occur until January 2004.

4 47. Bard was aware that the Recovery® filter was also used extensively
5 off-label, including for purely prophylactic reasons for trauma patients or patients
6 with upcoming surgeries such as bariatric (weight loss) and orthopedic procedures.

7 48. The Recovery® filter consists of two (2) levels of six (6) radially
8 distributed NITINOL (a nickel titanium alloy whose full name is Nickel Titanium
9 Naval Ordinance Laboratory) struts that are designed to anchor the filter into the
10 inferior vena cava and to catch any embolizing clots.

11 49. This filter has six short struts, which are commonly referred to as the
12 "arms," and six long struts, which are commonly referred to as the "legs.

13 50. Each strut is held together by a single connection to a cap located at
14 the top of the filter. According to the patent application filed for this device, the
15 short struts are primarily for "centering" or "positioning" within the vena cava, and
16 the long struts with attached hooks are designed primarily to prevent the device
17 from migrating in response to "normal respiratory movement" or "pulmonary
18 embolism."

19 51. The alloy NITINOL possesses "shape memory," meaning NITINOL
20 will change shape according to changes in temperature, then retake its prior shape
21 after returning to its initial temperature.

22 52. When placed in saline, the Recovery® filter's NITINOL struts
23 become soft and can be straightened to allow delivery through a small-diameter
24 catheter. The NITINOL struts then resume their original shape when warmed to
25 body temperature in the vena cava.

26 53. The Recovery® filter is inserted via catheter guided by a physician
27 (normally an interventional radiologist) through a blood vessel into the inferior
28

1 vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion.

2 54. According to the Instructions for Use of this medical device, only the
3 Recovery® Cone System could be used to retrieve the Recovery® filter (as well as
4 subsequent generations of Bard's IVC filters).

5 55. The Recovery® Cone System is an independent medical device
6 requiring approval by the FDA under the pre-market approval process or, if a
7 substantially equivalent medical device was already on the market, clearance by
8 the FDA pursuant to the 510(k) application process.

9 56. Although Bard marketed and sold the Recovery® Cone System
10 separately, it never sought or obtained approval or clearance from the FDA for this
11 device.

12 57. Bard's sale of the Recovery® Cone System was, therefore, illegal.

13 58. Bard illegally sold the Recovery® Cone System in order to promote
14 the Recovery® filter as having a retrieval option.

15 **B. Post-Market Performance Revealed The IVC Filters Failed to Perform**
16 **as Expected**

17 59. Once placed on the market, Bard immediately became aware of
18 numerous confirmed events where its Recovery® filter fractured, migrated, or
19 perforated the vena cava, caused thrombus and clotting, and caused serious injury.,
20

21 60. Premarket and post-market clinical trials revealed that the Recovery®
22 failed and caused serious risk of harm. In addition, peer-reviewed literature
23 reflected that such filters actually increased the risk of patients developing
24 thromboembolic events.

25 61. Approximately a month after the full-scale launch of the Recovery®
26 filter, on February 9, 2004, Bard received notice of the first death associated with
27 this filter. The next day, a MAUDE analysis was performed which revealed that
28 there had been at least two other migration-related adverse events reported to Bard

1 in 2003.

2 62. MAUDE is a database maintained by the FDA to house medical
3 device reports submitted by mandatory reporters (such as manufacturers and
4 device user facilities) and voluntary reporters (such as health care providers and
5 patients).

6 63. Instead of pulling the Recovery® filter off the market, Bard focused
7 on public relations and protecting its brand and image. By February 12, 2004,
8 Bard had formed a crisis communication team and drafted at least four
9 communiques to pass onto its sales force containing false information designed to
10 be relayed to concerned doctors.

11 64. By April of 2004, at least three deaths had been reported to Bard. Yet
12 again, instead of recalling its deadly device, Bard concealed this information from
13 doctors and patients and hired the public relations firm Hill & Knowlton to
14 address anticipated publicity that could affect stock prices and sales.

15 65. Bard made the decision to continue to market and sell the Recovery®
16 filter until its next generation product, the G2® IVC filter, was cleared by the
17 FDA.

18 66. The G2® filter, however, was not cleared for market until August 29,
19 2005.

20 67. 70. Meanwhile, the death count escalated.

21 68. On July 12, 2004, C.R. Bard CEO Timothy Ring received an
22 executive summary reporting that there were at least 12 filter migrations resulting
23 in four deaths and at least 17 reports of filter fracture, six cases of which involved
24 strut embolization to the heart.

25 69. This same report advised that fracture rates for the Recovery® filter
26 exceed reported rates of other filters.

27 70. These events revealed, or should have revealed, to Bard that the
28

1 Recovery® filter is prone to an unreasonably high risk of failure and patient injury
2 following placement in the human body.

3 71. Bard also learned that the Recovery® filter failed to meet migration
4 resistance testing specifications.

5 72. In addition, multiple early studies reported that the Recovery® filter
6 has a fracture and migration rate ranging from 21 % to 31.7%, rates that are
7 substantially higher compared to other IVC filters. More recently, fractures were
8 reported to be as high as 40% after five and a half years from the date of implant.

9 73. Bard had clear evidence that the Recovery® filter was not
10 substantially equivalent to the predecessor SNF, making the Recovery® filter
11 adulterated and misbranded, requiring its immediate withdrawal from the market.

12 74. At least one Bard executive concluded the Recovery® filter posed an
13 unreasonable risk of harm and required corrective action, including a recall.

14 75. Likewise, Bard's G2® filter was predicted to have fracture rates as
15 high as 37.5% after five years from date of implant.

16 76. Subsequent Bard IVC Filter models, including the electropolished
17 version of the G2® filter known as the Eclipse, only marginally increased fracture
18 resistance.

19 77. When IVC filter fractures occur, shards of the filter or even the entire
20 filter can travel to the heart, where they can cause cardiac tamponade, perforation
21 of the atrial wall, myocardial infarction, and/or death.

22 78. Bard IVC Filters similarly pose a high risk of tilting and perforating
23 the vena cava walls. When such tilting occurs, the filters can also perforate the
24 adjacent aorta, duodenum, small bowel, spine, or ureter, which may lead to and,
25 upon information and belief, already have led to retroperitoneal hematomas, small-
26 bowel obstructions, extended periods of severe pain, and/or death.

27 79. The Adverse Event Reports ("AERs") associated with all IVC filters
28

1 demonstrate that Bard IVC Filters are far more prone to failure than are other
2 similar IVC filters. A review of the FDA MAUDE database from the years 2004
3 through 2008 shows that Bard IVC Filters are responsible for the following
4 percentages of all IVC filter AERs:

- 5 a. 50% of all adverse events;
- 6 b. 64% of all occurrences of migration of the IVC Filters;
- 7 c. 69% of all occurrences of vena cava wall perforation; and
- 8 d. 70% of all occurrences of filter fracture.

9 80. These failures were often associated with severe patient injuries such
10 as:

- 11 a. Death;
- 12 b. Hemorrhage;
- 13 c. Cardiac/pericardial tamponade (pressure caused by a collection
14 of blood in the area around the heart);
- 15 d. Cardiac arrhythmia and other symptoms similar to myocardial
16 infarction;
- 17 e. Severe and persistent pain; and
- 18 f. Perforations of tissue, vessels and organs.

19 81. These failures and resulting injuries are attributable, in part, to the
20 fact that the Bard IVC Filter design was unable to withstand the normal
21 anatomical and physiological loading cycles exerted *in vivo*.

22 82. In addition to design defects, Bard IVC Filters suffer from
23 manufacturing defects. These manufacturing defects include, but are not limited
24 to, the existence of "draw markings" and circumferential grinding markings on the
25 exterior of the surface of the filters.

26 83. The presence of these draw markings and/or circumferential grinding
27 markings further compromises the structural integrity of the Bard IVC Filters
28

1 while in the body. In particular, the Recovery® filter is prone to fail at or near the
2 location of draw markings/circumferential grinding markings on the struts of the
3 filters. These exterior manufacturing defects render Bard IVC Filters too weak to
4 withstand normal placement within the human body.

