

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

GARY LEIGH PIAZZA,

Plaintiff,

v.

C.R. BARD, INC. and
BARD PERIPHERAL VASCULAR, INC.,

Defendants.

Case No. 1:15-cv-01048

COMPLAINT FOR DAMAGES

AND DEMAND FOR JURY TRIAL

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COMES NOW Plaintiff, GARY LEIGH PIAZZA, by and through her undersigned attorneys, and alleges as follows:

INTRODUCTION

1. This case involves the implantation of a device called an inferior vena cava filter that is intended to be placed into the vessel leading to the heart in order to filter all blood clots from being transported in the blood to the lungs, the heart and the brain.

2. This is a civil action to secure redress from C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. (collectively “Bard” or “Defendants”) for damages suffered by Plaintiff Gary Leigh Piazza as a result of Defendants’ defective Bard-branded inferior vena cava (“IVC”) filter marketed as the Bard G2 IVC Filter (the “Device.”)

3. Plaintiff brings this case for serious personal injuries that Plaintiff suffered as result of the failure of the surgically implanted defective and dangerous Device, which was researched, developed, manufactured, marketed sold and distributed by Defendants.

4. The Device’s failure has caused Plaintiff to suffer grievous ongoing physical, emotional, and economic losses, all of which will continue far into the future.

5. Prior to Plaintiff’s implantation of the Device, Defendants knew and should have known that the Device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct appropriate clinical testing, such as animal studies, to determine how the Device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Device and their other IVC filters had a high rate of perforation of tissues, fractures of the Device, migration from the implantation site, and excessive tilting within the vena cava once implanted.

c. Defendants knew and/or should have known that such failures exposed patients to the increased risk of serious injuries including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforation of tissue, vessels and organs; and the inability to remove the Device.

d. Defendants knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the Device.

e. Defendants knew or should have known that these risks were and are substantially higher than risks posed by other IVC filters.

f. Defendants knew and/or should have known that filters such as the Device are used to treat conditions which Defendants did not explicitly intend and which resulted in the Device not performing as safely as the ordinary consumer would expect.

6. Despite knowledge of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these and other risks posed by the Device.

7. Defendants failed to recall this dangerous Device at many opportunities, when Bard knew and had reason to know that the Device was unnecessarily dangerous for its intended purpose.

PARTIES

Plaintiff

8. Plaintiff Gary Leigh Piazza (“Plaintiff”) is a natural person who is a citizen of the State of New York residing in Buffalo.

Defendants

9. Defendant C.R. Bard, Inc. (“C.R. Bard”) is a corporation authorized to do business in the State of New York. Defendant C.R. Bard regularly sells and markets its medical devices in the State of New York. Defendant C.R. Bard is organized and existing by virtue of the laws of the State of Delaware and has its principal place of business in Murray Hill, New Jersey.

10. Defendant Bard Peripheral Vascular, Inc. (“BPV”) is a wholly-owned subsidiary corporation of C.R. Bard. Defendant BPV is a corporation authorized to do business in the State of New York. Defendant BPV regularly markets and sells its medical devices in the State of New York. Defendant BPV is organized and existing under the laws of the State of Arizona and has its principal place of business in Tempe, Arizona.

11. At all relevant times, Defendants engaged in the research, design, assembly, manufacture, testing, quality control, sale, advertising, marketing, distribution Bard IVC filters and their appurtenances and component parts in the U.S. and especially in New York..

12. Defendants, directly and/or through their agents, marketed and sold the Bard G2 IVC Filter, which is the subject of this lawsuit (“the Device”), other IVC filters, and other medical products in the State of New York. Defendants derived substantial revenue from marketing and selling these products in the State of New York. Defendants expected, or should have expected, that their business activities might subject them to legal action in the State of New York.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a)(1) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000.00, exclusive of interest and costs.

14. Venue is appropriate in this District, the Western District of New York, because a substantial part of the events or omissions giving rise to the claim occurred within the District, including the implantation of the IVC filter in Plaintiff and the malfunctioning of the same IVC filter.

ALLEGATIONS

A. IVC FILTERS

15. Inferior vena cava (“IVC”) filters first came onto the medical market in the 1960’s. Since that time, medical device manufacturers have introduced several different designs of IVC filters.

16. An IVC filter is a device that is designed to filter or “catch” blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either permanently or temporarily, in the inferior vena cava.

17. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called “deep vein thrombosis” or “DVT.” Once blood clots reach the lungs, they are considered “pulmonary emboli,” or “PE.” Pulmonary emboli are potentially fatal.

18. People at risk for DVT/PEs can undergo medical treatment to manage the risk. For example, a doctor may prescribe anti-clotting medications such as Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. For those who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

19. The first IVC filters marketed were permanent filters. These devices were designed to remain in the patient's IVC permanently. The medical literature refers to several studies that present long-term follow-up data (of up to 20 years and longer), that supports the use and efficacy of certain permanent filters.

20. Beginning in 2003, Defendants began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from the patient after the risk of blood clots has diminished.

21. These devices have only been approved by the FDA to prevent recurrent pulmonary embolism where anticoagulant therapies are contraindicated or have failed. Thus, any use other than in a patient with a history of pulmonary embolism who failed to control their blood clots with pharmaceutical anticoagulants is not an FDA approved and indicated uses, therefore it is an off-label use.

B. THE RECOVERY FILTER

1. Simon Nitinol Filter and Bard's Reach for Greater Market Share

22. Bard has distributed and marketed the Simon Nitinol¹ Filter in the United States since 1992. The Simon Nitinol Filter is a permanent IVC filter, which is substantially safer than Bard's optional filters and is still sold by Bard today. Bard modified the design of the Simon Nitinol Filter in order to make a device that was supposed to be equally safe to leave in permanently, or to retrieve once the risk of pulmonary embolism had passed. The modified device was ultimately marketed as the Recovery Filter System (the "Recovery Filter").