5 84. Bard was aware that Bard IVC Filters had substantially higher
6 reported failure rates than all other IVC filters for fracture, perforation,
7 migration, and death. For example:

- 8 a. On April 23, 2004, Bard's Corporate VP of Quality Assurance
9 sent an email noting that the Recovery® filter's reported
10 failure rates "did not look good compared to permanent filters"
11 and promised to remove the filter from the market if its
12 reported death rate became "significantly greater than the rest
13 of the pack."
- 14 b. On July 9, 2004, a BPV safety analysis of reported failure rates
15 determined that the Recovery® filter had a reported failure rate
16 that was 28 times higher than all other IVC filters.
- 17 c. On December 17, 2004, analysis determined that the "[r]eports
18 of death, filter migration (movement), IVC perforation, and
19 filter fracture associated with the Recovery® filter were seen
20 in the MAUDE database at reporting rates that were
21 4.6, 4.4, 4.1, and 5.3 times higher, respectively, than reporting
22 rates for all other filters These deficiencies were all
23 statistically significant ... [and were] significantly higher than
24 those for other removable filters."
- 25 d. By December 2004, according to BPV's own findings pursuant
26 to its safety procedure, the Recovery® filter had so many
27 reported failures that it was deemed not reasonably safe for
28

1 human use and required "correction."

2 e. A BPV safety analysis from June 28, 2011, revealed that the
3 Recovery® filter had a reported fracture rate 55 times higher
4 than the SNF.

5 f. Whereas the Recovery® filter was reported to have caused over
6 a dozen deaths by early 2005, the SNF has never - to Plaintiff's
7 knowledge - been reported as associated with a patient death.

8 **C. Defendants Knew Why the Recovery® Filter Was Failing and**
9 **Were Aware of Available Design Changes that Could Substantially Reduce**
10 **Failures**

11
12 85. Bard knew why the design changes made to the Recovery® filter
13 were causing failures.

14 86. Bard was aware that the diameter of the leg hooks was a substantial
15 factor in a filter's ability to resist migration and fatigue.

16 87. By reducing the diameter of the hooks on the Recovery® filter, Bard
17 had reduced the device's ability to remain stable and not fracture.

18 88. Bard also reduced the leg span of the Recovery® filter from that of
19 the SNF filter by 25%. As a result, Bard knew its retrievable IVC filters lacked a
20 sufficient margin of safety to accommodate expansion of the vena cava
21 (distension) after placement.

22 89. Bard was also aware that its failure to electropolish the wire material
23 prior to distribution meant that Bard IVC Filters had surface damage that reduced
24 their fatigue resistance.

25 90. Bard was also aware that the Recovery® filter had a high propensity
26 to tilt and perforate the vena cava, which substantially increased the risk of
27 fracture.
28

1 91. Bard was also aware that fatigue resistance could be increased by
2 decreasing the sharpness of the angle of the wire struts where they exited the cap
3 at the top of the IVC filters, and by chamfering (rounding or reducing the
4 sharpness) of the cap edge against which the struts rubbed.

5 92. A few examples of Bard's awareness of the unreasonably dangerous
6 problems with Bard IVC Filters include:

- 7 a. On June 18, 2003, BPV engineer Robert Carr sent an email
8 noting that chamfering the edge of the cap would reduce the
9 likelihood of fracture.
- 10 b. On March 16, 2004, a BPV engineer sent an email admitting
11 that the surface damage seen on the Recovery® filter from the
12 manufacturing process decreases fatigue resistance and that
13 electropolishing increases fatigue resistance.
- 14 c. In an April 2004 meeting, BPV was warned by its physician
15 consultants, Drs. Venbrux and Kaufman, that the migration
16 resistance of the Recovery® filter needed to be raised from 50
17 mmHg to 140 mmHg. They further warned BPV that Bard's
18 Recovery® filter was a "wimpy" filter and its radial force was
19 inadequate to assure stability.
- 20 d. On May 5, 2004, a BPV engineer sent an email stating that
21 adding a "chamfer" to the filter would "address the arm
22 fracture issue."
- 23 e. On May 26, 2004, a BPV engineer sent an email stating that a
24 proposed modified Recovery® filter design with a large
25 chamfer lasted 50 bending cycles before breaking, whereas
26 another proposed modified Recovery® filter with a small
27 chamfer broke after ten bending cycles.
- 28

1 93. Prior to Plaintiff being implanted with a Bard IVC Filter, Bard was
2 aware of other design changes that could make the Recovery® filter substantially
3 safer. In a report dated February 16, 2005, BPV describes the design changes to
4 the Recovery® filter, which became known as the G2® Filter. The report states
5 that the Recovery® filter has been modified to "to increase migration and fracture
6 resistance, and to minimize the likelihood of leg twisting, appendage snagging,
7 filter tilting, and caval perforation." The document goes on to describe the design
8 modifications, which include:

- 9 a. Increased ground wire diameter of the hook from .0085" to
10 .0105" in order to improve the fracture resistance of the hook
11 and to improve the migration resistance of the filter.
12 b. The leg span has been increased from 32mm to 40mm in order
13 to improve the ability of the filter to expand with a distending
14 vena cava reducing risk of migration.
15 c. The total filter arm length has increased from 20mm to 25mm,
16 enlarging the arm span from 30mm to 33mm to aid in filter
17 centering.
18 d. An additional inward bend has been applied to the end of the
19 filter arm in order to improve arm interaction with the vessel
20 wall and to address caval perforations and appendage
21 snagging.
22 e. The arc of filter arm, as it attaches to the sleeve, has been
23 modified to have a smooth radial transition instead of sharp
24 angle. This change was made in order to reduce the stress
25 concentration generated by the sharp angle and thus improve
26 fracture resistance in the area of the filter.
27 f. The report concludes that the design modifications have
28

1 substantially reduced the risk of fracture.

2 94. Subsequent design changes only marginally improved product safety,
3 but did not fully or adequately address the Bard IVC Filters' deadly defects.

4 95. Electropolishing was added to the Bard IVC Filters in 2010 to reduce
5 the risk of fracture. Electropolishing implanted Nitinol IVC filters was the
6 industry standard, and increased fatigue resistance by at least 25%, according to
7 Bard's internal testing.

8 96. Additional anchors were added to the anchoring system on the filter
9 in 2011, in what became known as the Meridian filter. The purpose of this
10 improvement was to decrease the risk of tilting, which increases the risk of
11 fracture and perforation, and reduce caudal migration.

12 97. Bard added penetration limiters with the introduction of Denali Filter
13 in May 20 2013.

14 98. Penetration limiters are designed to reduce perforation and
15 penetration of the vena cava.

16 **D. Bard Misrepresented and Concealed the IVC Filters' Risks and**
17 **Benefits**

18 99. Despite knowing that the Recovery® filter was substantially more
19 likely to fracture, migrate, tilt, and cause death than any other filter, Bard marketed
20 its IVC filters as being safer and more effective than all other filters throughout
21 the lifecycle of the product.

22 100. Bard further provided mandatory scripts to its Bard IVC filter sales
23 force, which required the sales force to falsely tell physicians that the Recovery®
24 filter was safe because it had the same reported failure rates as all other filters.

25 101. Even Bard's updated labeling in December 2004 downplayed and
26 concealed the Recovery® filter's dangerous effects because it suggested fractures
27 almost always cause no harm and that all filters had the same risk of failure.
28

1 102. Bard's updated labeling also downplayed the risk of harm by stating
2 that serious injuries had only been "reported" when Bard knew such injuries had in
3 fact occurred.

4 **E. Bard Chose to Keep Selling an Unsafe IVC Filter and Lied to Its**
5 **Own Sales Force to Ensure Market Share and Stock Prices**

6 103. Instead of warning the public or withdrawing the IVC Filters from the
7 market to fix the problems with its IVC filters, Defendants retained a public
8 relations firm, opened a task force to prevent information from getting out to the
9 public, and devised a plan to address the public if it did.

10 104. In 2004, Bard created a Crisis Communication Team that included
11 members of Bard's upper level management, Bard's legal department, and
12 independent consultants.

13 105. The Crisis Communication Team created a Crisis Communication
14 Plan, which summarized Bard's motivation for withholding risk information from
15 the public as follows:

16
17 The proliferation of unfavorable press in top-tier media outlets can cause an
18 onslaught of negative activity: a company's employee morale may suffer,
19 stock prices may plummet, analysts may downgrade the affected company's
20 rating, reputations may be ruined temporarily or even permanently.
21 Extensive preparation is critical to help prevent the spread of damaging
22 coverage.

23 106. In an April 2004 email, BPV consultant Dr. John Lehmann, a member
24 of the Crisis Communication Team, advised Bard to conceal from the public
25 Bard's information about the material risk of its IVC filters. Bard adopted his
26 advice. His email states, among other things:

27 Comparison with other filters is problematic in many ways, and we
28 should avoid/downplay this as much as possible. When pressed, we

1 simply paraphrase what was said in the Health Hazard. That "Estimates
2 based on available data suggest that there is no significant difference in
3 the rates of these complications between any of the IVC Filters currently
4 marketed in the U.S., including the Recovery IVC Filters.

5 ***

6 I wouldn't raise this subject if at possible. It would be a most unusual
7 reporter that will get this far. The testing data I saw in Arizona showed
8 that although RF was certainly within the boundaries of IVC Filters
9 tested, in larger veins it was near the bottom. I would avoid as much as
10 possible getting into this subject, because I'm not sure others would agree
11 with the conclusion that "Recovery Vena Cava Filter was just as or more
12 resistant to migration than all retrievable and non-retrievable competitors.

13 107. Bard also made false representations and/omissions to the BPV sales
14 force to keep them selling the IVC filters. Bard reassured the sales force that
15 despite the failures with the Recovery® filter, the Bard IVC Filters were safe
16 because they had the same failure rates as all other IVC filters.

17 108. By December 2004, BPV's own safety procedure deemed the
18 Recovery® filter not reasonably safe for human use. Yet Bard continued to market
19 and sell the Recovery® filter into September 2005 and continued to allow its
20 defective product to sit on shelves available to be implanted for an unknown
21 period of time after September 2005.

22 109. Even after the G2® filter was launched in September 2005, Bard still
23 failed to warn consumers of the increased risk posed by the Recovery® filter.
24 Instead, Bard again chose to conceal information about the serious risks of
25 substantial harm from the use of its defective product.

26 **THE G2®, RECOVERY® G2 AND G2® EXPRESS FILTERS**

27 110. On or about March 2, 2005, Bard submitted a Section 510Ck)
28 premarket notification of intent to market the G2® filter for the prevention of

1 recurrent pulmonary embolism via placement in the inferior vena cava. In doing
2 so, Bard cited the Recovery® filter as the substantially equivalent predicate IVC
3 filter, which was an inappropriate and illegal predicate device since it was being
4 marketed while adulterated and misbranded for failing, among other things, to be
5 as safe and effective as its predicate device, SNF. Bard stated that the only
6 differences between the Recovery® filter and the G2® filter were primarily
7 dimensional, and no material changes or additional components were added. It was
8 considered by Bard the next generation of the Recovery® filter

9 111. On March 30, 2005, however, the FDA rejected this application unless
10 Bard and BPV included "black box" warnings that read:

11
12 Warning: The safety and effectiveness of the Recovery® Filter System in
13 morbidly obese patients has not been established. There have been fatal
14 device-related adverse events reported in this population.

15 [and]

16 [C]entral venous lines may cause the filters to move or fracture.

17
18 112. On April 19, 2005, prior to formally responding to the FDA's request
19 to add a black box warning, BPV CEO Timothy Ring and C.R. Bard CEO John
20 Weiland received an executive summary reporting that there were at least 34
21 migrations and 51 fractures associated with Bard IVC Filters.

22 113. This same report advised Bard executives that there were then nine
23 deaths, six of which related to morbidly obese patients. Further, 18 of the 51
24 fractures resulted in fragments migrating to the heart.

25 114. On April 20, 2005, without alerting the FDA to the alarming
26 information Bard executives had the day before, Bard submitted a letter in
27
28

1 response to the FDA's request to add this black box warning stating that, "There is
2 currently a statement in the IFU linking all of our complications to death."

3 115. On August 29, 2005, the FDA cleared the G2® filter for the same
4 intended uses as the Recovery® filter, except that it was not cleared for retrievable
5 use.¹ Contrary to the FDA's suggestion, no black box warning was added to warn
6 the bariatric patient population of fatalities associated with the use of the filter.²

7 116. In September of 2005, Bard quietly and belatedly replaced the
8 Recovery® filter on hospital shelves with the G2® filter. Bard either told doctors
9 or led them to believe that the G2® was a new and improved version of the
10 Recovery® filter with the same option to retrieve the filter after implant.

11 117. At the same time Bard was selling the G2® (then a permanent use
12 filter without any retrievability option), Bard was also selling the SNF, which had
13 the same indication for use with nearly zero adverse events.

14 118. Bard marketed the G2® filter as having "enhanced fracture
15 resistance," "improved centering," and "increased migration resistance" without
16 any data to back up these representations. Even if such data existed, Bard
17 witnesses have testified that Bard would not share any such information with
18 doctors if requested.

19 119. Moreover, as with its predecessor Recovery® filter, Bard failed to
20 conduct adequate clinical and bench testing to ensure that the G2® filter would
21 perform safely and effectively once implanted in the human body.

22 120. The G2® filter's design causes it to be of insufficient integrity and
23 strength to withstand normal stresses within the human body so as to resist
24 fracturing, migrating, and/or tilting, and/or perforating the inferior vena cava.
25

26
27 ¹ The FDA did not clear the G2® filter to be used as a retrievable filter until January 15, 2008.

28 ² A warning was eventually added to the IFU in October of 2009.

1 121. In addition to the same design defects as its predecessor device, the
2 G2® filter suffers from the same manufacturing defects. These manufacturing
3 defects include, but are not limited to, the existence of "draw markings" and
4 circumferential grinding markings on the exterior of the surface of Bard IVC
5 Filters. The presence of these draw markings and/or circumferential grinding
6 markings further compromises the structural integrity of the G2® filter while *in*
7 *vivo*.

8 122. In particular, the G2® filter is prone to fail at or near the location of
9 draw markings/circumferential grinding markings on the struts of the IVC Filters.

10 123. Put simply, the G2® filter is not of sufficient strength to withstand
11 normal placement within the human body. The presence of the aforementioned
12 exterior manufacturing defects makes Bard IVC Filters more susceptible to
13 fatigue, failure, and migration.

14 124. Similarly, although Bard rounded the chamfer at the edge of the cap
15 of the G2® filter, it continued to fracture at that same location.

16 125. Thus, the G2® filter shares similar defects and health risks as the
17 Recovery® filter.

18 126. Almost immediately upon the release of the G2® filter, Bard received
19 notice of the same series of adverse events of migration, fracture, tilt, and
20 perforation causing the same type of harm as the Recovery® filter. This time,
21 however, a new and different adverse event emerged: the G2® filter would
22 caudally (moving against blood flow) migrate in the direction toward the groin.
23

24 127. The G2® filter failures were again associated with reports of severe
25 patient injuries such as:

- 26 a. Death;
- 27 b. Hemorrhage;

28

- 1 c. Cardiac/pericardial tamponade (pressure caused by a collection
- 2 of blood in the area around the heart);
- 3 d. Cardiac arrhythmia and other symptoms similar to myocardial
- 4 infarction;
- 5 e. Severe and persistent pain; and
- 6 f. Perforations of tissue, vessels and organs.

7 128. Bard represents the fracture rate of the G2® filter to be 1.2%. Based
8 upon a review of the data available in the public domain (including the FDA
9 MAUDE database statistics and the published medical literature), this
10 representation does not accurately reflect the true frequency of fractures for the
11 G2® filter.

12 129. As with the Recovery® filter, Bard was aware of clinical data
13 showing that the G2® filter was not the substantial equivalent of its predecessor
14 SNF device, requiring immediate recall of the adulterated and misbranded product.

15 130. A review of the MAUDE database from the years 2004 through 2008
16 demonstrates that the Bard IVC Filters (including the G2® Filter) are responsible
17 for the majority of all reported adverse events related to IVC filters.