23. Bard's stated purpose in designing the Recovery Filter was to increase the overall size of the market for these devices through off-label promotion and to increase Bard's

¹ Nitinol derives its name from its component parts and place of discovery: Nickel Titanium Naval Ordnance Laboratory.

percentage of that market. Specifically, Bard marketed the device for patients who were at risk for DVTs and PEs, but who had not actually had a documented pulmonary embolism as required by the FDA label. This new market included patients who were immobilized for periods of time after surgical procedures, *e.g.*, orthopedic patients, bariatric patients, and cancer patients.

24. Prior to the FDA's clearance of the Recovery Filter, Bard was losing market share in an IVC Filter market that was reported to be worth \$100,000,000.00 in sales. In July 2001, Bard's overall market share was 16-17%; by March 2003, it was down to 11-12%.

25. Bard's marketing manager explained Bard's marketing plan for the Recovery Filter in a March 28, 2003 Market Appraisal Memorandum. She wrote, "Users can be swayed by ease of use, low profile and aggressive marketing even in the absence of solid clinical history and in spite of negative clinical experience."

2. FDA Clearance

26. In 2002, Bard and BPV submitted a "me too" application to the FDA that Bard and BPV be permitted to market the Recovery Filter System for the prevention of recurrent pulmonary emboli, claiming it was substantially similar in safety, efficacy, design, and materials as the Simon Nitinol filter. On November 27, 2002, the FDA cleared the Bard Recovery Filter for sale and use in the prevention of recurrent pulmonary embolism via permanent placement in the inferior vena cava.²

27. In April 2003, Bard submitted a notification of intent to market and sell the Recovery Filter for the additional intended use of optional retrieval. Bard received FDA

² Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976, 21 U.S.C. § 321 *et seq.* The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. 21 C.F.R. §§ 807.81, 807.92(a)(3). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

clearance to begin marketing the Recovery Filter as both a permanent and retrievable filter on or about July 25, 2003.

28. Ultimately, Bard's plan to promote its retrievable devices for off-label uses and for unproven benefits succeeded. By 2009, the overall market for IVC filters had tripled, and Bard's percentage share of that market increased from 11-12% to 42%.

29. Among Bard's marketing claims to physicians was that the Recovery Filter was safer than all previously available filters, including the Simon Nitinol Filter. This claim was false.

3. The Design of the Recovery Filter

30. The Recovery Filter is cone-shaped, consisting of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, commonly referred to as the arms, and six long struts, commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top/apex of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating from "normal respiratory movement" or even massive pulmonary emboli.

31. The Recovery filter is inserted percutaneously by a deployment catheter that is guided by a physician through a blood vessel into the inferior vena cava. The Recovery Filter is designed to be retrieved in a similar fashion.

32. The Recovery Filter included several design changes from the Simon Nitinol Filter. These include, but are not limited to, the following:

- a. decreasing the leg span of the device;
- b. decreasing the hook diameter of each hook on the leg struts;

- c. decreasing the radial force of the struts; and
- d. changing the closed petal arm strut design to an open arm strut design.

4. Bard's Design Efforts Were Inadequate

33. Each of Bard's design changes had the unintended consequence of substantially reducing the Recovery Filter's stability, *i.e.*, increasing the likelihood that the filter would move, tilt, migrate completely out of the area of placement, and lack structural integrity, increase its propensity to perforate the vena cava and let more clots go by it..

34. However, because Bard failed to conduct adequate testing and research, Defendants failed to realize that these design changes would result in the device not being reasonably safe for user needs.

35. In a 2009 Bard IVC Filter franchise review, Bard's Filter Franchise Team described Bard's weaknesses as follows:

- a. Lack of thorough understanding dynamics of caval anatomy – impacting testing methods;
- b. A historical reactive/evolution design mindset;
- c. Product complications – forcing focus on reactive designing;
- d. Limited understanding of user needs.

36. Due to Bard's lack of understanding of caval anatomy and the forces the device would be exposed to once implanted, Bard set design specifications that were not clinically relevant and did not account for the forces these devices would actually see when implanted in the human body. For instance, Bard's decision to set the minimum safety standard for migration

resistance at 50 mmHg³ reflected a complete lack of understanding of the forces this device could be exposed to once implanted.

37. Bard also failed to test the device under reasonably foreseeable conditions that the device would be exposed to when used in an intended and expected manner. Among other things, Bard knew that these devices could be placed in appropriately sized vena cava that subsequently expanded beyond 28 mm in diameter. Bard knew that this expansion of the vena cava could decrease migration resistance if the device was challenged by a clot, and could lead to migration if the vena cava expanded beyond the leg span of the filter, such that the hooks were no longer in touch with the vena cava walls. Yet Bard chose not to test the device to simulate how it would perform if caval distension (expansion) were to occur. Bard also failed to test the device to determine how its stability and structural integrity would perform if the device tilted, fractured, or perforated the vena cava.

5. Pre-Market Expectations

38. Prior to introducing the Recovery Filter and later the G2 and Eclipse Filters to market, Bard and consumers expected that a properly placed filter would remain stable, maintain structural integrity, and would not perforate the vena cava when used in a reasonably foreseeable manner. Bard's internal documents reflect these expectations:

a. Bard filed patents for its retrievable filters, which state, "An elastic hook is formed on the free end of an appendage to pierce the vessel wall and insure that the filter does not migrate in response to normal respiratory functions or in the event of a massive pulmonary embolism."