18 131. On December 27, 2005, Bard's Medical Affairs Director sent an email
19 questioning why Bard was even selling the modified version of the Recovery®
20 filter, when Bard's SNF had virtually no complaints associated with it.

21 132. This further confirms the misbranded and adulterated nature of the
22 device, requiring corrective action, including recall.

23 133. On January 15, 2008, the FDA allowed a retrievable option for the
24 G2®filter, the G2 Express® filter. The G2 Express® filter (also known as the
25 "G2®X") is identical in design to the G2® filter except that it has a hook at the
26 top of the filters that allows it to be retrieved by snares, as well as Bard's Recovery
27 Cone.
28

1 134. The G2®X filter contained no design modifications or improvements
2 to alleviate the instability, structural integrity, and perforation problems that Bard
3 knew to exist with the G2®X Filter via the 510(k) process.

4 **THE ECLIPSE® FILTER**

5 135. In a failed effort to resolve the complications associated with its
6 previous filters, Bard designed the Eclipse® Vena Cava Filter as the next
7 generation in its retrievable IVC filter family.

8 136. The Eclipse® filter was cleared by the FDA on January 14, 2010. The
9 only design changes from the G2® family of filters to the Eclipse® filter was that
10 the Eclipse® filter was electropolished.

11 137. According to Bard's internal testing, electropolishing supposedly
12 increased fracture resistance by 25%. However, longitudinal studies published in
13 peer-reviewed medical literature found that among 363 patients implanted with the
14 Recovery® filter and 658 patients implanted with the G2® filter, the devices
15 experienced fracture rates of 40% and 37.5%, respectively, after five and a half
16 years. Thus, approximately 28.125% to 30% of Eclipse® filters would still be
17 projected to fracture within five and a half years.

18 138. Without meaningful design changes, the Eclipse® filter continued to
19 share several of the same design defects and complications associated with the
20 Recovery® filter and G2® family of filters.

21 139. Soon after Bard launched the Eclipse® filter, it began receiving
22 complaints and reports of injuries associated with the Eclipse® filter similar to
23 those received with its predecessor filters.

24 140. Bard, however, knew and/or soon learned that the Eclipse® filter was
25 not the substantial equivalent of the SNF, making this device also misbranded and
26 adulterated, and subject to recall.

27
28

1 141. At all times material hereto from the design phase, testing, and
2 manufacture of the Recovery® filter through the Eclipse® filter, Bard lacked a
3 thorough understanding dynamics of caval anatomy that impacted testing methods.

4 142. At this time, all Bard IVC Filters contain the same or substantially
5 similar defects resulting in the same or substantially similar mechanism of injury
6 to Plaintiff.

7 143. At this time, all Bard IVC Filters are misbranded and adulterated by
8 virtue of them failing to be the substantial equivalent of their predecessor devices,
9 all of which were required to be as safe and effective as the original predicate
10 device, the Simon Nitinol Filter, and none were/are, making them subject to IVC
11 action, including recall, in the interest of patient safety. The use of each of these
12 subject devices was inappropriate and illegal since each was being marketed while
13 adulterated and misbranded for failing, among other things, to be as safe and
14 effective as the originating predicate device, SNF.

15 144. At all relevant times, safer and more efficacious designs existed for
16 this product, as well as reasonable treatment alternatives.

17 **PLAINTIFF'S BARD IVC FILTER IMPLANT AND SUBSEQUENT**
18 **INJURIES**

19 145. On October 12, 2012, Plaintiff was implanted with a Bard Eclipse
20 IVC Filter at Sanford University of South Dakota Medical Center in Sioux Falls,
21 South Dakota.

22 146. On January 22, 2014, Plaintiff underwent medical treatment at
23 Sanford University of South Dakota Medical Center in Sioux Falls, South Dakota.
24 Plaintiff was informed that the filter had become embedded into her internal
25 organs. Plaintiff's physician attempted to remove the Bard filter from Plaintiff,
26 but was unable to remove it due to the defectiveness of the product. The filter
27 remains inside Plaintiff.
28

1 147. As a direct and proximate result of having Bard IVC Filters implanted
2 in them, Plaintiff has suffered permanent and continuous injuries and damages.
3 The injuries suffered and damages sought by Plaintiff includes, without limitation:
4 past and future pain and suffering; bodily injuries (including, without limitation,
5 perforation of organs and venous structures, thromboembolic events, and
6 cardiovascular injuries); disability; impairment; scarring; disfigurement;
7 dismemberment; physical; emotional and psychological trauma; anxiety; past and
8 future mental anguish; diminished capacity; loss of consortium; hedonic damages;
9 past medical expenses; future medical expenses reasonably expected to be
10 incurred; care giving costs; lost wages; loss of earning capacity; and any other
11 form of damages under the law of any forum which governs any individual case
12 (collectively, "Injuries and Damages").

13 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR**
14 **REPOSE**

15 148. Plaintiff incorporates by reference all prior allegations.

16 149. Plaintiff is within the applicable statute of limitations for her claims
17 because Plaintiff (and her healthcare professionals) did not discover, and could not
18 reasonably discover, the defects and unreasonably dangerous condition of their
19 Bard IVC Filters any sooner than it was discovered on January 22, 2014.

20 150. Plaintiff's ignorance of the defective and unreasonably dangerous
21 nature of the Bard IVC Filters, and the causal connection between these defects
22 and Plaintiff's injuries and damages, is due in large part to Bard's acts and
23 omissions in fraudulently concealing information from the public and
24 misrepresenting and/or downplaying the serious threat to public safety its products
25 present.
26
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1 151. In addition, Bard is estopped from relying on any statutes of
2 limitation or repose by virtue of its unclean hands, acts of fraudulent concealment,
3 affirmative misrepresentations and omissions.

4 152. Such conduct includes intentional concealment from Plaintiff,
5 Plaintiff's prescribing health care professionals, and the general consuming public
6 of material information that Bard IVC Filters had not been demonstrated to be safe
7 or effective, and carried with them the risks and dangerous defects described
8 above.

9 153. Bard had a duty to disclose the fact that Bard IVC Filters are not safe
10 or effective, not as safe as other filters on the market, defective, and unreasonably
11 dangerous, and that their implantation and use carried with it the serious risk of
12 developing perforation, migration, tilting, and/or fracture.

13 **COUNT I: STRICT PRODUCTS LIABILITY - MANUFACTURING**
14 **DEFECT**

15 154. Plaintiff incorporates by reference all prior allegations.

16 155. Prior to, on, and after the date the Bard IVC Filter was implanted in
17 Plaintiff, Bard designed, distributed, manufactured, sold, and marketed Bard IVC
18 Filters for use in the United States.

19 156. At all relevant times, Bard designed, distributed, manufactured,
20 marketed, and sold Bard IVC Filters that were unreasonably dangerous, unsafe,
21 and defective in manufacture when they left Bard's possession.

22 157. Upon information and belief, Bard IVC Filters contain a
23 manufacturing defect, in that they differed from the manufacturer's design or
24 specifications, or from other typical units of the same product line.

25 158. As a direct and proximate cause of Bard's design, manufacture,
26 marketing, and sale of Bard IVC Filters prior to, on, and after the date Plaintiff
27 used the Bard IVC Filter, Plaintiff suffered Injuries and Damages.
28

1 **COUNT II: STRICT PRODUCTS LIABILITY - INFORMATION DEFECT**

2 159. Plaintiff incorporates by reference all prior allegations.

3 160. At all relevant times, Bard engaged in the business of testing,
4 developing, designing, manufacturing, packaging, labeling, marketing and/or
5 promoting, selling and/or distributing Bard IVC Filters and through that conduct
6 has knowingly and intentionally placed Bard IVC Filters into the stream of
7 commerce with full knowledge that they reach consumers such as Plaintiff who
8 would become implanted with it.

9 161. Bard did in fact test, develop, design, manufacture, package, label,
10 market and/or promote, sell and/or distribute Bard IVC Filters to Plaintiff,
11 Plaintiff's prescribing health care professionals, and the consuming public.
12 Additionally, Bard expected that the Bard IVC Filters they were selling,
13 distributing, supplying, manufacturing, and/or promoting to reach, and did in fact
14 reach, prescribing health care professionals and consumers, including Plaintiff and
15 Plaintiff's prescribing health care professionals, without any substantial change in
16 the condition of the product from when it was initially distributed by Bard.

17 162. The Bard IVC Filters had potential risks and side effects that were
18 known or knowable to Bard by the use of scientific inquiry and information
19 available before, at, and after the manufacture, distribution, and sale of the Bard
20 IVC Filters.

21 163. Bard knew or should have known of the defective condition,
22 characteristics, and risks associated with Bard IVC Filters. These defective
23 conditions included, but were not limited to: (1) Bard IVC Filters posed a
24 significant and higher risk of failure than other similar IVC filters (fracture,
25 migration, tilting, and perforation of the vena cava wall); (2) Bard IVC Filter
26 failures result in serious injuries and death; and (3) certain conditions or post-
27

28

1 implant procedures, such as morbid obesity or open abdominal procedures, could
2 affect the safety and integrity of Bard IVC Filters.

3 164. Bard IVC Filters were in a defective and unsafe condition that was
4 unreasonably and substantially dangerous to any user or consumer implanted with
5 Bard IVC Filters, such as Plaintiff, when used in an intended or reasonably
6 foreseeable way.

7 165. The warnings and directions Bard provided with Bard IVC Filters
8 failed to adequately warn of the potential risks and side effects of Bard IVC
9 Filters.

10 166. These risks were known or were reasonably scientifically knowable to
11 Bard, but not known or recognizable to ordinary consumers, such as Plaintiff, or to
12 Plaintiff's treating doctors.

13 167. Bard IVC Filters were expected to and did reach Plaintiff without
14 substantial change in their condition, labeling, or warnings as manufactured,
15 distributed, and sold by Bard.

16 168. Additionally, Plaintiff and Plaintiff's physicians used Bard IVC
17 Filters in the manner in which they were intended to be used, making such use
18 reasonably foreseeable to Bard.

19 169. As a direct and proximate result of Bard's information defects, lack of
20 sufficient instructions or warnings prior to, on, and after the date Plaintiff used
21 Bard IVC Filters, Plaintiff suffered Injuries and Damages.

22 **COUNT III: STRICT PRODUCTS LIABILITY - DESIGN DEFECT**

23 170. Plaintiff incorporates by reference all prior allegations.

24 171. At all relevant times, Bard designed, tested, distributed,
25 manufactured, advertised, sold, marketed and otherwise placed into the stream of
26 commerce Bard IVC Filters for use by consumers, such as Plaintiff, in the United
27 States.
28

1 172. Bard IVC Filters were expected to, and did, reach Bard's intended
2 consumers, handlers, and persons coming into contact with the product without
3 substantial change in the condition in which they was researched, tested,
4 developed, designed, licensed, manufactured, packaged, labeled, distributed, sold,
5 and marketed by Bard.

6 173. At all times relevant, Bard IVC Filters were manufactured, designed
7 and labeled in an unsafe, defective, and inherently dangerous condition which was
8 dangerous for use by the public in general and Plaintiff in particular.

9 174. Bard IVC Filters, as researched, tested, developed, designed, licensed,
10 manufactured, packaged, labeled, distributed, sold, and marketed by Bard were
11 defective in design and formulation and unreasonably dangerous in that when they
12 left the hands of Bard's manufacturers and/or suppliers, the foreseeable risks
13 exceeded the alleged benefits associated with the use of Bard IVC Filters, and the
14 devices were more dangerous than the ordinary customer would expect.

15 175. Physicians implanted Bard IVC Filters as instructed via the
16 Instructions for Use and in a foreseeable manner as normally intended,
17 recommend, promoted, and marketed by Bard.

18 176. Plaintiff received and utilized Defendants' IVC Filters in a
19 foreseeable manner as normally intended, recommended, promoted, and marketed
20 by Bard.

21 177. At the time Bard placed its defective and unreasonably dangerous
22 Bard IVC Filters into the stream of commerce commercially, technologically, and
23 scientifically feasible alternative designs were attainable and available.

24 178. These alternative designs would have prevented the harm resulting in
25 Plaintiff's Injuries and Damages without substantially impairing the reasonably
26 anticipated or intended function of Bard IVC Filters.
27
28

1 179. As a direct and proximate result of the defective and unreasonably
2 dangerous condition of Bard IVC Filters, Plaintiff suffered Injuries and Damages.

3 **COUNT IV: NEGLIGENCE - DESIGN**

4 180. Plaintiff incorporates by reference all prior allegations.

5 181. At the time of the design, distribution, manufacture, advertising, sale,
6 and marketing of Bard IVC Filters, and their implantation in Plaintiff, Bard was
7 aware that Bard IVC Filters were designed and manufactured in a manner
8 presenting:

- 9 a. An unreasonable risk of fracture of portions of the filters;
10 b. An unreasonable risk of migration of the filters and/or portions
11 of the filters;
12 c. An unreasonable risk of filters tilting and/or perforating the
13 vena cava wall; and
14 d. Insufficient strength or structural integrity to withstand normal
15 placement within the human body.

16 182. At the time of the design, distribution, manufacture, advertising, sale,
17 and marketing of Bard IVC Filters, and their implantation in Plaintiff, Bard also
18 was aware that Bard IVC Filters:

- 19 a. Would be used without inspection for defects;
20 b. Would be used by patients with special medical conditions
21 such as those of the Plaintiffs;
22 c. Had previously caused serious bodily injury to its users with
23 special medical conditions such as those of the Plaintiffs;
24 d. Had no established efficacy;
25 e. Were less efficient than the predicate SNF;
26 f. Would be implanted in patients where the risk outweighed any
27 benefit or utility of the filters;
28

1 g. Contained instructions for use and warnings that were
2 inadequate; and

3 h. Required retrieval (as to the Recovery® and G2® filters) by a
4 device that was not approved or cleared by the FDA.

5 183. Bard had a duty to exercise due care and avoid unreasonable risk of
6 harm to others in the design of Bard IVC Filters.

7 184. Bard breached these duties by, among other things:

8 a. Designing and distributing a product in which it knew or
9 should have known that the likelihood and severity of potential
10 harm from the product exceeded the burden of taking safety
11 measures to reduce or avoid harm;

12 b. Designing and distributing a product which it knew or should
13 have known that the likelihood and severity of potential harm
14 from the product exceeded the likelihood of potential harm
15 from other IVC filters available for the same purpose;

16 c. Failing to perform reasonable pre- and post-market testing of
17 Bard IVC Filters to determine whether or not the products
18 were safe for their intended use;

19 d. Failing to use reasonable and prudent care in the design,
20 research, manufacture, and development of Bard IVC Filters so
21 as to avoid the risk of serious harm associated with the use of
22 Bard IVC Filters;

23 e. Advertising, marketing, promoting, and selling Bard IVC
24 Filters for uses other than as approved and indicated in the
25 products' labels;

26 f. Failing to establish an adequate quality assurance program used
27 in the manufacturing of Bard IVC Filters; and
28

1 g. Failing to perform adequate evaluation and testing of Bard IVC
2 Filters when such evaluation and testing would have revealed
3 the propensity of Bard IVC Filters to cause injuries similar to
4 those that Plaintiff suffered.

5 185. As a direct and proximate result of the above-described negligence in
6 design of Bard IVC Filters, Plaintiff suffered Injuries and Damages.

7 **COUNT V: NEGLIGENCE - MANUFACTURE**

8 186. Plaintiff incorporates by reference all prior allegations.

9 187. At all relevant times, Bard had a duty to exercise due care in the
10 manufacturing of Bard IVC Filters.

11 188. Bard breached this duty by, among other things:

- 12 a. Failing to adopt manufacturing processes that would reduce the
13 foreseeable risk of product failure;
- 14 b. Failing to use reasonable care in manufacturing the product and
15 by producing a product that differed from their design or
16 specifications or from other typical units from the same
17 production line;
- 18 c. Failing to use reasonable and prudent care in the design,
19 research, manufacture, and development of Bard IVC Filters
20 and their manufacturing process so as to avoid the risk of
21 serious harm associated with the use of Bard IVC Filters; and
- 22 d. Failing to establish an adequate quality assurance program used
23 in the manufacturing of the IVC Filters.