³ "mmHg" refers to a millimeter of mercury and is a unit of pressure.

b. Bard's Product Performance Specifications for its retrievable filters provide specifications that are to ensure "user needs," which are that the devices must not migrate, fracture, or perforate the vena cava.

c. Bard's premarket testing, which failed to account for real world conditions, predicted that there would be no fractures, migration, or perforation failures.

d. Bard's pre-market design and testing documents state that if a clot challenges a filter, "pressure below the filter increases significantly and tends to drive the filter toward the heart," and that "the device must not migrate in response to such a challenge."

e. In a June 2004 Health Hazard Evaluation, Bard's Medical Director stated that clot-induced migrations are a malfunction of the device and a failure to carry out its intended function.

f. Bard's own quality engineers working on the retrievable filter projects admitted that if one of its filters is driven into the heart by a clot challenge, then the device failed to perform as intended.

g. In 2004, Bard conducted a physician focus group regarding what were the expected complications from IVC filters. The physicians reported that an IVC Filter must not migrate no matter how big a clot is.

h. Bard also marketed its retrievable filters as being "self-centering," meaning that they would not tilt or migrate from their placement in the vena cava.

6. Bard's Post-Market Surveillance Revealed the Recovery Filter Did Not Perform as Expected

39. Once the Recovery Filter was released to market, there were reported complaints, Bard's own investigations, and epidemiological studies that demonstrated that the design

changes made from the Simon Nitinol Filter to its Recovery Filter had substantially reduced the stability, structural integrity, and perforation resistance of the device.

40. Even when properly placed, the Recovery Filter had an increased propensity to move, fracture, and/or perforate the vena cava when exposed to normal and expected *in vivo* (within the body) forces.

41. When fracture and migration failures occur, shards of the device or the entire device can travel to the heart, where they can cause cardiac tamponade (pressure caused by a collection of blood in the area around the heart), perforation of the atrial wall, perforation of vessels, myocardial infarction, and/or death. These fractured shards may also become embedded in tissue or migrate to other organ systems and vasculature, such as the renal veins and heart and lungs, rendering them too dangerous to remove. When tilting, penetrating and perforating the vena cava walls occurs, the device can perforate nearby organs and vessels such as the aorta, duodenum, small bowel, and ureter, which may lead to hemorrhage, retroperitoneal hematomas, small bowel obstructions, extended periods of severe pain, and or/death. Further, given the risks of injury in attempting to remove devices that have penetrated or perforated the vena cava, the device may not be removable or may require complex and dangerous open vascular surgical removal. Moreover, Bard was aware that these failures and resulting injuries were far more likely to occur with the Recovery Filter versus other available IVC Filters. For instance:

a. On April 23, 2004, Bard's Corporate VP of Quality Assurance sent an email noting that the Recovery Filter's reported failure rates "did not look good compared to permanent filters" and promised to remove the filter from the market if its reported death rate became "significantly greater than the rest of the pack."

b. Multiple studies reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.

c. In February 2004, Bard's Marketing Manager, Janet Hudnall, sent an email admitting that the Recovery Filter was being reported to have tilted at significantly high rate even though it was initially properly placed. She requested that this high rate of failure be downplayed to consumers.

d. In June 2004, Bard's divisional head of Quality Assurance, Doug Uelmen, admitted: "Bard has been in the permanent filter market for 10 years (SNF). We have had a great deal of experience with a traditional patient base, experiencing a very low and unremarkable adverse event rate. We have now moved into the optional filter market with RNF and have experienced increased failures."

e. By July 2004, Bard was aware that the Recovery Filter had a reported fracture rate that was **28 times** higher than all other available IVC Filters.

f. In December 2004, Bard performed a risk assessment of the Recovery Filter, which analyzed reported failure rates. Bard concluded: "Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rate for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters." Dr. Ciavarella, Bard's Medical Director, concluded that this risk (substantially higher reported failure rates) was not known or obvious to consumers, and that Bard should consider providing a warning regarding the reported increased failure rate.

g. By December 2004, according to Bard's own policy and procedures for when devices should be recalled, the Recovery filter was considered unreasonably dangerous for human health and required product correction and recall. But the Bard Defendants did nothing.

42. The Adverse Event Reports (AERs) associated with IVC filter devices demonstrate that certain Bard IVC filters are far more prone to device failure than are other similar devices.

43. A review of the FDA MAUDE database from the years 2004 through 2008, demonstrates that Bard's IVC filters are responsible for the following percentages of all AERs:

- a. 50% of all adverse events;
- b. 64% of all occurrences of migration of the device;
- c. 69% of all occurrences of vena cava wall perforation; and
- d. 70% of all occurrences of filter fracture.

44. These failures are attributable, in part, to the fact that the Recovery Filter was not designed to be able to withstand normal anatomical and physiological loading cycles.

45. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings compromises the structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. The Recovery Filter is not of sufficient strength to withstand normal placement within the human body. The presence

of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

7. **Bard's Engaged in a Design Review Regarding Migration Failures of the Recovery IVC Filter.**

46. In late 2003, as migrations failures for the Recovery Filter continued to mount, Bard convened a group to reexamine the adequacy of the design of the Recovery Filter as it relates to its ability to remain stable after implantation. The group established a number of action items, including an investigation into what the minimum migration resistance specification of 50 mmHg had been based on comparison testing of the migration resistance of the Recovery Filter to other available filters, and comparing the radial force difference between the range of available devices.

47. This design review revealed that the minimum safety migration resistance specification was unsupported and had been set artificially low. Bard developed this critical safety standard based on undocumented informal estimates, obtained from then-unidentified physicians, that the greatest pressure below a filter that could be seen in the vena cava was 35 mmHg. Bard then tested the device in three (3) sheep and claimed that the test results confirmed that 35 mmHg was the highest pressure that could ever be seen in the vena cava under worst case conditions. However, the test results from the sheep show pressure levels well above 50 mmHg, which Bard completely ignored.

48. Further, Bard's investigation concluded that multiple properly placed Recovery Filters migrated and caused deaths because the filters lacked adequate strength to resist clot challenges and/or lacked an adequate margin of safety to accommodate post-placement distention of the vena cava. This further confirmed that the safety specification of 50 mmHg was

inadequate and that Bard's testing, which predicted no migration failures, did not accurately reflect real world conditions.

49. As part of this design review in early 2004, Bard also spoke with its two longtime physician consultants, Drs. Venbrux and Kaufman. The doctors warned Bard that their input on the migration resistance specification had just been an "estimate" and that Bard needed to consider revising the migration resistance specification from 50 mmHg to 140 mmHg. They further warned Bard that the Recovery Filter was a "wimpy" filter and its radial force also needed to be increased to ensure stability.

50. The design review also revealed that the Recovery Filter had migration resistance values that were far below most other filters, including the Simon Nitinol Filter. Bard's internal records reveal that this was a known contributing factor to the Bard anchoring mechanism's failure.

51. Bard knew that caval distension (expansion of the vena cava diameter beyond the size at placement) could occur from multiple factors. These factors included: anesthesia, hydration following medical procedures such as bariatric procedures, exertion from exercise, coughing, and straining during bowel movements. However, Bard to date has failed to make any efforts to determine the size of vena cava distension that can occur as a result of the tipping, tilting or migration of the filters.

8. Bard's Investigated the Cause of the Fractures.

52. In 2004, Bard also investigated what was causing the Recovery Filter to fracture. Among other things, Bard believed that movement, whether tilting or migration of more than 2 cm, substantially increased the risk of fracture. Bard also determined that perforation of struts through the wall of the vena cava was causing fractures. Bard also discovered that tilt also led to the inability to retrieve the device and/or could lead to fractures during retrievals.

53. Bard was aware that the diameter of the leg hooks is a substantial factor in a filter's ability resist migration and fatigue resistance.

54. By reducing the diameter of the hooks on the Recovery filter, Bard had reduced its ability to remain stable and not fracture.

55. Bard also reduced the leg span of the Recovery Filter from that of the Simon Nitinol filter by 25%, and as a result, knew that the device lacked a sufficient margin of safety to accommodate expansion of the vena cava (distension) after placement.

56. Bard was also aware that its failure to electropolish the wire material prior to distribution meant that the Device had surface damage that reduced its fatigue resistance.

57. Bard was also aware that the Recovery Filter had a high propensity to tilt and perforate the vena cava, which substantially increased the risk of fracture.

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

59. A few examples of this knowledge and awareness include:

a. On June 18, 2003, BPV engineer, Robert Carr, sent an email noting that chamfering the edge of cap would reduce the likelihood of fracture.

b. On March 16, 2004, a BPV engineer sent an email admitting that the surface damage, as seen on the Recovery Filter from the manufacturing process, decreases fatigue resistance and that electropolishing increases fatigue resistance.

c. Drs. Venbrux's and Kaufman's warnings that the migration resistance of the Recovery Filter needed to be raised from 50 mmHg to 140 mmHg and that the device was "wimpy."

d. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to filter will "address the arm fracture issue."

e. On May 26, 2004, a BPV engineer sent an email stating that a proposed modified Recovery Filter design with a large chamfer lasted 50 bending cycles before breaking, whereas another proposed modified Recovery Filter with a small chamfer broke after 10 bending cycles.

f. On December 27, 2005, Bard's Medical Affairs Director sent an email questioning why Bard is even selling the modified version of the Recovery Filter, when the Simon Nitinol Filter has virtually no complaints associated with it.

9. Bard Stopped Selling the Recovery Filter and Pushed the Bard G2 Filter into the Marketplace.

60. In or around April 2004, Bard, without notifying consumers of the design and manufacturing flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct its design flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter.

61. Once Bard began marketing and selling the redesigned product in approximately August 2005, Bard quietly stopped selling the Recovery Filter. But, Bard continued to market the Recovery Filter as being safer and more effective than all prior filters up until the day the Recovery Filter was removed from the market. Moreover, Bard never issued a recall for the Recovery Filter, which had a three-year shelf life.

62. Instead of warning the public or withdrawing the device from the market, Bard retained a publicity firm and opened a task force to prevent information from getting out to the public, creating a Crisis Communication Team in 2004.

63. In an April 2004 email, BPV consultant Dr. Lehman, a member of the Crisis Communication Team, advised Bard to conceal material risk information from the public. Bard adopted his advice. In an email, Dr. Lehman wrote, “Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard. That ‘Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device.’” Dr. Lehman went on:

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

64. By December 2004, BPV's own safety procedure deemed the Recovery Filter not reasonably safe for human use. Bard continued to sell the Device into September of 2005.

C. THE G2 FILTER SYSTEM

65. On August 29, 2005, Bard obtained clearance to market the G2 Filter through the 510k process, representing to the FDA that the G2 Filter was substantially equivalent in respect to safety and efficacy as the Recovery Filter.

66. The Bard G2 filter appears as follows:



67. Bard asserted that the differences between the Recovery Filter and the G2 Filter were primarily dimensional and that it had made no material changes or added additional components. The G2 Filter was only cleared for permanent implantation until January 15, 2008. Thus, between September 2005 through all of 2007, Bard sold two filters, the Simon Nitinol Filter and G2 Filter, with the exact same indications for use.

68. Bard marketed the G2 Filter as having “enhanced fracture resistance,” “improved centering,” and “increased migration resistance” over all of its previous filters. Bard’s marketing brochure states that supporting data was “on file.” Yet, Bard refused to share this allegedly supporting evidence with consumers when it was asked for it. In reality, Bard knew or had reason to know these claims were false and misleading. Bard knew that the Simon Nitinol Filter was far less likely to fracture, migrate, tilt, or perforate the vena cava than the G2 or the Recovery Filter

69. Further, Bard again failed to conduct adequate testing for long term safety and efficacy and failed to conduct adequate bench testing and animal studies to ensure that the device would perform safely and effectively once implanted in the human body and subjected to

reasonably foreseeable in vivo stresses. Further, Bard still did not have a thorough and/or adequate understanding of vena caval dynamics. Not surprisingly, the G2 Filter's design still lacked adequate structural integrity, stability, and perforation resistance to withstand normal in vivo body stresses within the human without failing.