24
25 189. As a direct and proximate result of the above-described negligence in
26 manufacture of Bard IVC Filters, Plaintiff suffered Injuries and Damages.

27 **COUNT VI: NEGLIGENCE - FAILURE TO RECALL/RETROFIT**

28 190. Plaintiff incorporates by reference all prior allegations.

1 191. At this time, all Bard IVC Filters are misbranded and adulterated by
2 virtue of them failing to be the substantial equivalent of their predecessor device,
3 making them subject to corrective action, including recall, in the interest of patient
4 safety.

5 192. Prior to, on, and after the date of Plaintiff's implantation with Bard
6 IVC Filters, and at all relevant times, Bard knew or reasonably should have known
7 that Bard IVC Filters and their warnings were defective and dangerous or were
8 likely to be dangerous when used in a reasonably foreseeable manner.

9 193. Prior to, on, and after the date of Plaintiff's implantation with Bard
10 IVC Filters and at all relevant times thereafter, Bard became aware that the defects
11 of Bard IVC Filters resulted in Bard IVC Filters causing injuries similar to those
12 Plaintiff suffered.

13 194. Reasonable manufacturers and distributors under the same or similar
14 circumstances would have recalled or retrofitted Bard IVC Filters, and would
15 thereby have avoided and prevented harm to many patients, including Plaintiffs.

16 195. In light of this information and Bard's knowledge described above,
17 Bard had a duty to recall and/or retrofit Bard IVC Filters.

18 196. Bard breached its duty to recall and/or retrofit Bard IVC Filters.

19 197. As a direct and proximate result of Bard's negligent failure to recall or
20 retrofit, Plaintiff suffered Injuries and Damages.

21 **COUNT VII: NEGLIGENCE - FAILURE TO WARN**

22 198. Plaintiff incorporates by reference all prior allegations

23 199. At all relevant times, Bard knew or should have known that Bard IVC
24 Filters were defective and dangerous or were likely to be dangerous when used in
25 a reasonably foreseeable manner.

26 200. Such danger included the propensity of Bard IVC Filters to cause
27 injuries similar to those suffered by Plaintiffs.
28

1 201. At all relevant times, Bard also knew or reasonably should have
2 known that the users of Bard IVC Filters, including Plaintiff, would not realize or
3 discover on their own the dangers presented by Bard IVC Filters.

4 202. Reasonable manufacturers and reasonable distributors, under the
5 same or similar circumstances as those of Bard prior to, on, and after the date of
6 Plaintiff's use of Bard IVC Filters, would have warned of the dangers presented by
7 Bard IVC Filters, or instructed on the safe use of Bard IVC Filters.

8 203. Prior to, on, and after the date of Plaintiff's use of the IVC Filters,
9 Bard had a duty to adequately warn of the dangers presented by Bard IVC Filters
10 and/or instruct on the safe use of Bard IVC Filters.

11 204. Bard breached these duties by failing to provide adequate warnings
12 to Plaintiff communicating the information and dangers described above and/or
13 providing instruction for safe use of Bard IVC Filters.

14 205. As a direct and proximate result of Bard's negligent failure to warn,
15 Plaintiff suffered Injuries and Damages.

16 **COUNT VIII: NEGLIGENCE MISREPRESENTATION**

17 206. Plaintiff incorporates by reference all prior allegations.

18 207. Prior to, on, and after the dates during which Plaintiff was implanted
19 with the IVC Filters, Bard negligently and carelessly represented to Plaintiff,
20 Plaintiff's treating physicians, and the general public that Bard IVC Filters were
21 safe, fit, and effective for use.

22 208. These representations were untrue.

23 209. Bard owed a duty in all of its undertakings, including the
24 dissemination of information concerning its IVC filters, to exercise reasonable
25 care to ensure that it did not in those undertakings create unreasonable risks of
26 personal injury to others.
27

28

1 210. Bard disseminated to health care professionals and consumers
2 through published labels, labeling, marketing materials, and otherwise information
3 concerning the properties and effects of Bard IVC Filters with the intention that
4 health care professionals and consumers would rely upon that information in their
5 decisions concerning whether to prescribe and use Bard IVC Filters.

6 211. Bard, as medical device designers, manufacturers, sellers, promoters
7 and/or distributors, knew or should reasonably have known that health care
8 professionals and consumers, in weighing the potential benefits and potential risks
9 of prescribing or using Bard IVC Filters, would rely upon information
10 disseminated and marketed by Bard to them regarding the Bard IVC Filters.

11 212. Bard failed to exercise reasonable care to ensure that the information
12 they disseminated to health care professionals and consumers concerning the
13 properties and effects of Bard IVC Filters was accurate, complete, and not
14 misleading and, as a result, disseminated information to health care professionals
15 and consumers that was negligently and materially inaccurate, misleading, false,
16 and unreasonably dangerous to consumers such as Plaintiffs.

17 213. Bard, as designers, manufacturers, sellers, promoters, and/or
18 distributors, also knew or reasonably should have known that patients receiving
19 Bard IVC Filters as recommended by health care professionals in reliance upon
20 information disseminated by Bard as the manufacturer/distributor of Bard IVC
21 Filters would be placed in peril of developing the serious, life-threatening, and
22 life-long injuries including, but not limited to, tilting, migration, perforation,
23 fracture, lack of efficacy, and increased risk of the development of blood clots, if
24 the information disseminated and relied upon was materially inaccurate,
25 misleading, or otherwise false.

26 214. Bard had a duty to promptly correct material misstatements it knew
27 others were relying upon in making healthcare decisions.
28

1 215. Bard failed in each of these duties by misrepresenting to Plaintiff and
2 the medical community the safety and efficacy of Bard IVC Filters and failing to
3 correct known misstatements and misrepresentations.

4 216. As a direct and proximate result of Bard's negligent
5 misrepresentations, Plaintiff suffered Injuries and Damages.

6 **COUNT IX: NEGLIGENCE PER SE**

7 (Violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807,
8 820)

9 217. Plaintiff incorporates by reference all prior allegations.

10 218. At all times herein mentioned, Bard was subject to a variety of
11 federal, state, and local laws, rules, regulations and ordinances, including the
12 Federal Food, Drug and Cosmetic Act ("FFDCA") and its applicable regulations,
13 concerning the manufacture, design, testing, production, processing, assembling,
14 inspection, research, promotion, advertising, distribution, marketing, promotion,
15 labeling, packaging, preparation for use, consulting, sale, warning, and post-sale
16 warning and other communications of the risks and dangers of Bard IVC Filters.

17 219. By reason of its conduct as alleged herein, Bard violated provisions
18 of statutes and regulations, including but not limited to:

- 19 a. FFDCA, 21 U.S.C. §§331 and 352, by misbranding Bard IVC
20 Filters;
21 b. FFDCA, 21 U.S.C. § 321, by making statements and/or
22 representations via word, design, device, or any combination
23 thereof failing to reveal material facts with respect to the
24 consequences that may result from the use of Bard IVC Filters
25 to which the labeling and advertising relates;
26

- 1 c. 21 C.F.R. § 1.21, by misleading its consumers and patients by
- 2 concealing material facts in light of representations made
- 3 regarding safety and efficacy of its Bard IVC Filters;
- 4 d. 21 C.F.R. § 801, by mislabeling Bard IVC Filters as to safety
- 5 and effectiveness of its products and by failing to update its
- 6 label to reflect post-marketing evidence that Bard IVC Filters
- 7 were associated with an increased risk of injuries due to tilting,
- 8 fracture, migration and perforation;
- 9 e. 21 C.F.R. §§801.109 and 801.4 by learning that Bard IVC
- 10 Filters were adulterated and misbranded and failing to correct
- 11 and recall the devices.
- 12 f. 21 C.F.R. § 803, by not maintaining accurate medical device
- 13 reports regarding adverse events of tilting, fracture, migration
- 14 and perforation and/or misreporting these adverse events
- 15 maintained via the medical device reporting system;
- 16 g. 21 C.F.R. § 807, by failing to notify the FDA and/or the
- 17 consuming public when its Bard IVC Filters were no longer
- 18 substantially equivalent with regard to safety and efficacy with
- 19 regard to post-marketing adverse events and safety signals;
- 20 h. 21 C.F.R. § 820, by failing to maintain adequate quality
- 21 systems regulation including, but not limited to, instituting
- 22 effective corrective and preventative actions;
- 23 i. 21 CFR 201.128, by promoting each of their subject devices
- 24 off-label and for conditions, purposes and uses beyond their
- 25 labeled and intended uses; and
- 26 j. 210 CFR 801.4, by their knowledge of off-label uses of their
- 27 devices for unintended and unlabeled conditions, purposes and
- 28

1 uses, and failing as required to provide adequate labeling
2 which accords with such unlabeled and unintended uses.