70. For instance, the new minimum safety migration resistance design requirement for the G2 Filter was that its migration resistance had to be "statistically greater" than that of the predicate Simon Nitinol Filter. Bard's testing established that the G2 Filter failed this requirement. However, instead of going back and modifying the device further to ensure this safety requirement was met, Bard changed the minimum safety requirement so that it just had to be better than the Recovery Filter.

71. Compounding this utter lack of concern for patient safety, Bard also decided that G2 filters could be reworked or reloaded on the jig used to form the filters up to five times in order to save money. Bard did this despite knowing that this would significantly decrease the migration resistance of such devices. To allow for this, Bard readopted the same minimum safety migration resistance specification that had been adopted and proven to be utterly unsupported for the Recovery Filter, *e.g.*, 50 mmHg.

72. Thus, knowing that the specification and migration resistance of the Recovery Filter had been inadequate and was resulting in patient death, Bard's premarket design requirement was that the device had to be at least as good as the Simon Nitinol Filter regarding migration resistance. When the G2 Filter failed that requirement, Bard simply changed the design requirement so that the G2 Filter just had to be at least as good as the device that it was known to be inadequate and causing patient deaths, the Recovery Filter.

73. The redesigned G2 Filter also still had substantially less radial force than did the Simon Nitinol Filter.

74. Bard again failed to account for how movement (tilt/migration), perforation, and fracture would affect device performance, despite knowing that these failures had occurred with the Recovery Filter.

75. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and the existence of “draw markings” and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while in vivo. In particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure and migration.

76. Within months of being released to market, post-market safety data revealed to Bard that the safety problems introduced with the Recovery Filter persisted. Some representative examples of this knowledge include the following:

a. Bard again received large numbers of adverse event reports reporting that properly placed G2 Filter were, *inter alia*, fracturing, migrating, tilting, and perforating the vena cava, often resulting in serious injuries and death.

b. By November 2005, Bard was aware of a “safety signal” regarding the high rate of reported perforation and movement failures.

c. In a December 25, 2005 email, Bard's Medical Director, Dr. David Ciavarella, questioned why Bard was even selling the G2 filter given the numerous reported failures when the Simon Nitinol Filter had virtually no reported adverse events.

d. By no later than February 2006, internal safety investigations revealed that the G2 Filter's design continued to fail to ensure adequate stability, as the device continued to tilt and migrate at unreasonably high rates. Indeed, within months of being on the market, the G2 filter was found to migrate at rates that violated Bard's own safety threshold. The G2 Filter also exhibited a previously unseen failure: it would migrate downwards as well as upwards and side to side in the vena cava.

e. As with the Recovery Filter, Bard knew that movement, whether it be tilt or migration, increased the risk of fracture and strut perforation through the vena cava, as well as making the device irretrievable. For example, in a February 2006 Health Hazard Evaluation regarding G2 Failures, Bard's Medical Director acknowledged that tilt increases the risk of fracture and perforation and that events can cause serious injury and death. Similarly, a 2009 PowerPoint Presentation prepared by Bard's engineers, stated that movement causes tilt and that "tilted filter elements are more likely to penetrate IVC and adjacent structures due to change in the angle between the elements and the IVC." The PowerPoint states that tilting and perforation or penetration leads to fracture.

f. Bard's investigations into comparative failure risks between the different available devices continually showed that the G2 filters posed a substantially higher risk of migration, tilt, perforation and fracture.

g. By 2008, physicians were reporting that they believed there were fundamental design flaws with the G2 filter that was causing it to move, fracture, and perforate,

and requesting evidence on the reported complication rates for the device. Bard's corporate policy was to refuse to disclose such failure rate data.

h. In a document dated April 1, 2010, senior Bard employees admitted that there were known quality problems with the G2 line of filters, that Bard's own sales force had lost faith in the product, and that doctors were refusing to use it. The document sets forth Bard's plan to reduce the risk of tilting, perforation, fracture, and migration by improving the anchoring system on the G2 line of filters. This became the Meridian filter, which was cleared through the 510(k) process on October 24, 2011.

i. Recent medical studies report that the G2 will suffer a 38 to 40 percent fracture rate at four to five years.

77. As with the Recovery Filter, these failures often caused severe patient injuries such as:

- a. death;
- b. hemorrhage;
- c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. severe and persistent pain; and
- f. perforations of tissue, vessels and organs.

78. Despite being aware from February 2006 that the G2 Filter was not safe for its intended use and was substantially more likely to fail and cause patient injuries than all other available IVC Filters devices, Bard continued to sell the device into 2010 and even continued to market it as safer than Bard's permanent filter, the Simon Nitinol Filter.

D. FDA WARNING LETTER

79. On July 13, 2015, the FDA issued a Warning Letter to Bard notifying that its IVC Filters were adulterated and misbranded under federal law.

80. The FDA notified Bard that its IVC Filters were adulterated and misbranded because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Section 820,

81. The FDA also notified Bard that it had failed to comply with adverse event reporting requirements of 21 C.F.R. 803.

82. The FDA cited numerous specific violations, including the failure to establish and maintain procedures to ensure that product complaints are adequately investigated and reported, and a consistent pattern of Bard underreporting the severity of injuries caused by device failures and failing to report device malfunctions all together.

83. For instance, the FDA cited numerous examples of Bard reporting G2 and other IVC filter failures resulting in deaths and other serious injuries as if there was no patient injury involved. The FDA also found that Bard had failed to establish and maintain a procedure to ensure that the toxic acids and chemicals used in the manufacture of its filters were reduced to acceptable levels prior to distribution.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

84. In December 2009, an embolus lodged in Ms. Piazza's right carotid artery, causing a stroke.

85. During bed rest after recovery from the stroke, Ms. Piazza developed a deep vein thrombosis in one of her legs.

86. Dr. Judy Sutton, a physician, advised Ms. Piazza that, in order to prevent the thrombosis (clot) from traveling to her heart or lungs, she needed to be implanted with an IVC filter.