3 220. These statutes, rules and regulations, along with those listed in Count
4 XIV, are designed to protect the health, safety, and well-being of consumers like
5 Plaintiffs.

6 221. Bard's violation of these statutes, rules and regulations, as well as
7 those detailed in Count XIV, constitutes negligence per se.

8 222. As a direct and proximate result of Bard's negligence *per se*, Plaintiff
9 suffered Injuries and Damages.

10 **COUNT X: BREACH OF EXPRESS WARRANTY**

11 223. Plaintiff incorporates by reference all prior allegations.

12 224. Plaintiff, though her medical providers, purchased Bard IVC Filters
13 from Bard.

14 225. At all relevant times, Bard was a merchant of goods of the kind
15 including medical devices and vena cava filters (i.e, Bard IVC Filters).

16 226. At the time and place of sale, distribution, and supply of Bard IVC
17 Filters to Plaintiff (and to other consumer and the medical community), Bard
18 expressly represented and warranted that Bard IVC Filters were safe; that they
19 were well-tolerated, efficacious, fit for their intended purpose, and of marketable
20 quality; that they did not produce any unwarned-of dangerous side effects; and
21 that they was adequately tested.

22 227. At the time of Plaintiff's purchase from Defendants, Bard IVC Filters
23 were not in a merchantable condition, and Bard breached its expressed warranties,
24 in that Bard IVC Filters:

- 25
- 26 a. Were designed in such a manner so as to be prone to an
27 unreasonably high incidence of fracture, perforation of vessels
28 and organs, and/or migration;

- b. Were designed in such a manner so as to result in a
unreasonably high incidence of injury to the vessels and
organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface
of the filter was inadequately, improperly, and inappropriately
constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

228. As a direct and proximate result of Bard's breach of express warranty, Plaintiff suffered Injuries and Damages.

COUNT XI: BREACH OF IMPLIED WARRANTY

229. Plaintiff incorporates by reference all prior allegations.

230. Bard impliedly warranted that Bard IVC Filters were of merchantable quality and safe and fit for the use for which Bard intended them, and Plaintiff in fact used them.

231. Bard breached its implied warranties by:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Bard IVC Filters would cause harm;
- b. Manufacturing and/or selling Bard IVC Filters when those filters did not conform to representations made by Bard when they left Bard's control;
- c. Manufacturing and/or selling Bard IVC Filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;

- 1 d. Manufacturing and/or selling Bard IVC Filters that carried
- 2 foreseeable risks associated with the Bard IVC Filter design or
- 3 formulation which exceeded the benefits associated with that
- 4 design;
- 5 e. Manufacturing and/or selling Bard IVC Filters when they
- 6 deviated in a material way from the design specifications,
- 7 formulas, or performance standards or from otherwise identical
- 8 units manufactured to the same design specifications,
- 9 formulas, or performance standards; and
- 10 f. Impliedly representing that its filters would be effective in the
- 11 prevention of pulmonary emboli.

12 232. As a direct and proximate result of Bard's breach of its implied
13 warranty, Plaintiff suffered Injuries and Damages.

14 **COUNT XII: FRAUDULENT MISREPRESENTATION**

15 233. Plaintiff incorporates by reference all prior allegations.

16 234. At all times relevant to this cause, and as detailed above, Bard
17 intentionally provided Plaintiff, Plaintiff's physicians, the medical community, and
18 the public at large with false or inaccurate information. Bard also omitted material
19 information concerning Bard IVC Filters, including, but not limited to,
20 misrepresentations regarding the following topics:

- 21 a. The safety of the Bard IVC Filters;
- 22 b. The efficacy of the Bard IVC Filters;
- 23 c. *i* The rate of failure of the Bard IVC Filters;
- 24 d. The pre-market testing of the Bard IVC Filters;
- 25 e. The approved uses of the Bard IVC Filters; and
- 26 f. The ability to retrieve the device at any time over a person's
- 27 life.
- 28

1 235. The information Bard distributed to the public, the medical
2 community, and Plaintiff was in the form of reports, press releases, advertising
3 campaigns, labeling materials, print advertisements, commercial media containing
4 material representations, and instructions for use, as well as through their officers,
5 directors, agents, and representatives.

6 236. These materials contained false and misleading material
7 representations, which included: that Bard IVC Filters were safe and fit when used
8 for their intended purpose or in a reasonably foreseeable manner; that they did not
9 pose dangerous health risks in excess of those associated with the use of other
10 similar IVC filters; that any and all side effects were accurately reflected in the
11 warnings; and that they were adequately tested to withstand normal placement
12 within the human body.

13 237. Bard made the foregoing misrepresentations knowing that they were
14 false or without reasonable basis. These materials included instructions for use and
15 a warning document that was included in the package of Bard IVC Filters that
16 were implanted in Plaintiffs.

17 238. Bard's intent and purpose in making these misrepresentations was to
18 deceive and defraud the public and the medical community, including Plaintiff's
19 health care providers; to gain the confidence of the public and the medical
20 community, including Plaintiff's health care providers; to falsely assure the public
21 and the medical community of the quality of Bard IVC Filters and their fitness for
22 use; and to induce the public and the medical community, including Plaintiff's
23 healthcare providers to request, recommend, prescribe, implant, purchase, and
24 continue to use Bard IVC Filters, all in reliance on Bard's misrepresentations.

25 239. The foregoing representations and omissions by Bard were false.

26 240. Bard IVC Filters are not safe, fit, and effective for human use in their
27 intended and reasonably foreseeable manner.
28

1 241. Further, the use of Bard IVC Filters is hazardous to the users' health,
2 and Bard IVC Filters have a serious propensity to cause users to suffer serious
3 injuries, including without limitation the injuries Plaintiff suffered.

4 242. Finally, Bard IVC Filters have a statistically significant higher rate of
5 failure and injury than do other comparable IVC filters.

6 243. In reliance upon the false and negligent misrepresentations and
7 omissions made by Bard, Plaintiff and Plaintiff's health care providers were
8 induced to, and did use Bard IVC Filters, thereby causing Plaintiff to sustain
9 severe and permanent personal injuries and death.

10 244. Bard knew and had reason to know that Plaintiff, Plaintiff's health
11 care providers, and the general medical community did not have the ability to
12 determine the true facts intentionally and/or negligently concealed and
13 misrepresented by Bard, and would not have prescribed and implanted Bard IVC
14 Filters if the true facts regarding Bard IVC Filters had not been concealed and
15 misrepresented by Bard.

16 245. Bard had sole access to material facts concerning the defective nature
17 of the products and their propensities to cause serious and dangerous side effects
18 in the form of dangerous injuries and damages to persons who were implanted
19 with Bard IVC Filters.

20 246. At the time Bard failed to disclose and intentionally misrepresented
21 the foregoing facts, and at the time Plaintiff used Bard IVC Filters, Plaintiff and
22 Plaintiff's health care providers were unaware of Bard's misrepresentations and
23 omissions.

24 247. As a direct and proximate result of Bard's fraudulent
25 misrepresentations, Plaintiff suffered Injuries and Damages.
26

27 **COUNT XIII: FRAUDULENT CONCEALMENT**

28 248. Plaintiff incorporates by reference all prior allegations.

1 249. In marketing and selling Bard IVC Filters, Bard concealed material
2 facts from Plaintiff and Plaintiff's healthcare providers.

3 250. These concealed material facts include, but are not limited to:

- 4 a. Bard IVC Filters were unsafe and not fit when used for their
5 intended purpose or in a reasonably foreseeable manner;
6 b. Bard IVC Filters posed dangerous health risks in excess of
7 those associated with the use of other similar IVC filters;
8 c. That there were additional side effects related to implantation
9 and use of Bard IVC Filters that were not accurately and
10 completely reflected in the warnings associated with Bard IVC
11 Filters; and
12 d. That Bard IVC Filters were not adequately tested to withstand
13 normal placement within the human body.

14 251. Plaintiff and Plaintiff's healthcare providers were not aware of these
15 and other facts concealed by Bard.

16 252. In concealing these and other facts, Bard intended to deceive Plaintiff
17 and Plaintiff's healthcare providers.

18 253. Plaintiff and Plaintiff's healthcare providers were ignorant of and
19 could not reasonably discover the facts Bard fraudulently concealed and
20 reasonably and justifiably relied on Bard's representations concerning the
21 supposed safety and efficacy of Bard IVC Filters.

22 254. As a direct and proximate result of Defendants' fraudulent
23 concealment of material facts, Plaintiff suffered Injuries and Damages.

24 **COUNT XIV: VIOLATION OF SOUTH DAKOTA STATE LAW**
25 **PROHIBITING CONSUMER FRAUD AND UNFAIR DECEPTIVE TRADE**
26 **PRACTICES**

27 255. Plaintiff incorporates by reference all prior allegations.
28

1 256. Bard had a statutory duty to refrain from unfair or deceptive acts or
2 practices in the sale and promotion of Bard IVC Filters.

3 257. Bard knowingly, deliberately, willfully and/or wantonly engaged in
4 unfair, unconscionable, deceptive, fraudulent, and misleading acts or practices in
5 violation of South Dakota's consumer protection laws identified below.

6 258. Through its false, untrue, and misleading promotion of Bard IVC
7 Filters, Bard induced Plaintiff to purchase and/or pay for the purchase of Bard IVC
8 Filters.

9 259. Bard misrepresented the alleged benefits and characteristics of Bard
10 IVC Filters; suppressed, omitted, concealed, and failed to disclose material
11 information concerning known adverse effects of Bard IVC Filters;
12 misrepresented the quality and efficacy of Bard IVC.

13 260. Filters as compared to much lower-cost alternatives; misrepresented
14 and advertised that Bard IVC Filters were of a particular standard, quality, or
15 grade that they were not; misrepresented Bard IVC Filters in such a manner that
16 later, on disclosure of the true facts, there was a likelihood that Plaintiff would
17 have opted for an alternative IVC filter or method of preventing pulmonary
18 emboli.

19 261. Bard's conduct created a likelihood of, and in fact caused, confusion
20 and misunderstanding.

21 262. Bard's conduct misled, deceived, and damaged Plaintiff, and Bard's
22 fraudulent, misleading, and deceptive conduct was perpetrated with an intent that
23 Plaintiff rely on said conduct by purchasing and/or paying for purchases of Bard
24 IVC Filters.

25 263. Moreover, Bard knowingly took advantage of Plaintiff, who was
26 unable to protect her own interests due to ignorance of the harmful adverse effects
27 of Bard IVC Filters.
28

1 264. Bard's conduct was willful, outrageous, immoral, unethical,
2 oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff
3 and offends the public conscience.

4 265. Plaintiff purchased Bard's IVC Filters primarily for personal, family,
5 or household purposes.

6 266. As a result of Bard's violative conduct in South Dakota, Plaintiff
7 purchased and/or paid for purchases of Bard IVC Filters that were not made for
8 resale.

9 267. Bard engaged in unfair competition or IVC acts or practices in
10 violation of S.D. Code Laws § 37-24-1, *et seq.*

11 268. As a direct and proximate result of Bard's violations of these statutes,
12 Plaintiff suffered Injuries and Damages and seek all available damages under
13 South Dakota law.

14 **PUNITIVE DAMAGES ALLEGATIONS**

15 269. Plaintiff incorporates by reference all prior allegations.

16 270. At all times material hereto, Bard knew or should have known that
17 Bard IVC Filters were unreasonably dangerous with respect to the risk of tilt,
18 fracture, migration and/or perforation.

19 271. At all times material hereto, Bard attempted to misrepresent and did
20 knowingly misrepresent facts concerning the safety of Bard IVC Filters.

21 272. Bard's misrepresentations included knowingly withholding material
22 information from the medical community and the public, including Plaintiff's
23 physicians, concerning the safety of its Bard IVC Filters.

24 273. Bard's conduct, alleged throughout this Complaint, was willful,
25 wanton and malicious, and undertaken with a conscious indifference and disregard
26 to the consequences that consumers of their products faced, including Plaintiff.
27
28

1 274. At all times material hereto, Bard knew and willfully and
2 intentionally and/or recklessly disregarded the fact that Bard IVC Filters have an
3 unreasonably high rate of tilt, fracture, migration, and/or perforation.

4 275. Notwithstanding the foregoing, Bard continued to market Bard IVC
5 Filters aggressively to consumers, including Plaintiff, without disclosing the
6 aforesaid side effects.

7 276. Bard knew of its Bard IVC Filters' lack of warnings regarding the risk
8 of fracture, migration, and/or perforation, but willfully and intentionally concealed
9 and/or recklessly failed to disclose that risk and continued to market, distribute,
10 and sell its filters without said warnings so as to maximize sales and profits at the
11 expense of the health and safety of the public, including Plaintiff, in conscious
12 disregard of the foreseeable harm caused by Bard IVC Filters.

13 277. Bard's willful and intentional and/or reckless failure to disclose
14 information deprived Plaintiff's physicians of necessary information to enable
15 them to weigh the true risks of using Bard IVC Filters against its benefits.

16 278. Bard's conduct is reprehensible, evidencing an evil hand guided by an
17 evil mind and was undertaken for pecuniary gain in reckless and conscious
18 disregard for the substantial risk of death and physical injury to consumers,
19 including Plaintiff.

20 279. Such conduct justifies an award of punitive or exemplary damages in
21 an amount sufficient to punish Bard's conduct and deter like conduct by Bard and
22 other similarly situated persons and entities in the future.

23
24 **PRAYER FOR RELIEF**

25 **WHEREFORE**, Plaintiff demands judgment against Defendants for:

26 A. Compensatory damages, including without limitation past and future
27 medical expenses; past and future pain and suffering; past and future
28 emotional distress; past and future loss of enjoyment of life; past and

1 future loss of consortium; past and future lost wages and loss of earning
2 capacity; funeral and burial expenses; and other consequential damages
3 as allowed by law;

4 B. Punitive damages in an amount sufficient to punish Defendants and deter
5 similar conduct in the future;

6 C. Disgorgement of profits;

7 D. Restitution;

8 E. Statutory damages, where authorized;

9 F. Costs of suit;

10 G. Reasonable attorneys' fees, where authorized;

11 H. Prejudgment interest as allowed by law;

12 I. Post-judgment interest at the highest applicable statutory or common law
13 rate from the date of judgment until satisfaction of judgment;

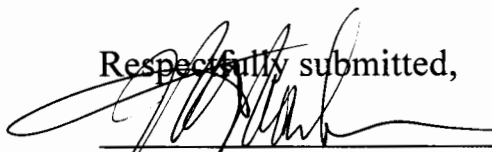
14 J. Such other additional and further relief as Plaintiff may be entitled to in
15 law or in equity.

16 **JURY DEMAND**

17 Plaintiff hereby demands a trial by jury as to all claims in this action.

18
19 Dated: January 12, 2016

20
21 Respectfully submitted,



22
23 Michael F. Marlow (SDBN 1099)
24 **Johnson, Miner, Marlow, Woodward &**
25 **Huff, Prof. LLC**
26 P.O. Box 667
27 200 West Third Street
28 Yankton, SD 57078
Tel: 605-665-5009
Fax: 605-665-4788

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James A. Morris, Esq. (C SBN 296852)
Pro hac pending
jmorris@jamlawyers.com
MORRIS LAW FIRM
6310 San Vicente Blvd, Suite 360
Los Angeles, CA 90048
Tel: 323-302-9488
Fax: 323-931-4990
Attorneys for Plaintiff