87. On January 11, 2010, Dr. Richard Curl implanted a Bard G2 IVC filter in Ms. Piazza, while she was a patient at Buffalo General Hospital in Buffalo, New York

88. Until around May 2015, Ms. Piazza noticed no symptoms> She had no reason to even consider that there might be any problem with the Device.

89. In around May 2015, Ms. Piazza began suffering a constant stabbing and/or burning pain in her abdomen and lower back, which she evaluated as an 8 on a pain scale of 1 to 10.

90. Because of this pain, Ms. Piazza went to her primary care physician, Dr. Thierman. In August 2015, Ms. Piazza underwent a computerized tomography (and/or burning pain in her abdomen and Later the same day, she received a phone call from Dr. Thierman telling her the results of her CT scan. Dr. Thierman told Ms. Piazza that the IVC filter had migrated and fractured, and that this migration/fracture was the cause of her pain and suffering. The physician explained that, because of the IVC filter's migration and fracture, it would require a "massive" surgical operation to remove it.

91. Ms. Piazza was later informed that the IVC filter had perforated her aorta and possibly her duodenum.

92. On September 11, 2015, Ms. Piazza underwent surgery to remove the IVC filter. The surgery was an open laparotomy performed by Dr. W. Michael Park at the Cleveland Clinic in Ohio. It required a 12-inch incision from Ms. Piazza's waist to her navel.

93. Dr. Park successfully removed the IVC filter and the fractured arm of the filter. He told Ms. Piazza that the surgery was fully successful, but warned her that she might require further operations as a consequence of the injuries that the IVC filter caused her, including from scar tissue.

94. As a consequence of her surgery, Ms. Piazza was unable to drive for approximately one month. Many daily life activities became difficult and caused her to suffer a great deal of pain and suffering. Also, for approximately six weeks, Ms. Piazza was also unable to perform rehabilitative exercises that were prescribed for her because of a stroke that she had suffered in 2009. Even now, Ms. Piazza must be very careful with her bodily movement and cannot fully perform her rehabilitation program as she used to because she needs to avoid additional pain and suffering and to avoid reinjuring her body where Dr. Park attempted to mend her tissue during the IVC filter revision surgery.

FIRST CLAIM FOR RELIEF:
NEGLIGENCE

95. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

96. At all times relevant to this cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Device.

97. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Device that was implanted in Plaintiff.

98. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion,

distribution and sale of the Device and to timely withdraw/remove/recall these filters from the market so as to avoid exposing others to foreseeable and unreasonable risks of harm.

99. Defendants knew or had reason to know that the Device was dangerous or were likely to be dangerous when used in its intended or reasonably foreseeable manner.

100. At the time of manufacture and sale of the Device, Defendants knew or should have known that the Device was:

a. defectively designed and manufactured so as to present a unreasonable risk of the Device perforating the vena cava wall;

b. defectively designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the Device;

c. defectively designed and manufactured so as to present a unreasonable risk of migration of the Device and/or portions of the Device;

d. defectively designed and manufactured so as to present a unreasonable risk of the Device tilting in the vena cava wall;

e. defectively designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and

f. defectively designed and manufactured so as to present a unreasonable risk in that the Device cannot be removed, cannot be removed utilizing a minimally invasive percutaneous technique and/or can only be removed through an open vascular surgical procedure.

101. At the time of manufacture and sale of the Device, Defendants knew or should have known that the Device in its intended use or in a reasonably foreseeable manner created a

significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the Device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

102. Defendants knew or reasonably should have known that consumers of the Device would not realize the danger associated with using the Device in its intended use and/or in a reasonably foreseeable manner.

103. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Device in, among other ways, the following acts and omissions:

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. 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 likelihood of potential harm from other devices available for the same purpose;

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

d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Device's substantially dangerous condition or about facts making the product likely to be dangerous;

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

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Device;

g. Advertising, marketing and recommending the use of the Device while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Device;

h. Representing that the Device was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Device with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with the good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Device so as to avoid the risk of serious harm associated with the use;

k. Advertising, marketing, promoting and selling the Device for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Device;

m. Failing to establish and maintain an adequate post-market surveillance program.

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

105. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

SECOND CLAIM FOR RELIEF:
NEGLIGENT FAILURE TO WARN

106. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

107. At all times relevant to this cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Device.

108. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Device that was implanted in Plaintiff.

109. Defendants had a duty to exercise reasonable and prudent care to give appropriate warnings about particular risks of the Device which Defendants knew or should have known are involved in the reasonably foreseeable uses of the Device.

110. Defendants knew or reasonably should have known that the Device was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

111. At the time of manufacture and sale of the Device, Defendants knew or should have known that the Device:

- a. Was defectively designed and manufactured so as to present a unreasonable risk of the Device perforating the vena cava wall;
- b. Was defectively designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the Device;
- c. Was defectively designed and manufactured so as to present a unreasonable risk of migration of the Device and/or portions of the Device;
- d. Was defectively designed and manufactured so as to present a unreasonable risk of the Device tilting in the vena cava wall;
- e. Was defectively designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and.
- f. Was defectively designed and manufactured so as to present a unreasonable risk in that the Device cannot be removed, cannot be removed utilizing a minimally invasive percutaneous technique and/or can only be removed through an open vascular surgical procedure.

112. At the time of manufacture and sale of the Device, Defendants knew or should have known that using the Device in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not

limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the Device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

113. Defendants knew or reasonably should have known that consumers of the Device would not realize the danger associated with using the Device in its intended use and/or in a reasonably foreseeable manner.

114. Defendants breached their duty to exercise reasonable and prudent care in failing to give appropriate warnings about the particular risks of the Device and further failed to disclose that the safety profile of the Device was worse than competitor filters.

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

116. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF:
STRICT LIABILITY FAILURE TO WARN

117. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

118. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold IVC filters such as the Device, 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.

119. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Device into the stream of commerce, Defendants knew or should have known the Device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Device, which was implanted in Plaintiff, that the Device, *inter alia*, posed a significant and higher risk than other similar devices of failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

120. Defendants 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.

121. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the Device was distributed and implanted in Plaintiff.

122. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Device, and further failed to adequately provide instructions on the safe and proper use of the Device. Furthermore, the foreseeable risks of harm

from the Device could have been reduced or avoided by providing reasonable instructions and/or warnings and the failure to provide those instructions or warnings makes the Device unreasonably dangerous and renders the Device defective.

123. No health care provider, including Plaintiff's, or patient would have used the Device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the Device.

124. 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.

125. Plaintiff and Plaintiff's health care providers used the Device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted Device used to prevent pulmonary emboli.

126. The Device implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

127. The Device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

128. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

FOURTH CLAIM FOR RELIEF:
STRICT LIABILITY DESIGN DEFECT

129. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

130. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Device, including the one implanted in Plaintiff.

131. The Device was in a condition unreasonably dangerous and was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession, or with changes that were reasonably foreseeable to Defendants.

132. The Device implanted in Plaintiff was defective in design because it failed to perform as safely as an ordinary consumer would expect when used as intended or when uses in a manner reasonably foreseeable by Bard and/or the risk of danger in the design outweighed the benefits of the filter.

133. The Device implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

134. Plaintiff and Plaintiff's health care providers used the Device in a manner that was reasonably foreseeable to Defendants.

135. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the Device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the Device.

136. As a direct and proximate result of the Device's defective design, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering,

mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

FIFTH CLAIM FOR RELIEF:
STRICT LIABILITY MANUFACTURING DEFECT

137. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

138. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Device that was implanted into Plaintiff. The Device was unreasonably dangerous at the time it left Defendants' control because of a manufacturing defect, i.e., it was different from its intended design and failed to perform as safely as the intended design would have performed.

139. The Device implanted in Plaintiff was in a condition unreasonably dangerous and the filter was expected to and did reach Plaintiff and/or her physicians without substantial change affecting that condition.

140. Plaintiff and Plaintiff's health care providers used the Device in a manner that was reasonably foreseeable to Defendants.

141. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

142. As a direct and proximate result of the Device's manufacturing defect, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the

Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF:
BREACH OF EXPRESS WARRANTY

143. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

144. Through sales representatives, consultants, printed materials and other advertising and marketing efforts, Defendants made express representations to healthcare providers and patients, including Plaintiff and Plaintiff's healthcare providers, about the safety and efficacy of the Device.

145. Plaintiff and Plaintiff's healthcare providers relied upon the aforementioned express representations made by Defendants in deciding to purchase and implant the Device.

146. The Device does not conform to the express representations of fact made by Defendants through sales representatives, consultants, printed materials, and other advertising and marketing efforts and Plaintiff and/or her physicians relied on these express representations in the purchase, use and implantation of the Device in Plaintiff.

147. The Device's failure to conform to the foregoing express representations made by Defendants caused Plaintiff's injuries.

SEVENTH CLAIM FOR RELIEF:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

148. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

149. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce IVC filters such as the Device for use as a surgically implanted Device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

150. At the time and place of the sale, distribution, and supply of Defendants' Device to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Device was safe and effective for its intended and reasonably foreseeable use.

151. Defendants knew of the intended and reasonably foreseeable use of the Device, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

152. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Device was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

153. Plaintiff and Plaintiff's healthcare providers relied upon the aforementioned implied representations made by Defendants in deciding to purchase and implant the Device.

154. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Device was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Device from Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Device was inadequately, improperly and inappropriately prepared and/or finished causing the Device to weaken and fail.

155. Plaintiff and Plaintiff's health care providers acted reasonably in relying on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the Device was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Device were manufactured and sold.

156. Defendants placed the Device into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Device was manufactured and sold.

157. Defendants breached their implied warranty because the Device is not fit for its intended use(s) and/or the use(s) reasonably foreseeably by the Defendant.

158. As a proximate result of Defendants' breaching their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor

Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

EIGHTH CLAIM FOR RELIEF:
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

159. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

160. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Device for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

161. At the time and place of the sale, distribution, and supply of Defendants' Device to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Device was safe and effective for its intended and reasonably foreseeable use.

162. Defendants knew of the intended and reasonably foreseeable use of the Device, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

163. Defendants knowingly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Device was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

164. Plaintiff and Plaintiff's healthcare providers relied upon the aforementioned implied representations made by Defendants in deciding to purchase and implant the Device.

165. The representations and warranties made by Defendants were false, misleading, and inaccurate because the Device was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner.

Specifically, at the time of Plaintiff's purchase of the Device from Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Device was inadequately, improperly and inappropriately prepared and/or finished causing the Device to weaken and fail.

166. Plaintiff and Plaintiff's health care providers acted reasonably in relying on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the Device was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Device was manufactured and sold.

167. Defendants placed the Device into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the Device was expected to and did reach Plaintiff without substantial change in the condition in which the Device was manufactured and sold.

168. Defendants breached their warranty of fitness for a particular purpose because the Device is not fit for the specific purpose for which the Defendant's knowingly sold it and for

which, in reliance on the judgment of the Defendant's, Plaintiff and/or her physicians bought and implanted the Device.

169. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that her injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

NINTH CLAIM FOR RELIEF:
FRAUDULENT CONCEALMENT

170. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

171. Defendants were and are under a continuing duty to disclose the true character, quality and nature of the Device that was implanted in Plaintiff, but instead they concealed them, thus breaching this duty.

172. At all times relevant to this cause, Defendants fraudulently concealed material information concerning the Device from Plaintiff, Plaintiff's health care providers, and the general medical community relating to the safety of the Device, the efficacy the Device and the rate of failure of the Device.

173. Defendants concealed the applicable facts intentionally in order to defraud or mislead Plaintiff.

174. Plaintiff and Plaintiff's healthcare providers reasonably relied on Defendants' omission to state that the true character, quality and nature of the Device was far worse than promised in deciding to purchase and implant the Device.

175. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

176. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Device.

177. Plaintiff and Plaintiff's health care providers could not reasonably have discovered the claims made herein until at the earliest in May of 2015, when the Device was first suspected to have injured her.

178. Defendants' conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

TENTH CLAIM FOR RELIEF:
NEGLIGENT MISREPRESENTATION

179. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

180. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with

false, misleading or incorrect information, or omitted or failed to disclose material information/facts/facts concerning the Device that the Defendant's knew or should have known was in fact false and misleading, Defendants' made these false and misleading statements intending that the statements would be relied on by Plaintiff, Plaintiff's health care providers and the general medical community and Plaintiff and her health care providers justifiably relied upon the Defendant's false and misleading statements. The Defendant's false and misleading statements concerned the following material facts and subjects: The safety of the Device;

- a. The efficacy of the Device;
- b. The rates of failure of the Device; and
- c. The approved uses of the Device.

181. The false and misleading information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Device. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Device that was implanted in Plaintiff.

182. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Device and its fitness for use; and to induce

the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Device.

183. The foregoing representations and omissions by Defendants were in fact false. The Device is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of IVC filters like the Device is hazardous to the user's health, and said Device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the Device has a significantly higher rate of failure and injury than do other comparable devices.

184. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Device, thereby causing Plaintiff to sustain severe and permanent personal injuries.

185. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the Device had not been concealed and misrepresented by Defendants.

186. Defendants were and are under a duty to impart correct information to Plaintiff and Plaintiff's healthcare providers.

187. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Device.

188. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Device, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

189. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Device.

190. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

ELEVENTH CLAIM FOR RELIEF:
FRAUDULENT MISREPRESENTATION

191. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

192. At all times relevant to this cause, Defendants intentionally made false statements of material fact to Plaintiff, Plaintiff's health care providers, and the general medical community or intentionally omitted or intentionally failed to disclose material information concerning the Device knowing that such statements and omissions were in fact false and misleading or without concern for whether the statements or omissions were true or false.

193. Defendants made these false and misleading statements intending that the statements would be relied on by Plaintiff, Plaintiff's health care providers and the general medical community and Plaintiff and her health care providers relied upon the Defendant's false and misleading statements. The Defendant's false and misleading statements concerned the following material facts and subjects:

- a. The safety of the Device;
- b. The efficacy of the Device;
- c. The rates of failure of the Device; and
- d. The approved uses of the Device.

194. The false and misleading information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Device. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Device that was implanted in Plaintiff.

195. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Device and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Device.

196. The foregoing representations and omissions by Defendants were in fact false. The Device is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Device is hazardous to the user's health, and said Device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries

Plaintiff suffered. Further, the Device has a significantly higher rate of failure and injury than do other comparable devices.

197. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did, use the Device, thereby causing Plaintiff to sustain severe and permanent personal injuries.

198. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the Device had not been concealed and misrepresented by Defendants.

199. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Device.

200. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Device, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

201. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Device.

202. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

TWELFTH CLAIM FOR RELIEF:
PUNITIVE DAMAGES ALLEGATIONS

203. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

204. Plaintiff is 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.

205. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Device was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

- a. Inform or warn Plaintiff or her health care providers of the dangers;
- b. To establish and maintain an adequate quality and post-market surveillance system; and
- c. Recall the Device from the market.

206. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

207. Defendants' actions were malicious, wanton and reckless. Defendants' conduct were not motivated by an interest in manufacturing and selling a safe and better medical product, but rather to take over the market, squeeze out the competition, so that profits would increase significantly.

208. Defendants' conduct was directed by its Board of Directors and CEO.

Defendants acted through their agents to increase the Bard market share, without regard for the safety and efficacy of its devices.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues which may be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court order Defendants to provide the following relief:

1. All applicable damages, including:
 - a. General and consequential damages, including pain and suffering, mental anguish, loss of enjoyment of life, disability, scarring and disfigurement, risk of requiring additional medical care and surgical procedures, ongoing medical monitoring, and other losses proximately caused by the Device according to proof at trial;
 - b. Medical and other special damages, past, present, and future, according to proof at the time of trial;
2. Punitive damages;
3. Costs of suit, including payment of experts' fees and expenses;
4. Reasonable attorneys' fees;
5. Prejudgment and post judgment interest as provided by law; and,
6. Such other and further relief as the Court may deem just and proper.

Dated: December 14, 2015

LIEFF CABRASER HEIMANN &
BERNSTEIN, LLP

By: /s/ Wendy R. Fleishman

Wendy R. Fleishman (State Bar No. 122744)
250 Hudson Street, 8th Floor
New York, NY 10013-1413
Telephone: (212) 355-9500
Facsimile: (212) 355-9592
wfleishman@lchb.com

Attorney for Plaintiff

1278350.9

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Gary Leigh Piazza

(b) County of Residence of First Listed Plaintiff Erie County, NY (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Wendy R. Fleishman, Esq. Lief Cabraser Heimann & Bernstein, LLP 250 Hudson Street, 8th Floor, New York, NY 10013; 212-355-9500

DEFENDANTS

C.R. Bard, Inc. Bard Peripheral Vascular, Inc.

County of Residence of First Listed Defendant Union County, N.J. (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Estate, etc.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District, 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 USC s 1332

Brief description of cause: defective surgically-implanted filter for blood clots - products liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE David G. Campbell, U.S.D.J., D. Ariz. DOCKET NUMBER 2:15-md-02641 (MDL)

DATE 12/14/2015 SIGNATURE OF ATTORNEY OF RECORD /s/ Wendy R. Fleishman

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.